YESCARTA®, THE FIRST CAR T THERAPY FOR CERTAIN TYPES OF RELAPSED OR REFRACTORY LARGE B-CELL LYMPHOMA

The following data reflect results from the ZUMA-1 pivotal trial*1

INDICATION
YESCARTA® is a CD19-directed genetically modified autologous T cell immunotherapy indicated for the treatment of adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma.

Limitation of Use: YESCARTA® is not indicated for the treatment of patients with primary central nervous system lymphoma.

IMPORTANT SAFETY INFORMATION
BOXED WARNING: CYTOKINE RELEASE SYNDROME AND NEUROLOGIC TOXICITIES

- Cytokine Release Syndrome (CRS), including fatal or life-threatening reactions, occurred in patients receiving YESCARTA®. Do not administer YESCARTA® to patients with active infection or inflammatory disorders. Treat severe or life-threatening CRS with tocilizumab or tocilizumab and corticosteroids.
- Neurologic toxicities, including fatal or life-threatening reactions, occurred in patients receiving YESCARTA®, including concurrently with CRS or after CRS resolution. Monitor for neurologic toxicities after treatment with YESCARTA®. Provide supportive care and/or corticosteroids as needed.
- YESCARTA® is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the YESCARTA® REMS.

Important Safety Information continued on adjacent page.

VISIT YESCARTAHCP.COM/CENTERS TO FIND A LIST OF AUTHORIZED TREATMENT CENTERS

*ZUMA-1 was an open-label, single-arm study in 101 adult patients who received YESCARTA® therapy. Patients received lymphodepleting chemotherapy prior to a single infusion of YESCARTA® at a target dose of 2 x 10⁶ viable CAR T cells/kg body weight (maximum of 2 x 10⁸ viable CAR T cells). Patients had refractory disease to their most recent therapy, or had relapsed within 1 year after autologous hematopoietic stem cell transplantation.

†The median time from leukapheresis to product delivery.
IMPORTANT SAFETY INFORMATION
(continued)

CYTOKINE RELEASE SYNDROME (CRS): CRS occurred in 94% of patients, including 13% with ≥ Grade 3. Among patients who died after receiving YESCARTA®, 4 had ongoing CRS at death. The median time to onset was 2 days (range: 1-12 days) and median duration was 7 days (range: 2-58 days). Key manifestations include fever (78%), hypotension (41%), tachycardia (26%), hypoxia (22%), and chills (20%). Serious events that may be associated with CRS include cardiac arrhythmias (including atrial fibrillation and ventricular tachycardia), cardiac arrest, cardiac failure, renal insufficiency, capillary leak syndrome, hypotension, hypoxia, and hemophagocytic lymphohistiocytosis/macrophage activation syndrome. Ensure that 2 doses of tocilizumab are available prior to infusion of YESCARTA®. Monitor patients at least daily for 7 days at the certified healthcare facility following infusion for signs and symptoms of CRS. Monitor patients for signs or symptoms of CRS for 4 weeks after infusion. Counsel patients to seek immediate medical attention should signs or symptoms of CRS occur at any time. At the first sign of CRS, institute treatment with supportive care, tocilizumab or tocilizumab and corticosteroids as indicated.

NEUROLOGIC TOXICITIES: Neurologic toxicities occurred in 87% of patients. Ninety-eight percent of all neurologic toxicities occurred within the first 8 weeks, with a median time to onset of 4 days (range: 1-43 days) and a median duration of 17 days. Grade 3 or higher occurred in 31% of patients. The most common neurologic toxicities included encephalopathy (57%), headache (44%), tremor (31%), dizziness (21%), aphasia (18%), delirium (17%), insomnia (9%) and anxiety (9%). Prolonged encephalopathy lasting up to 173 days was noted. Serious events including leukoencephalopathy and seizures occurred with YESCARTA®. Fatal and serious cases of cerebral edema have occurred in patients treated with YESCARTA®. Monitor patients at least daily for 7 days at the certified healthcare facility following infusion for signs and symptoms of neurologic toxicities. Monitor patients for signs or symptoms of neurologic toxicities for 4 weeks after infusion and treat promptly.

YESCARTA® REMS: Because of the risk of CRS and neurologic toxicities, YESCARTA® is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the YESCARTA® REMS. The required components of the YESCARTA® REMS are: Healthcare facilities that dispense and administer YESCARTA® must be enrolled and comply with the REMS requirements. Certified healthcare facilities must have on-site, immediate access to tocilizumab, and ensure that a minimum of 2 doses of tocilizumab are available for each patient for infusion within 2 hours after YESCARTA® infusion, if needed for treatment of CRS. Certified healthcare facilities must ensure that healthcare providers who prescribe, dispense or administer YESCARTA® are trained about the management of CRS and neurologic toxicities. Further information is available at www.YESCARTAREMS.com or 1-844-454-KITE (5483).

HYPERSENSITIVITY REACTIONS: Allergic reactions may occur. Serious hypersensitivity reactions including anaphylaxis may be due to dimethyl sulfoxide (DMSO) or residual gentamicin in YESCARTA®.

SERIOUS INFECTIONS: Severe or life-threatening infections occurred in 36% of patients, and in 23% with ≥ Grade 3. Grade 3 or higher infections with an unspecified pathogen occurred in 16% of patients, bacterial infections in 9%, and viral infections in 4%. YESCARTA® should not be administered to patients with clinically significant active systemic infections. Monitor patients for signs and symptoms of infection before and after YESCARTA® infusion and treat appropriately. Administer prophylactic anti-microbials according to local guidelines. Febrile neutropenia was observed in 36% of patients and may be concurrent with CRS. In the event of febrile neutropenia, evaluate for infection and manage with broad spectrum antibiotics, fluids and other supportive care as medically indicated. Hepatitis B virus (HBV) reactivation, in some cases resulting in fulminant hepatitis, hepatic failure and death, can occur in patients treated with drugs directed against B cells. Perform screening for HBV, HCV, and HIV in accordance with clinical guidelines before collection of cells for manufacturing.

PROLONGED CYTOPENIAS: Patients may exhibit cytopenias for several weeks following lymphodepleting chemotherapy and YESCARTA® infusion. Grade 3 or higher cytopenias not resolved by Day 30 following YESCARTA® infusion occurred in 28% of patients and included thrombocytopenia (18%), neutropenia (15%), and anemia (3%). Monitor blood counts after YESCARTA® infusion.

HYPOGAMMAGLOBULINEMIA: B-cell aplasia and hypogammaglobulinemia can occur. Hypogammaglobulinemia occurred in 15% of patients. Monitor immunoglobulin levels after treatment and manage using infection precautions, antibiotic prophylaxis and immunoglobulin replacement. The safety of immunization with live viral vaccines during or following YESCARTA® treatment has not been studied. Vaccination with live virus vaccines is not recommended for at least 6 weeks prior to the start of lymphodepleting chemotherapy, during YESCARTA® treatment, and until immune recovery following treatment.

SECONDARY MALIGNANCIES: Patients may develop secondary malignancies. Monitor life-long for secondary malignancies. In the event that a secondary malignancy occurs, contact Kite at 1-844-454-KITE (5483) to obtain instructions on patient samples to collect for testing.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES: Due to the potential for neurologic events, including altered mental status or seizures, patients are at risk for altered or decreased consciousness or coordination in the 8 weeks following YESCARTA® infusion. Advise patients to refrain from driving and engaging in hazardous occupations or activities, such as operating heavy or potentially dangerous machinery, during this initial period.

ADVERSE REACTIONS: The most common adverse reactions (incidence ≥ 20%) include CRS, fever, hypotension, encephalopathy, tachycardia, fatigue, headache, decreased appetite, chills, diarrhea, febrile neutropenia, infections-pathogen unspecified, nausea, hypoxia, tremor, cough, vomiting, dizziness, constipation, and cardiac arrhythmias.

Please see Brief Summary of Prescribing Information, including BOXED WARNING, on the following pages.

BRIEF SUMMARY OF PRESCRIBING INFORMATION FOR YESCARTA®
(axicabtagene ciloleucel) suspension for intravenous infusion
SEE PACKAGE INSERT FOR FULL PRESCRIBING INFORMATION

WARNING: CYTOKINE RELEASE SYNDROME and NEUROLOGIC TOXICITIES

- Cytokine Release Syndrome (CRS), including fatal or life-threatening reactions, occurred in patients receiving YESCARTA. Do not administer YESCARTA to patients with active infection or inflammatory disorders. Treat severe or life-threatening CRS with tocilizumab or tocilizumab and corticosteroids [see Dosage and Administration (2.2, 2.3), Warnings and Precautions (5.1)].
- Neurologic toxicities, including fatal or life-threatening reactions, occurred in patients receiving YESCARTA, including concurrently with CRS or after CRS resolution. Monitor for neurologic toxicities after treatment with YESCARTA. Provide supportive care and/or corticosteroids, as needed [see Dosage and Administration (2.2, 2.3), Warnings and Precautions (5.2)].
- YESCARTA is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the YESCARTA REMS [see Warnings and Precautions (5.3)].

1 INDICATIONS AND USAGE

YESCARTA is a CD19-directed genetically modified autologous T cell immunotherapy indicated for the treatment of adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma. Limitation of Use: YESCARTA is not indicated for the treatment of patients with primary central nervous system lymphoma.

2 DOSAGE AND ADMINISTRATION

2.2 Administration: YESCARTA is for autologous use only. The patient’s identity must match the patient identifiers on the YESCARTA cassette and infusion bag. Do not infuse YESCARTA if the information on the patient-specific label does not match the intended patient [see Dosage and Administration (2.2.3)].

Preparing Patient for YESCARTA Infusion: Confirm availability of YESCARTA prior to starting the lymphodepleting regimen. Pre-treatment: Administer a lymphodepleting chemotherapy regimen of cyclophosphamide 500 mg/m² intravenously and fludarabine 30 mg/m² intravenously on the fifth, fourth, and third day before infusion of YESCARTA. Premedication: Administer acetaminophen 650 mg PO and diphenhydramine 12.5 mg intravenously or PO approximately 1 hour before YESCARTA infusion. Avoid prophylactic use of systemic corticosteroids, as it may interfere with the activity of YESCARTA.

Preparation of YESCARTA for Infusion: Coordinate the timing of YESCARTA thaw and infusion. Confirm the infusion time in advance, and adjust the start time of YESCARTA thaw such that it will be available for infusion when the patient is ready. Confirm patient identity: Prior to YESCARTA preparation, match the patient’s identity with the patient identifiers on the YESCARTA cassette. Do not remove the YESCARTA product bag from the cassette if the information on the patient-specific label does not match the intended patient. Once patient identification is confirmed, remove the YESCARTA product bag from the cassette and check that the patient information on the cassette label matches the bag label. Inspect the product bag for any breaches of container integrity such as breaks or cracks before thawing. If the bag is compromised, follow the local guidelines (or call Kite at 1-844-454-KITE). Place the infusion bag inside a second sterile bag per local guidelines. Thaw YESCARTA at approximately 37°C using either a water bath or dry thaw method until there is no ice inside a second sterile bag per local guidelines. Thaw YESCARTA at approximately 37°C using either a water bath or dry thaw method until there is no ice visible in the infusion bag. Gently mix the contents of the bag to disperse clumps of cellular material. If visible cell clumps remain continue to gently mix the contents of the bag. Small clumps of cellular material should disperse with gentle manual mixing. Do not wash, spin down, and/or re-suspend YESCARTA in new media prior to infusion. Once thawed, YESCARTA may be stored at room temperature (20°C to 25°C) for up to 3 hours.

Administration: For autologous use only. Ensure that tocilizumab and emergency equipment are available prior to infusion and during the recovery period. Do NOT use a leukodepleting filter. Central venous access is recommended for the infusion of YESCARTA. Confirm the patient’s identity matches the patient identifiers on the YESCARTA product bag. Prime the tubing with normal saline prior to infusion. Infuse the entire contents of the YESCARTA bag within 30 minutes by either gravity or a peristaltic pump. YESCARTA is stable at room temperature for up to 3 hours after thaw. Gently agitate the product bag during YESCARTA infusion to prevent cell clumping. After the entire content of the product bag is infused, rinse the tubing with normal saline at the same infusion rate to ensure all product is delivered. YESCARTA contains human blood cells that are genetically modified with a replication incompetent retroviral vector. Follow universal precautions and local biosafety guidelines for handling and disposal to avoid potential transmission of infectious diseases.

Monitoring: Administer YESCARTA at a certified healthcare facility. Monitor patients at least daily for 7 days at the certified healthcare facility following infusion for signs and symptoms of CRS and neurologic toxicities. Instruct patients to remain within proximity of the certified healthcare facility for at least 4 weeks following infusion.

2.3 Management of Severe Adverse Reactions

Cytokine Release Syndrome (CRS): Identify CRS based on clinical presentation [see Warnings and Precautions (5.1)]. Evaluate and treat other causes of fever, hypoxia, and hypotension. If CRS is suspected, manage according to the recommendations in Table 1. Patients who experience Grade 2 or higher CRS (e.g., hypotension, not responsive to fluids, or hypoxia requiring supplemental oxygen) should be monitored with continuous cardiac telemetry and pulse oximetry. For patients experiencing severe CRS, consider performing an echocardiogram to assess cardiac function. For severe or life-threatening CRS, consider intensive care support therapy.

Table 1. CRS Grading and Management Guidance

<table>
<thead>
<tr>
<th>CRS Grade</th>
<th>Tocilizumab</th>
<th>Corticosteroids</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade 1</td>
<td>Symptoms require symptomatic treatment only (e.g., fever, nausea, fatigue, headache, myalgia, malaise).</td>
<td>N/A</td>
</tr>
<tr>
<td>Grade 2</td>
<td>Symptoms require and respond to moderate intervention. Oxygen requirement less than 40% FiO₂ or hypertension responsive to fluids or low-dose of one vasopressor or Grade 2 organ toxicity (b).</td>
<td>Administer tocilizumab (c) 8 mg/kg intravenously over 1 hour (not to exceed 800 mg). Repeat tocilizumab every 8 hours as needed if not responsive to intravenous fluids or increasing supplemental oxygen. Limit to a maximum of 3 doses in a 24-hour period; maximum total of 4 doses.</td>
</tr>
<tr>
<td>Grade 3</td>
<td>Symptoms require and respond to aggressive intervention. Oxygen requirement greater than or equal to 40% FiO₂ or hypertension requiring high-dose or multiple vasopressors or Grade 3 organ toxicity or Grade 4 transaminis</td>
<td>Per Grade 2</td>
</tr>
<tr>
<td>Grade 4</td>
<td>Life-threatening symptoms. Requirements for ventilator support, continuous veno-venous hemodialysis (CVVHD) or Grade 4 organ toxicity (excluding transaminis).</td>
<td>Per Grade 2</td>
</tr>
</tbody>
</table>

(a) Lee et al 2014; (b) Refer to Table 2 for management of neurologic toxicity; (c) Refer to tocilizumab prescribing information for details.

Neurologic Toxicity: Monitor patients for signs and symptoms of neurologic toxicities (see Table 2). Rule out other causes of neurologic symptoms. Patients who experience Grade 2 or higher neurologic toxicities should be monitored with continuous cardiac telemetry and pulse oximetry. Provide intensive care support therapy for severe or life-threatening neurologic toxicities. Consider non-seeding, anti-seizure medicines (e.g., levetiracetam) for seizure prophylaxis for any Grade 2 or higher neurologic toxicities.
Table 2. Neurologic Toxicity Grading and Management Guidance

<table>
<thead>
<tr>
<th>Grading Assessment</th>
<th>Concurrent CRS</th>
<th>No Concurrent CRS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade 2</td>
<td>Administer tocilizumab per Table 1 for management of Grade 2 CRS. If no improvement within 24 hours after starting tocilizumab, administer dexamethasone 10 mg intravenously every 6 hours if not already taking other corticosteroids. Continue dexamethasone use until the event is Grade 1 or less, then taper over 3 days.</td>
<td>Administer dexamethasone 10 mg intravenously every 6 hours. Continue dexamethasone use until the event is Grade 1 or less, then taper over 3 days.</td>
</tr>
</tbody>
</table>

Consider non-sedating, anti-seizure medicines (e.g., levetiracetam) for seizure prophylaxis.

| Grade 3            | Administer tocilizumab per Table 1 for management of Grade 2 CRS. In addition, administer dexamethasone 10 mg intravenously with the first dose of tocilizumab and repeat dose every 6 hours. Continue dexamethasone use until the event is Grade 1 or less, then taper over 3 days. | Administer dexamethasone 10 mg intravenously every 6 hours. Continue dexamethasone use until the event is Grade 1 or less, then taper over 3 days. |

Consider non-sedating, anti-seizure medicines (e.g., levetiracetam) for seizure prophylaxis.

| Grade 4            | Administer tocilizumab per Table 1 for management of Grade 2 CRS. Administer methylprednisolone 1000 mg intravenously per day with first dose of tocilizumab and continue methylprednisolone 1000 mg intravenously per day for 2 more days; if improves, then manage as above. | Administer methylprednisolone 1000 mg intravenously per day for 3 days; if improves, then taper over 3 days. |

Consider non-sedating, anti-seizure medicines (e.g., levetiracetam) for seizure prophylaxis.

4 CONTRAINDICATIONS: None.
5 WARNINGS AND PRECAUTIONS
5.1 Cytokine Release Syndrome (CRS): CRS, including fatal or life-threatening reactions, occurred following treatment with YESCARTA. In Study 1, CRS occurred in 94% (101/108) of patients receiving YESCARTA, including ≥ Grade 3 (Lee grading system) CRS in 13% (14/108) of patients. Among patients who died after receiving YESCARTA, four had ongoing CRS events at the time of death. The median time to onset was 2 days (range: 1 to 12 days) and the median duration of CRS was 7 days (range: 2 to 58 days). Key manifestations of CRS include fever (78%), hypotension, hypoxia, and hemophagocytic lymphohistiocytosis/macrophage activation syndrome (HLH/MAS) [see Adverse Reactions (6)]. Ensure that 2 doses of tocilizumab are available prior to infusion of YESCARTA. Monitor patients at least daily for 7 days at the certified healthcare facility following infusion for signs and symptoms of CRS. Monitor patients for signs or symptoms of CRS for 4 weeks after infusion. Counsel patients to seek immediate medical attention should signs or symptoms of CRS occur at any time [see Patient Counseling Information (17)]. At the first sign of CRS, institute treatment with supportive care, tocilizumab or tocilizumab and corticosteroids as indicated [see Dosage and Administration (2.3)].

5.2 Neurologic Toxicities: Neurologic toxicities, that were fatal or life-threatening, occurred following treatment with YESCARTA. Neurologic toxicities occurred in 87% of patients. Ninety-eight percent of all neurologic toxicities occurred within the first 8 weeks of YESCARTA infusion, with a median time to onset of 4 days (range: 1 to 43 days). The median duration of neurologic toxicities was 17 days. Grade 3 or higher neurologic toxicities occurred in 31% of patients. The most common neurologic toxicities included encephalopathy (57%), headache (44%), tremor (31%), dizziness (21%), ataxia (15%), delirium (15%), insomnia (9%) and anxiety (9%). Prolonged encephalopathy lasting up to 173 days was noted. Serious events including leukoencephalopathy and seizures occurred with YESCARTA. Fatal and serious cases of cerebral edema have occurred in patients treated with YESCARTA. Monitor patients at least daily for 7 days at the certified healthcare facility following infusion for signs and symptoms of neurologic toxicities. Monitor patients for signs or symptoms of neurologic toxicities for 4 weeks after infusion and treat promptly [see Management of Severe Adverse Reactions (2.3); Neurologic Toxicities].

5.3 YESCARTA REMS: Because of the risk of CRS and neurologic toxicities, YESCARTA is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the YESCARTA REMS [see Boxed Warning and Warnings and Precautions (5.1 and 5.2)]. The required components of the YESCARTA REMS are: Healthcare facilities that dispense and administer YESCARTA must be enrolled and comply with the REMS requirements. Certified healthcare facilities must have on-site, immediate access to tocilizumab, and ensure that a minimum of two doses of tocilizumab are available for each patient for infusion within 2 hours after YESCARTA infusion, if needed for treatment of CRS.

- Certified healthcare facilities must ensure that healthcare providers who prescribe, dispense or administer YESCARTA are trained about the management of CRS and neurologic toxicities.

Further information is available at www.yescartarems.com or 1-844-454-KITE (5483).
5.4 Hypersensitivity Reactions: Allergic reactions may occur with the infusion of YESCARTA. Serious hypersensitivity reactions including anaphylaxis, may be due to dimethyl sulfoxide (DMSO) or residual gentamycin in YESCARTA.

5.5 Serious Infections: Severe or life-threatening infections occurred in patients after YESCARTA infusion. In Study 1, infections (all grades) occurred in 38% of patients. Grade 3 or higher infections occurred in 23% of patients. Grade 3 or higher infections with an unspecified pathogen occurred in 16% of patients, bacterial infections in 9%, and viral infections in 4%. YESCARTA should not be administered to patients with clinically significant active systemic infections. Monitor patients for signs and symptoms of infection before and after YESCARTA infusion and treat appropriately. Administer prophylactic anti-microbials according to local guidelines. Fever or neutropenia was observed in 36% of patients after YESCARTA infusion and may be concurrent with CRS. In the event of febrile neutropenia, evaluate for infection and manage with broad spectrum antibiotics, fluids and other supportive care as medically indicated. Viral Reactivation: Hepatitis B virus (HBV) reactivation, in some cases resulting in fulminant hepatitis, hepatic failure and death, can occur in patients treated with drugs directed against B cells. Perform screening for HBV, HIV, and HSV in accordance with clinical guidelines before collection of cells for manufacturing.

5.6 Prolonged Cytophenias: Patients may exhibit cytophenias for several weeks following lymphodepleting chemotherapy and YESCARTA infusion. In Study 1, Grade 3 or higher cytophenias not resolved by Day 30 following YESCARTA infusion occurred in 28% of patients and included thrombocytopenia (18%), neutropenia (15%), and anemia (3%). Monitor blood counts after YESCARTA infusion.

5.7 Hypogammaglobulinemia: B-cell aplasia and hypogammaglobulinemia can occur in patients receiving treatment with YESCARTA. In Study 1, hypogammaglobulinemia occurred in 15% of patients. Monitor immunoglobulin levels after treatment with YESCARTA and manage using infection precautions, antibiotic prophylaxis and immunoglobulin replacement. The safety of immunization with live viral vaccines during or following YESCARTA treatment has not been studied. Vaccination with live virus vaccines is not recommended for at least 6 weeks prior to the start of lymphodepleting chemotherapy, during YESCARTA treatment, and until immune recovery following treatment with YESCARTA.

5.8 Secondary Malignancies: Patients treated with YESCARTA may develop secondary malignancies. Monitor life-long for secondary malignancies. In the event that a secondary malignancy occurs, contact Kite at 1-844-454-KITE (5483) to obtain instructions on patient samples to collect for testing.

5.9 Effects on Ability to Drive and Use Machines: Due to the potential for neurologic events, including altered mental status or seizures, patients receiving YESCARTA are at risk for altered or decreased consciousness or decision-making in the 8 weeks following YESCARTA infusion. Advise patients to refrain from driving and engaging in hazardous occupations or activities, such as operating heavy or potentially dangerous machinery, during this initial period.

6 ADVERSE REACTIONS: The following adverse reactions are described in Warnings and Precautions: Cytokine Release Syndrome, Neurologic Toxicities, Hypersensitivity Reactions, Serious Infections, Prolonged Cytophenias, Hypogammaglobulinemia.

6.1 Clinical Trials Experience: Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of another drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. The safety data described in this section reflect exposure to YESCARTA in the clinical trial (Study 1) in which 108 patients with relapsed/refractory B-cell NHL received CAR-positive T cells based on a recommended dose which was weight-based [see Clinical Trials (14)]. Patients with a history of CNS disorders (such as seizures or cerebrovascular ischemia) or autoimmune disease requiring systemic immunosuppression were ineligible. The median duration of follow up was 8.7 months. The median age of the study population was 58 years (range: 23 to 76 years); 68% were men. The baseline ECOG performance status was
43% with ECG 0, and 57% with ECG 1. The most common adverse reactions (incidence ≥ 20%) include CRS, fever, hypotension, encephalopathy, tachycardia, fatigue, headache, decreased appetite, chills, diarrhea, febrile neutropenia, infections-pathogen unspecified, nausea, hypoxia, tremor, cough, vomiting, dizziness, constipation, and cardiac arrhythmias. Serious adverse reactions occurred in 52% of patients. The most common serious adverse reactions (≥ 2%) include encephalopathy, fever, lung infection, febrile neutropenia, cardiac arrhythmia, cardiac failure, urinary tract infection, renal insufficiency, aphasia, cardiac arrest, Clostridium difficile infection, delirium, hypotension, and hypoxia. The most common (≥ 10%) Grade 3 or higher reactions include febrile neutropenia, fever, CRS, encephalopathy, infections-pathogen unspecified, hypotension, hypoxia, and lung infections. Forty-five percent (49/108) of patients received tocilizumab after infusion of YESCARTA.

### Summary of Adverse Reactions Observed in at Least 10% of the Patients Treated with YESCARTA in Study 1

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>Any Grade (%)</th>
<th>Grades 3 or Higher (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cardiac disorders</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tachycardia</td>
<td>57</td>
<td>2</td>
</tr>
<tr>
<td>Arrhythmia</td>
<td>23</td>
<td>7</td>
</tr>
<tr>
<td><strong>Gastrointestinal disorders</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diarrhea</td>
<td>38</td>
<td>4</td>
</tr>
<tr>
<td>Nausea</td>
<td>34</td>
<td>1</td>
</tr>
<tr>
<td>Vomiting</td>
<td>26</td>
<td>1</td>
</tr>
<tr>
<td>Constipation</td>
<td>23</td>
<td>0</td>
</tr>
<tr>
<td>Abdominal pain</td>
<td>14</td>
<td>1</td>
</tr>
<tr>
<td>Dry mouth</td>
<td>11</td>
<td>0</td>
</tr>
<tr>
<td><strong>General disorders and administration site conditions</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fever</td>
<td>86</td>
<td>16</td>
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<tr>
<td>Fatigue</td>
<td>46</td>
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<tr>
<td>Chills</td>
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<td>Edema</td>
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<td><strong>Immune system disorders</strong></td>
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<tr>
<td>Cytokine release syndrome</td>
<td>94</td>
<td>13</td>
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<td>Hypogammaglobulinemia</td>
<td>15</td>
<td>0</td>
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<tr>
<td><strong>Infections and infestations</strong></td>
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<tr>
<td>Infections-pathogen unspecified</td>
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<tr>
<td>Viral infections</td>
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<td>Bacterial infections</td>
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<tr>
<td><strong>Investigations</strong></td>
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<tr>
<td>Decreased appetite</td>
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<td>Dehydration</td>
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<td><strong>Musculoskeletal and connective tissue disorders</strong></td>
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<tr>
<td>Motor dysfunction</td>
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<td>Pain in extremity</td>
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<td><strong>Nervous system disorders</strong></td>
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<td><strong>Psychiatric disorders</strong></td>
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<td><strong>Respiratory, thoracic and mediastinal disorders</strong></td>
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<td>Cough</td>
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<td><strong>Renal and urinary disorders</strong></td>
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<td>Renal insufficiency</td>
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<tr>
<td><strong>Vascular disorders</strong></td>
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<tr>
<td>Hypertension</td>
<td>57</td>
<td>15</td>
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<tr>
<td>Hypotension</td>
<td>15</td>
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<tr>
<td><strong>Other adverse reactions</strong></td>
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</tbody>
</table>
| The following events were also counted in the incidence of CRS: tachycardia, arrhythmia, fever, chills, hypoxia, renal insufficiency, and hypotension. For a complete list of events that contributed to the incidence of certain adverse reactions, please see footnote below Table 3 in Section 6.1 of the Full Prescribing Information.

Other clinically important adverse reactions that occurred in less than 10% of patients treated with YESCARTA include the following: blood and lymphatic system disorders: coagulopathy (2%); cardiac disorders: cardiac failure (6%) and cardiac arrest (4%); immune system disorders: hemophagocytic lymphohistiocytosis/macrophage activation syndrome (HLH/MAS) (1%), hypersensitivity (1%); infections and infestations disorders: fungal infections (6%); nervous system disorders: ataxia (6%), seizure (4%), dyscalculia (2%), and myoclonus (2%); respiratory, thoracic and mediastinal disorders: pulmonary edema (9%); skin and subcutaneous tissue disorders: rash (9%); vascular disorders: capillary leak syndrome (3%).

### Grade 3 or 4 Laboratory Abnormalities Occurring in ≥ 10% of Patients in Study 1 Following Treatment with YESCARTA Based on CITAE (N=108) Lymphopenia 100%, Leukopenia 96%, Neutropenia 93%, Anemia 66%, Thrombocytopenia 58%, Hyponatremia 50%, Hypophosphatemia 19%, Uric acid increased 13%, Direct Bilirubin increased 13%, Hypokalemia 10%, Alanine Aminotransferase increased 10%.

6.2 Immuneogenicity: YESCARTA has the potential to induce anti-product antibodies. The immunogenicity of YESCARTA has been evaluated using an enzyme-linked immunosorbent assay (ELISA) for the detection of binding antibodies against FMC63, the originating antibody of the anti-CD19 CAR. Three patients tested positive for pre-dose anti-FMC63 antibodies at baseline and Months 1, 3, or 6 in Study 1. There is no evidence that the kinetics of initial expansion and persistence of YESCARTA, or the safety or effectiveness of YESCARTA, was altered in these patients.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy: Risk Summary: There are no available data with YESCARTA use in pregnant women. No animal reproductive and developmental toxicity studies have been conducted with YESCARTA to assess whether it can cause fetal harm when administered to a pregnant woman. It is not known if YESCARTA has the potential to be transferred to the fetus. Based on the mechanism of action, if the transduced cells cross the placenta, they may cause fetal toxicity, including B-cell lymphocytopenia. Therefore, YESCARTA is not recommended for women who are pregnant, and pregnancy after YESCARTA infusion should be discussed with the treating physician. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% - 4% and 15% - 20%, respectively.

8.2 Lactation: Risk Summary: There is no information regarding the presence of YESCARTA in human milk, the effect on the breastfed infant, and the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother’s clinical need for YESCARTA and any potential adverse effects on the breastfed infant from YESCARTA or from the underlying maternal condition.

8.3 Females and Males of Reproductive Potential: Pregnancy Testing: Pregnancy status of females with reproductive potential should be verified. Sexually-active females of reproductive potential should have a pregnancy test prior to starting treatment with YESCARTA. Contraception: See the prescribing information for fludarabine and cyclophosphamide for information on the need for effective contraception in patients who receive the lymphodepleting chemotherapy. There are insufficient exposure data to provide a recommendation concerning duration of contraception following treatment with YESCARTA. Infertility: There are no data on the effect of YESCARTA on fertility.

8.4 Pediatric Use: The safety and efficacy of YESCARTA have not been established in pediatric patients.

8.5 Geriatric Use: Clinical trials of YESCARTA did not include sufficient numbers of patients aged 65 years and older to determine whether they respond differently or have different safety outcomes as compared to younger patients.

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Medication Guide). Ensure that patients understand the risk of manufacturing failure (1% in clinical trial). In case of a manufacturing failure, a second manufacturing of YESCARTA may be attempted. In addition, while the patient awaits the product, additional chemotherapy (not the lymphodepletion) may be necessary and may increase the risk of adverse events during the pre-infusion period. Advise patients to seek immediate attention for any of the following: Cytokine Release Syndrome, Neurologic Toxicities, Serious Infections, Prolonged Cytopenia [see Warnings and Precautions (5.1, 5.2, 5.3, 5.5) and Adverse Reactions (6) for more information and signs and symptoms]. Advise patients for the need to: Refrain from driving or operating heavy or potentially dangerous machinery after YESCARTA infusion until at least 8 weeks after infusion [see Warnings and Precautions (5.2)]. Have periodic monitoring of blood counts. Contact Kite at 1-844-454-KITE (5483) if they are at least 8 weeks after YESCARTA infusion.

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Lend a Hand to Rising Stars
Fostering growth pays big dividends

This issue of Managed Healthcare Executive recognizes the top 10 emerging leaders in our industry, as selected by our editorial advisory board. These remarkable individuals include leaders who have demonstrated their expertise in areas such as the human genome, opioid risk management, innovative cloud solutions, care management technology, and mental healthcare. They demonstrate the key attributes that define up-and-coming leaders: vision, drive, confidence, resourcefulness, and tenacity.

Emerging leaders, as represented by this group, are often the product of organizations that actively encourage and develop their capabilities and acknowledge their contributions, as exemplified by the vast number of nominations we received this year.

There are many different ways to cultivate emerging leaders, but the most successful organizations incorporate these five critical aspects:

1. **Identify potential leaders**
   While there are a number of analytical assessment tools available to identify prospective leaders, perhaps the best tool is a management team engaged in the identification, formal and informal, of team members demonstrating leadership potential. Once identified, having a process that includes regular updates on how their skills are evolving, offering appropriate training, and establishing meaningful career paths can set a trajectory for growth for these individuals.

2. **Offer mentoring**
   One of the most valuable tools for grooming emerging leaders is providing a trusted resource that can be a sounding board for their ideas, provide feedback on how they are approaching projects and issues, and serve as a source of support and encouragement. In the best case, mentors should be drawn from the ranks of upper management and outside of a direct reporting relationship to the candidate.

3. **Provide challenges**
   Putting prospective leaders to the test with opportunities that require creativity, goal setting, resourcefulness, and getting buy-in from various departments within the organization is an important step in determining how successful these individuals will be as leaders. Often, emerging leaders will exceed expectations on these types of opportunities, reinforcing their selection as future leaders.

4. **Let them lead**
   When management positions open up, look first to your pool of emerging leaders. Even better, give them opportunities to build out new products or services and take their skills to a whole new level.

5. **Recognize accomplishments**
   Recognition is important but needs to be personalized. Monetary rewards only go so far. Conference participation, appointment to community boards, and nomination to regional and national recognition programs are a few ways to let emerging leaders feel the love.

   These individuals are not only the future of their organizations, but even more important, they are the future of our industry. Their importance cannot be overstated.

   Healthcare in the U.S. is at a critical point. Rising costs, governmental indecision, aging and sicker populations, high deductibles, and a high level of consumer dissatisfaction create a rich environment for new and disruptive approaches. Savvy organizations understand this environment and are making the investment in finding and developing their next crop of leaders that can lead us all into the future.

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Don Hall, MPH, is principal at DeltaSigma, LLC. in Littleton, CO. He is a member of the Managed Healthcare Executive advisory board.

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Managed Healthcare Executive.com
Mission: Managed Healthcare Executive provides healthcare executives at health plans and provider organizations with analysis, insights, and strategies to pursue value-driven solutions.
Healthcare executives must recognize the impact migraines have on people at home and in the workplace, as there is a serious need for additional treatment options, according to a new report. The 2018 Migraine Impact Report evaluates the physical, social, and economic challenges of migraine. The Eli Lilly and Company-sponsored quantitative opinion survey includes responses from 1,018 U.S. adults, including 518 people who have been diagnosed with migraine, 200 people who know someone with migraine, and 300 people who do not know someone with migraine.

Among those surveyed, people diagnosed with migraine experienced an average 15.4 completely pain-free days over the previous 30 days. They also noted that the symptoms of their migraine prevented them from doing what they wanted to do for one week (6.9 days) over the previous 30 days.

"More than 36 million Americans battle migraine, many of whom lack a treatment option that addresses their symptoms and allows them to function in their day-to-day lives or is tolerable for them," says Sheena Aurora, MD, medical fellow at Eli Lilly and Company.

As a practicing neurologist, Aurora encourages the industry to prioritize and recognize the impact of migraine and new treatments.

"Despite its prevalence, migraine is often underestimated or dismissed as 'simply a headache,'" she says. "Migraine is a neurologic disease that can seriously affect a person's life, and there are many people living with migraine who are unable to work and take care of their families. In fact, millions of people with migraine are losing at least one month per year to the disease—something I saw firsthand with many patients." Over the last two decades, innovation in migraine treatment has been limited—"but with new preventive therapies on the horizon... these new options may substantially improve care for those living with this disease," says Aurora.

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**Competitive Landscape: Anti-CGRP Class For Migraine Prevention**

<table>
<thead>
<tr>
<th>Company</th>
<th>Compound</th>
<th>BLA Submission</th>
<th>Delivery</th>
<th>Frequency</th>
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<td>Self-injected</td>
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<td>Eli Lilly</td>
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<td>Teva Pharmaceuticals</td>
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<td>Self-injected</td>
<td>Monthly and quarterly</td>
</tr>
<tr>
<td>Alder BioPharmaceuticals</td>
<td>eptinezumab</td>
<td>BLA submission planned for second half of 2018</td>
<td>Intravenously or self-injected</td>
<td>Quarterly</td>
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</table>

Pipeline drugs
The most prominent focus of pipeline activity is a new and promising category of drug products known as CGRP (calcitonin gene-related peptide) antagonists. Researchers have determined that CGRP levels are highly elevated in migraine sufferers and medications that can bind to and inhibit the activity of CGRP may yield significant value in helping to better manage migraine and cluster headache.

There are four CGRP antagonists in late-stage development (see table pg. 8). Recent late-stage clinical trials with these drugs demonstrate significant reductions in monthly migraine or headache days compared to placebo, and with minimal side effects, according to a study in Current Treatments in Neurology.

Other treatment pipeline drugs include:
- Lasmiditan, an investigational, first-in-class molecule for the acute treatment of migraine. It is the only oral drug in development of its kind that selectively targets 5-HT1F receptors, including those expressed in the trigeminal pathway, and has been designed for the acute treatment of migraine without the vasoconstrictor activity associated with some migraine therapies. If approved, lasmiditan could represent the first significant innovation for the acute treatment of migraine in more than 20 years. In December 2017, Lilly announced positive results from the second of two phase 3 studies evaluating lasmiditan for the acute treatment of migraine. Lilly plans to submit a New Drug Application (NDA) for lasmiditan to the FDA in the second half of 2018.
- Ubrogepant, a novel, highly potent, orally-administered CGRP antagonist from Allegan is being evaluated for the acute treatment of migraine. Ubrogepant met its main goals in the first of two phase 3 studies. In a trial of 1,327 adults with migraines, ACHIEVE-I, the drug bested a placebo at reducing the pain or symptoms from a single “moderate to severe” attack. Results of the second phase 3 trial, ACHIEVE II, are expected in coming months. Allegan anticipates filing of an NDA to the FDA in 2019.

To be determined
These agents offer renewed hope for migraine sufferers, but hope must be balanced with questions that will remain largely unanswered at product introduction:
- Long-term data with use of these agents is largely limited at this point, and as such, whether these products provide long-term reliable durability of effect, safety, and tolerability will be determined, according to the Current Treatments in Neurology study.
- While safety and tolerability of these products in clinical trials thus far appears good, it must be recognized that CGRP has many complex functions in the nervous and vascular systems. CGRP receptors are also found in the adrenal glands, kidneys, pancreas, and bone. There is at least a theoretical risk that blocking CGRP could hinder any beneficial physiologic functions CGRP activity may provide. And, since the activities of these drugs have been shown to be prolonged in the body, any undesirable effects may not be quickly and easily reversed, according to the Current Treatments in Neurology study.
- Pricing of these products will not be determined until product launch, however analysts estimate pricing for preventive CGRP antagonists could range from about $8,500 to $20,000 per year, according to The Verge. Without direct comparative data demonstrating enhanced safety and efficacy versus current standards of migraine care (preventative and abortive), cost effectiveness of the therapies will be determined.

Startling stats
- People who do not have migraine often underestimate the pain and average duration of migraine. On a scale of one to 10, those surveyed who did not know someone with migraine underestimated the pain of a typical migraine (an average score of 6.2 compared to an average score of 7.1 given by people diagnosed with migraine).
- Migraine frequently adds stress and may result in less time with family. Nearly three out of four parents surveyed who were diagnosed with migraine (72%) agreed they wish they could do more to manage their disease.
- Migraine may impact a person’s career potential. Among employed respondents diagnosed with migraine, seven out of 10 (68%) agreed they have been less productive at work due to migraine.
- Most respondents diagnosed with migraine (81%) agreed they wish they could do more to manage their disease.
- Those diagnosed with migraine experienced on average only 15.4 completely pain-free days over the previous 30 days. Respondents also noted their migraine prevented them from doing what they wanted to do for one week (6.9 days) over the previous 30 days.

Source: The 2018 Migraine Impact Report
Managed Healthcare Executive has selected 10 emerging industry leaders working in the areas of pharmacy, health plans, health systems, and technology

By KAREN APPOLD

EUAN ASHLEY
MD, PhD, professor of medicine and genetics at Stanford University and founding director of the Stanford Center for Inherited Cardiovascular Disease, Stanford University

Ashley joined Stanford’s faculty in 2006 and led a team that carried out the first clinical interpretation of the human genome. By applying genomics to medicine, Ashley is helping patients and families with genetic risk of heart disease manage their condition and health. He works with colleagues to diagnose and treat entire families who are at risk for life-threatening heart abnormalities using genetic sequencing. This approach helps identify and treat rare and previously undiagnosed diseases. He was also the first co-chair of the steering committee of the National Institutes of Health's Undiagnosed Diseases Network.

MHE: Why did you choose your profession?
Ashley: Growing up in the west of Scotland, a region with one of the highest rates of heart disease in the world, I saw my father—a general practitioner—deliver amazing, personalized care to the community. I could think of no higher calling than to try to emulate that.

MHE: What has been your biggest learning experience?
Ashley: Some of our most important lessons come from outside our industry. In most sectors, you aim to proactively identify problems and address them before they occur. In medicine, we rarely get ahead of disease; instead, we treat it when it occurs.
MHE: What change would you like to see in healthcare in the next 10 years?
Ashley: We have to become much more proactive. We need to better understand people’s risks and implement programs that help mitigate these risks before disease occurs. At Stanford Health Care, we call that precision health—using technology to predict, prevent, and cure disease precisely.

MHE: If you could sit down to dinner with anyone involved in healthcare, who would it be?
Ashley: I would love to sit down and chat with Peter Abildgaard. In 1775 Denmark, he figured out that an electric shock can stop and restart the heart. He tried it on a chicken and basically invented the defibrillator.

DAVID CALABRESE

RPh, MHP, senior vice president and chief pharmacy officer, OptumRx

Over the last 12 years of his career, Calabrese has dedicated his work to pharmacy benefit management. His leadership work in areas such as opioid risk management, evidence-based pharmacy and therapeutics committee execution, compound drug management, and pharmacy benefit management transparency have been well-publicized as key benchmarks within the industry.

MHE: Why did you choose your profession?
Calabrese: I followed in the footsteps of my grandfather, who ran an independent pharmacy in our Connecticut hometown. I was inspired at an early age by his integrity, sense of caring, dedication to the profession, and how well-respected and valued he was among those he served within our community. Throughout my career, I’ve attempted to emulate his professionalism and combine that with the strong sense of accountability and work ethic my parents instilled in me, to help drive further advancements in population-based pharmacy care.

MHE: What has been your biggest learning experience?
Calabrese: An appreciation for the enormous
Ten Emerging Industry Leaders

“My hope is that the future state will more closely reflect one in which data and electronic health information is more fully unlocked and seamlessly shared across the healthcare continuum.” —David Calabrese

value of effective data management and analytics in helping to transform our healthcare system from a “volume-based” business to a much more desirable “value-based” model. Within Optum, our ability to harness the power of such capabilities, extending well beyond just pharmacy data, has enabled important advancements in clinical programming. Transforming data into timely, meaningful “next best actions” is helping to empower enhanced provider and patient engagement, drive more rapid adoption of new evidence-based standards, and more positively impact both the overall quality and economics of care.

MHE: What change would you like to see in healthcare in the next 10 years?
Calabrese: While I’ve witnessed enormous strides in advancing the state of healthcare in the United States over the years, I still remain fairly disheartened by the level of disconnectedness that prevails across our industry. My hope is that the future state will more closely reflect one in which data and electronic health information is more fully unlocked and seamlessly shared across the healthcare continuum to achieve more patient-centered, higher-quality care, greater cost-efficiency, and a healthier society.

MHE: If you could sit down to dinner with anyone involved in healthcare, who would it be?
Calabrese: It would be Sidney Garfield, MD, the lesser-known cofounder of Kaiser Permanente and one of the pioneers of managed healthcare in the United States. Throughout his career, he held firmly to the belief that healthcare should not simply be focused on care for the sick, but more broadly emphasize a focus upon the entire spectrum of care from prevention, to education, to wellness and health maintenance. His ultimate goal was to make healthcare more accessible, efficient, and affordable for everyone, while still providing the highest quality medical care. Today, his vision remains as a beacon of guidance for advancing the future of healthcare.

TINA FREESE DECKER
MHA, MSIE, FACHE, executive vice president and chief operating officer, Spectrum Health

Freese Decker oversaw a $300 million transformation of care models and installation of Epic, an electronic clinical and revenue cycle platform. She also championed the launch of MedNow at Spectrum Health, a proprietary telemedicine service. By employing a virtual medicine strategy, the health system reduced hospital utilization and costs, and increased virtual visits by 355% over the prior year. In addition, the health system saw positive movement in employee and physician satisfaction during this extensive care transformation effort.

Freese Decker was also integral to Spectrum Health’s graduate medical education transition to a direct sponsorship model, resulting in a new Spectrum Health/Michigan State University department for 300 residents and fellows. This model improves the learning experience by increasing connectivity and engagement between residents, fellows, and faculty physicians.

MHE: Why did you choose your profession?
Freese Decker: I saw a need to remove barriers, make access easier for everyone, and positively impact the community’s health for generations to come. A consumer partnership focus is fundamental to my leadership strategy as ev-

Continued on page 14
You know something called H.R. 1628 Section 12 might change everything.

No one knows your business better than you. And with how quickly healthcare changes, you also know that you have to evolve with it. MB’s expanded healthcare team is here to offer your business creative ideas on how to stay on top of changing healthcare regulations and technology to better help the people you care for.

MB Financial Bank
Ten Emerging Industry Leaders

Continued from page 12

indexed by our health system’s new digital tools: MyHealth patient portal and MedNow telemedicine tool, which help more than 500,000 consumers every year.

MHE: What has been your biggest learning experience?
Freese Decker: The speed at which our industry is changing forced me to realize that we needed to lead rather than follow; to be innovative and create new solutions rather than be reactive. We must push the boundaries and conceive of new ways to provide care and coverage. As a result, we are collaborating with new and different partners such as major retailers and genetic wellness researchers. We have also developed new care models, such as community health workers who visit patients in their homes to assist them with health needs.

MHE: What change would you like to see in healthcare in the next 10 years?
Freese Decker: I would like to see health systems be aligned with keeping people healthy and reducing the total cost of care. This will require innovative business models, a focus on delighting and engaging with consumers, and new payment models that reward health and wellness through prediction and prevention.

MHE: If you could sit down to dinner with anyone involved in healthcare, who would it be?
Freese Decker: I would prefer to meet someone outside of the industry for a different perspective: Alan Mulally, former president and CEO of Ford Motor Company, who brought it back from the brink of bankruptcy. He transformed the company to think and work differently. Healthcare is being disrupted by new entrants to the industry. To be successful as an incumbent, we need to understand how others improved and embraced ideas. We must take our legacy systems and culture and reshape them into a 21st century, consumer-first organization.

GRANT GEIGER
founder and CEO, EIR Healthcare

Geiger, 30, started his healthcare career at Siemens Healthcare and later at Cerner Corp., developing products and services for the healthcare information technology industry. At Siemens Healthcare, he became the youngest director in the company and led a project management team that oversaw a $23 million a year capital budget and worked on $100 million in projects.

Geiger started EIR Healthcare in 2016 to continue his father’s legacy of engineering and design. EIR creates modular healthcare rooms that decrease construction time by 30% to 50%
and money spent by 30% compared to traditional construction when building hospitals. These pre-fabricated hospital rooms are delivered to a healthcare facility. Called MedModular, the product is the first of its kind to link industrial engineering, ship building, and hospital construction. Rooms are inserted into a building and are already wired for electric, HVAC, and plumbing—creating a plug-and-play solution.

MHE: Why did you choose your profession?
Geiger: I always felt like my profession chose me. I graduated from Drexel University and participated in its co-op program, which allowed me to gain real-world work experience while in school. Since then, I’ve always worked in healthcare. It’s the best way to have a positive influence on society.

MHE: What has been your biggest learning experience?
Geiger: My biggest learning experience, which has been reaffirmed time and again, is that at the end of the day, the people in our industry do care about human life. We want to improve outcomes for everyone. This has taught me compassion and knowledge of the human experience. So many people struggle daily with health issues. Our industry is continuously searching for ways to improve the patient experience.

MHE: What change would you like to see in healthcare in the next 10 years?
Geiger: I would like to see the introduction of the next generation of healthcare leadership and thinking. These leaders will push the tipping point within life science, pharma, information technology, and infrastructure. If we are able to introduce significant changes within healthcare, simultaneously we will usher in innovation in the delivery of care that hasn’t been seen in almost 100 years.

MHE: If you could sit down to dinner with anyone involved in healthcare, who would it be?
Geiger: Florence Nightingale—simply because I would love the opportunity to have a current conversation with someone who had such a grand vision. Her ideas and concepts around care for patients, medical statistics, and training standards ushered in a major revolution in care in the 19th century. Perhaps even now she would have ideas and suggestions on opportunities for reform today.

ERIN HAFER

MPH, director, New Programs Integration and Network Development, Community Health Plan of Washington (CHPW)

Hafer has extensive experience working with managed care and delivery systems in integrating healthcare reform opportunities through strategic planning, product development, payment model innovation, and legislative advocacy. She partners closely with federal and state agencies and community partners on healthcare transformation activities. Hafer has developed models to improve access to care for individuals with complex conditions such as mental health and substance use disorders. One such model includes the innovative Mental Health Integration Program (MHIP), which embeds mental health professionals in the primary care delivery system. MHIP outcomes include decreasing inpatient admissions, lowering arrest rates for patients receiving services, reducing the average time to improve clinical depression symptoms by half, and saving the hospital more than $11.2 million during the initial 14 months of statewide MHIP implementation—a net savings of $66 per member per month.

MHE: Why did you choose your profession?
Hafer: I am driven by a commitment to social justice and equity. After starting my career in community organizing with migrant farmworkers and political organizing, I worked in healthcare advocacy. Given my desire to affect change at the health systems’ level and improve population health strategies, the next natural step was to pursue my master’s degree in public health. I was drawn to CHPW due to its mission as a not-for-profit health plan, governed by federally qualified community health centers. In my 11 years at CHPW, I’ve been fortunate to work in several different business areas including public policy, product development, strategy and analytics, and network development. These experiences allowed me to focus on both operational implementation and health systems innovations.

“I always felt like my profession chose me.”
—Grant Geiger

“After starting my career in community organizing with migrant farmworkers and political organizing, I worked in healthcare advocacy.”
—Erin Hafer
MHE: What has been your biggest learning experience?
Hafer: Working in product development and health system innovation can be challenging, especially in an ever-changing environment. There is often tension between operational performance and innovation. Building a sustainable culture for innovation requires dedicated resources and an intentional focus on innovation as an organizational goal.

MHE: What change would you like to see in healthcare in the next 10 years?
Hafer: I would like to see better integration of physical and behavioral healthcare regardless of the care setting and a stronger incorporation of social determinants of health such as housing status, income, education, and ethnicity/race. While there is general acknowledgment of the role that behavioral health and social determinants of health play in health outcomes, there are still many limitations in how healthcare dollars can be used to address these issues. Through better incorporation of the social determinants of health, we will be better positioned to improve not only individual and population health, but also health equity.

MHE: If you could sit down to dinner with anyone involved in healthcare, who would it be?
Hafer: Having experienced the implementation of the ACA, including Medicaid expansion first-hand, I have seen the benefits of improved access to health coverage. I would love to hear Former President Barack Obama’s reflections on the challenges in passing the ACA and what he feels has worked well and what could be improved.

VEENA GOEL JONES
MD, medical director, Digital Patient Experience, Sutter Health and Pediatric Hospitalist at Sutter Health’s Palo Alto Medical Foundation

Jones completed inaugural fellowships in pediatric hospital medicine and clinical informatics programs at Stanford University. She joined Sutter Health in 2016 at age 30 as medical director of digital patient experience, while simultaneously practicing as a pediatric hospitalist. She helps set clinical priorities for digital health

“No matter what incentives are created by healthcare laws, hospital policies, and financial models, at the end of the day, the field of healthcare is about helping people.”
—Veena Goel Jones
implementations including the organization’s online patient portal, telemedicine initiatives, off-site call center operations, and strategic partnerships, and offers subsequent stewardship over the operational implementations of these programs. Her passions lie in harnessing technology and digital tools to empower patients and their families to make informed decisions as they navigate all aspects of their healthcare.

MHE: Why did you choose your profession?

Jones: It is my greatest privilege as a pediatrician to help children and their families navigate illnesses and the healing process. I chose this profession because I have always been humbled and moved by children’s innocence and resilience. During the course of my medical training, I also developed a passion to improve the overall quality and delivery of care within healthcare systems. I am fortunate to have found a career that allows me to leverage digital technology to lead organizational change, while also revolutionizing the experience of patients and providers.

MHE: What has been your biggest learning experience?

Jones: The most powerful experiences I have had in healthcare have been at the patient bedside, from seeing a family struggle to access care for a loved one, to holding a parent’s hand as they have grieved the loss of their child, to bringing a smile to an ailing patient’s face. These are just a few examples of situations that have taught me that no matter what incentives are created by healthcare laws, hospital policies, and financial models, at the end of the day, the field of healthcare is about helping people. Maintaining this perspective keeps me grounded and keeps the patient at the forefront of my mind when it comes to making decisions and leading change.

MHE: What change would you like to see in healthcare in the next 10 years?

Jones: I would like to see digital health solutions more thoughtfully integrated into healthcare delivery systems to make it easier for people to access the right care, via the means they desire, when they need it. From artificial intelligence platforms to telemedicine, there is great potential for such technology to become ubiquitous within healthcare if payment and incentive models can evolve to make care more affordable.

MHE: If you could sit down to dinner with anyone involved in healthcare, who would it be?

Jones: William Osler, MD—the father of modern medicine. He pushed against previously accepted standards in medicine with his vision for patient-centered medical education. I would be fascinated to get his perspectives on innovating and adapting how we can provide patient-centered care in the digital age.

ASHISH KACHRU

MBA, founder and CEO, Altruista Health

After working in several industries, Kachru joined UnitedHealthcare as the national director of its business risk management division overseeing many safety net health plans. He soon realized that for the healthcare system to create a lasting positive change in a member’s health, the system would have to be organized around value-based care. To enable this change, technology would play an important role. Kachru founded Altruista Health with a mission to drive improvements in cost savings and health outcomes through such technology. He led the development of a suite of applications called GuidingCare, which ties payers, providers, and members together on a single platform to manage the entire continuum of care. GuidingCare is on track to double its 38 million members this year; its use by provider organizations and health plans continues to grow.

MHE: Why did you choose your profession?

Kachru: I worked in several other industries before healthcare—manufacturing, nanotechnology, consumer product goods, and venture capital. But because several of my family members work in healthcare, the mission to serve others was a strong motivator. I was passionate about leaning into my experience from other industries to drive positive change in healthcare.

MHE: What has been your biggest learning experience?

Kachru: Healthcare is vastly different from any other industry in which consumers drive the market. Rules that apply in other industries don’t often apply.”

—Ashish Kachru

“Healthcare is vastly different from any other industry in which consumers drive the market. Rules that apply in other industries don’t often apply.”

—Ashish Kachru
Patrick Mitsch
PharmD, pharmacy director, UCare

After receiving a doctor of pharmacy degree from the University of Minnesota in 2012, Mitsch worked as a retail pharmacy manager for CVS. He then joined CVS’ health insurance arm, Caremark, in 2013 as a clinical pharmacist in its Medicare business unit. He came to UCare, a not-for-profit health plan, in 2015, and he quickly ascended to director of pharmacy in 2017. At UCare, Mitsch, now 31, uses his community experience to lead innovative quality programs that advance medication adherence and focus on preventive opioid management, cost containment, and member and provider education.

MHE: Why did you choose your profession?
Mitsch: Growing up, I saw a pharmacist’s impact firsthand as my grandfather cared for my grandmother who had Alzheimer’s disease. This pharmacist always ensured that my grandfather had the necessary knowledge to manage my grandmother’s complex medication regimen. This experience led me to want to become a community pharmacist. After achieving this goal and being able to impact patient care on an individual level, I soon realized the benefits of influencing patient care on a population health level. As director of pharmacy at UCare, I can positively impact patient care for those communities and populations that need it most, including communities where I grew up and worked.

MHE: What change would you like to see in healthcare in the next 10 years?
Mitsch: Working for a health plan that serves many underserved populations has taught me that we need to have a holistic view when approaching patient care. For example, if we want to drive medication adherence for these members, we need to meet them where they are and understand the cultural, economic, and social issues that may be barriers.

MHE: What has been your biggest learning experience?
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MHE: If you could sit down to dinner with anyone involved in healthcare, who would it be?
Mitsch: Scott Gottlieb, the acting commissioner of the FDA. Gottlieb came into his role at an unenviable time with the opioid crisis and high drug prices constantly making headlines. He has taken a sensible approach to addressing these issues—increasing generic drug approvals, pushing a high-risk opioid off the market, and advocating for more widespread availability of medication-assisted treatment for opioid addicts. He has taken positive first steps to address these tough issues.

MHE: If you could sit down to dinner with anyone involved in healthcare, who would it be?
Kachru: Ted Kennedy—who was extremely passionate about healthcare reform throughout his political career. To have this much passion and drive for a single cause, and to dedicate your entire career to it, is very impressive. I’d like to understand what fueled his passion and how it kept him going, even during times when he did not achieve his goals.
MICHAIL POLEN

Executive Vice President, Medicare and Operations, WellCare Health Plans, Inc.

Since joining WellCare in 2005 as director of business planning and analytics, Polen, 38, has taken on roles of increasing responsibility. Today he serves as WellCare's executive vice president of Medicare and operations. Under his leadership, the company has transformed its Medicare program through membership growth and market expansion. He has also led enterprise-wide improvements in quality, operations, provider networks, and customer experience.

MHE: Why did you choose your profession?
Polen: When I began my career, I wanted to do something that was interesting, challenging, and allowed me to do some good in the world. This led me to healthcare—a dynamic industry where things are always changing. Rising costs and an aging baby boomer population are putting unprecedented demands on our current system. I wanted to help provide solutions so that today's seniors would have quality, cost-effective healthcare as they age.

MHE: What has been your biggest learning experience?
Polen: Managed care is a highly regulated industry. We work closely with government partners to meet strict care delivery metrics and guidelines to ensure we're providing access to the highest quality, most cost-effective healthcare for our members. This can be a challenge, but it has taught me to be open to change, to be nimble during adversity, to find new ways to solve problems, and to offer innovative solutions.

MHE: What change would you like to see in healthcare in the next 10 years?
Polen: I'd like to find a way to offer consumers greater transparency. When people have access to information about the cost and quality of their healthcare, they can make more informed decisions. When buying electronics, for example, there are dozens of ways to research and comparison shop for the best new models. But when we visit doctors or fill prescriptions—perhaps the most important purchases we make for ourselves and our families—we often don't have the information we need to make the most informed decision. I predict the demand for more transparency will only grow, and providers, hospitals, payers, and other healthcare stakeholders will need to work together to provide that information for patients.

MHE: If you could sit down to dinner with anyone involved in healthcare, who would it be?
Polen: I'd like to sit down with Amazon CEO

"The healthcare industry needs to be more innovative; there are plenty of ideas but not enough actual game changers.”
—Michael Polen

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Jeff Bezos to hear more about his vision for healthcare. Amazon is known for disrupting major industries, and now with JP Morgan and Berkshire Hathaway, the company announced it will form its own independent company to offer health insurance to its employees. The healthcare industry needs to be more innovative; there are plenty of ideas but not enough actual game changers. I’d like to see more industry leaders engage industry outsiders to further develop disruptive ideas aimed at addressing the age-old issues of healthcare costs, access, and outcome transparency.

When founding Babyscripts in 2014, Sebastian, 30, and Segura, 30, had a vision of using Internet-enabled medical devices and big data to transform the delivery of pregnancy care. The duo partnered with health systems and raised $8.6 million in venture and angel financing for their business. They also orchestrated large partnerships with General Electric, March of Dimes, StartUp Health, and the White House. The result is the first toolkit for tech-enabled prenatal and postpartum care. The pair are also the architects of the first “Prenatal Care Moonshot,” focused on eliminating preterm birth by 2027.

MHE: Why did you choose your profession?
Sebastian: I chose it for two reasons. First was my obsession with data and self-tracking. Through my involvement in the quantified self-movement, I have seen the promise and pitfalls of Big Data firsthand. The second reason was more personal; I saw my family’s experience and struggle with the current status of healthcare.

Segura: It was partially opportunity and partially responsibility. While healthcare information technology is an up and coming industry, Sebastian and I chose to pursue a career in transforming prenatal care because of the debt we both had to our mothers and mothers everywhere. There were no companies solely focused on moms in that space. We strove to change that.

MHE: What has been your biggest learning experience?
Sebastian: Healthcare is a slow-moving beast that is extremely resistant to change—you won’t see rocket-like growth like that seen in consumer segments. This has forced me to be cautious with setting expectations with both our investors and employees.

Segura: That entrepreneurship is harder than what you see on TV. But really, what I’ve come to appreciate is that the best things in life are not free. Everything worth fighting for will be difficult, and the biggest reward is surviving.
MHE: What change would you like to see in healthcare in the next 10 years?
Sebastian: Complete interoperability and the ability to combine data across several different patient journeys together to form one holistic view. One can dream, right?

Segura: More transparency in every part of how we deliver healthcare—from the pricing of services to the reasons for why certain events and outcomes occur. More transparency means more accountability, which is how our healthcare system will ultimately change.

MHE: If you could sit down to dinner with anyone involved in healthcare, who would it be?
Sebastian: Atul Gawande, MD, and Johnathan Bush, together! Gawande authored one of the first books I read in healthcare, “Complications: A Surgeon’s Notes on an Imperfect Science,” and I’ve been a fan of his ever since. It was a firsthand view of how the healthcare system is both protocol-oriented, yet, at the same time, human. Once I started Babyscripts, I witnessed Bush, CEO of athenahealth, a healthcare technology company, in action. His leadership ability is on-point. Underneath his antics and eccentric behavior is one of the sharpest and most knowledgeable minds in healthcare.

Segura: Ignaz Semmelweis—the man who championed the simple notion of washing your hands. He was driven mad by naysayers. I would sit down with him and simply thank him for never giving up.

“Sebastian and I chose to pursue a career in transforming prenatal care because of the debt we both had to our mothers and mothers everywhere.”

—Juan Pablo Segura

Selection criteria and process
MHE identified more than 30 finalists based on nominations received and independent research. Then, the editorial advisory board reviewed the finalists and selected 10 standouts.

To be considered, candidates had to meet the following requirements:

- Worked in the industry 15 years or fewer;
- Led key initiatives at their organizations or relevant organizations;
- Took actions that led to measurable, positive industry impacts;
- Accomplished something new or unique in the industry; and
- Continued to take on more advanced roles and responsibilities.
Enterprise Imaging

How one health system is benefiting by DONNA MARBURY

Enterprise imaging technology helps health systems and hospitals make radiology information more interoperable and accessible across clinical and business lines. That’s because the technology, which includes software that retrofits with existing systems or new hardware that provides interoperable solutions, allows images and other multimedia clinical content to be captured, reviewed, stored, distributed, and integrated into other technology systems such as EHRs and other vendor neutral viewers.

Enterprise imaging solutions will comprise 27% of imaging information technology, archiving, and management purchases by 2021, according to a report by Signify Research. The report notes that enterprise imaging is also the fastest growing segment of the imaging technology market.

How enterprise imaging creates business insight

Because traditional imaging technology is often siloed so that image capturing, storage, and analytics are separate functions from the rest of the IT systems, investing in an enterprise imaging system benefits more than just a hospital’s radiology department, says Mitchell Goldburgh, global solutions manager of enterprise imaging and analytics for NTT DATA Services technology company.

"By uniting all the functions on one platform, an enterprise system provides greater insight into operations through business intelligence and operational dashboards, and allows users to move more easily through their work," he says. "Work flows are organized in one system and users can access images and reports in a variety of locations and formats. Data can be more easily integrated for pre-

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Six elements of an enterprise imaging technology strategy:

A 2016 survey of 100 College of Healthcare Information Management Executives found that these six elements are the most important when developing an enterprise imaging technology strategy:

1 **Governance**
   Clinical, administrative, and IT departments should have early input on how enterprise imaging technology is implemented and overseen across the organization.

2 **Enterprise viewer**
   This viewer allows for images and scans to be read on desktop, laptop, and mobile devices.

3 **Vendor neutral archive**
   This medical imaging technology, also called VNA, allows for images and documents to be stored in a format that can be accessed across multiple systems.

4 **Image exchange**
   This technology allows for images and clinical data to be digitally exchanged between providers inside and outside of facilities using web-based services.

5 **Work flow exchanges**
   These solutions use algorithms to allow radiologists and other clinicians the ability to store, direct, and synchronize images and data based on user access rights and preferences, workload, time, and facility.

6 **Analytics**
   Having the ability to analyze costs, trends, and other actionable data along with clinical data is valuable when developing population health strategies and can make quality metrics more robust.
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dictive and prescriptive analytics, for population health and other purposes.

An enterprise system speeds up efforts to improve quality, use resources more efficiently, and monitor patient experience factors, Goldburgh says, noting that it also reduces the complexity of maintaining image data systems, because there is one repository with a common set of work flows.

Finally, he says, enterprise imaging can provide a complete record of all imaging across multiple EHRs and health systems, and therefore increase collaboration and improve care quality.

Costs for enterprise imaging technology vary depending on required functionality by intradepartment and interdepartment care coordination, Goldburgh says. Ultimately, he says the technology should lead to cost savings due to the consolidation of work processes.

Case study: Phoenix Children’s Hospital

Phoenix Children’s Hospital began using enterprise imaging technology in March 2017, as a part of a 15-year strategic partnership with Philips. The partnership gives the hospital access to advanced computed tomography (CT), magnetic resonance imaging (MRI), and angiography, along with patient monitoring, clinical informatics, and 3D printing that allows for research and innovation along with integrated picture archiving and communication systems and other IT solutions, says Richard Towbin, MD, division chief of radiology at Phoenix Children’s Hospital.

“We’ve had a long-term relationship with Philips going back 10 years, so we have been acquiring equipment based on our needs over a period of time. The enterprise agreement extended it and formalized aspects of it,” Towbin says, adding that the agreement moves beyond radiology to include other hospital IT components.

Silvie Casanova, public relations director of Philips North America, says a long-term enterprise imaging partnership between vendors and health systems can include:

- Research and innovation programs;
- First-to-market medical technologies; and
- Integrated solutions that combine hardware, software, and make information between IT systems interoperable (such as imaging systems and EHRs).

“We engage in new business models with shared accountability to improve health outcomes. It’s not just about buying technology from us, we see Phoenix as a partner that we are codeveloping technologies with,” Casanova says. “That way we can possibly get other health systems to adopt the same technology and we can support those health systems with what we codeveloped with Phoenix Children’s.”

Since adopting the new imaging and clinical informatics technology, Towbin says that the hospital’s radiology department has improved CT dose management using iterative reconstructions of images. Also, the 3D laboratory, which is part of the enterprise imaging technology, allows them to create life-size models of organs and tumors to study alongside MRI and CT images.

“We have been able to reduce radiation doses between 30% to 70%, if not more, at the same time maintaining or improving image quality. This allows us to make better diagnoses,” Towbin says. “We’re looking to develop efficient processes for patient turnaround time, cost management, and radiation exposure reduction.”

In the next decade, more analytic components will be added to imaging, and artificial intelligence will be a key part of image evaluation, says Towbin. Monitoring devices and molecular imaging will also help develop more precision therapies that will lower healthcare costs and help predict outcomes, he says.

Donna Marbury is a writer in Columbus, Ohio.

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Essential elements of an enterprise imaging system:

- A platform for clinical images and multimedia content
- An enterprise viewer that integrates a secured image exchange service that can work internally with EHRs or with outside vendors that need to exchange images
- An analytics platform that allows users to gain clinical insights from the imaging

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Keeping Pace with Pop Health

95%  
2015 Fifty nine percent of C-suite respondents to a 2015 survey predicted that by 2017 they would be “very prepared” to take on more value-based payment.

20%  
2018 Only one in five had actually met that threshold by 2018.

Confidence remains high

83%  
Percentage of respondents who rated population health either “very” or “critically” important to the industry.

Source: Numerof & Associates online survey of more than 400 healthcare executives, 2017

Mental Health Matters

Approximately 1 in 5 U.S. adults—or 18.5%—experiences mental illness in a given year.

$193.2 billion

The amount serious mental illness costs America in lost earnings per year.

Source: National Alliance on Mental Illness

Higher Spending, Higher Maternal Mortality

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Source: Contemporary OB/GYN Special 2018 Coverage “How America is Failing Mothers,” January 2018