

Hennessy's Highlights

The Latest Oncology News From Mike Hennessy Jr, President & CEO

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Early Phase Clinical Research Center Is Poised to Provide New Benefits in Hawaii and Beyond

Although it has already distinguished itself as a National Cancer Institute (NCI)-designated center (a status it has held since 1996), the University of Hawaii Cancer Center in Honolulu hopes to further expand its impact and address unmet treatment needs for patients with cancer in Hawaii and other Pacific islands, as well as those of Hawaiian descent living on the US mainland, by providing access to phase 1 clinical trials with its planned Early Phase Clinical Research Center.¹

"We are able to conduct certain types of clinical trials, but these are dominantly NCI Community Oncology Research Program studies because we have health disparity issues and health care access issues," Naoto T. Ueno, MD, PhD, FACP, the center's director and interim coleader of the cancer biology program, translational and clinical research, said in an interview with *OncologyLive*.

The plans for the Early Phase Clinical Research Center were announced in September 2019 after the University of Hawaii Cancer Center received a \$6.5 million grant from the National Institutes of Health to "build a clinical research center that will significantly improve access to experimental treatments for patients [with cancer] in Hawaii." This grant matched the \$6.5 million approved by the Hawaii legislature for the project, bringing its total funding to \$13 million.²

The main goal of the Early Phase Clinical Research Center is to provide access to cutting-edge therapeutics to Hawaiians without the need to travel to the continental United States, Ueno explained. This travel often has led to hardship for patients and their families in terms of finances, separation from loved ones, and disconnects in care, he added.

Recent research findings underscore the improved efficacy and safety of modern agents being evaluated in phase 1 clinical trials. In a retrospective study published in

The Lancet, study authors analyzed patient-level data from NCI-sponsored, investigator-initiated phase 1 trials from January 2000 to May 2019 of patients with solid tumors.³

Results from the study showed that among response-evaluable patients (n=9325), the overall response rate (ORR) for all trials during the study period was 12.2% (95% CI, 11.5%-12.8%), with a 2.7% (95% CI, 2.4%-3.0%) complete response (CR) rate. Notably, the ORR increased from 9.6% from 2000 to 2005 (95% CI, 8.7%-10.6%) to 18.0% from 2013 to 2019 (95% CI, 15.7%-20.5%; $P < .0001$); the CR rates increased from 2.5% (95% CI, 2.0%-3.0%) to 4.3% (95% CI, 3.2%-5.7%), respectively. Additionally, the improvement in efficacy came without a significant negative impact on tolerability; the risk of treatment-related death was found to not change over time from 2000 to 2019 ($P = .52$).³

As the only NCI-designated center within 2500 miles, the University of Hawaii Cancer Center serves a very large catchment area relative to other cancer centers, covering approximately 7 million square miles and approximately 2 million individuals. Outside of Hawaii, the center serves individuals in other areas of the Pacific, including American Samoa, Guam, Palau, and the Northern Mariana Islands.^{1,4}

Research has indicated that Native Hawaiian and Pacific Islander patients are severely underrepresented in early-phase clinical trials examining anticancer therapeutics. Findings from a 2021 review published in *Future Oncology*, demonstrated that across all regions globally, Native Hawaiian and Pacific Islander participants represented just 0.1% of the total number of participants (n=9972). Similarly, among patients (n=3197) in US-only trials, Native Hawaiian and Pacific Islander patients again comprised just 0.1% of the population. Study authors noted that "participation of Native

Hawaiian/Pacific Islander and American Indian/Native Alaskan patients was extremely low."⁵

The increased representation of Native Hawaiian and Pacific Islander patients in phase 1 clinical trials that the Early Phase Clinical Research Center aims to achieve is crucial for not only giving care to the patients who need it in the immediate term but also for drug development, Ueno said.

According to Ueno, the goal is to have the center operational by mid-2025. Construction is expected to be completed by the end of 2024, he said. "The ultimate goal is for our patients to stay [in Hawaii] and have a similar opportunity for quality care compared with the mainland." ■



Naoto T. Ueno, MD, PhD, FACP

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Outreach and Engagement: Colleagues Come Together to Improve Community Care

It is crucial that community outreach offices engage in conversations centered around key matters affecting National Cancer Institute (NCI)-designated cancer centers such as Cancer Center Support Grants (CCSGs) and catchment, according to Kiara Ellis, MSW.

“[Working in community outreach], we serve as a key bridge in developing best practices that will be impactful,” Ellis said. “There are centers that do a lot of work with their patient population—how do we approach [them] about clinical trials? How do we share information about these complicated cancers? What is it they want to know? It’s the outreach offices that drive that work. Sometimes they can be underutilized or not tapped [into] for that expertise in all settings. But being able to bring relationships to the cancer centers anchors the center in its community. Without that component and great support for that component, the cancer center [doesn’t have] the legs it needs to be interactive in its community.”

Bringing members of NCI-designated cancer center community outreach and engagement (COE) offices together serves to extend an office’s impact in its community. Since its formation in 2019, the Cancer Center Community Impact Forum (CCCIF), a national annual meeting of COE professionals in the US, has highlighted matters essential to COE offices. During the 2023 CCCIF, key topics such as catchment and CCSGs were discussed, giving community outreach professionals the opportunity to see how peers are engaging their community to extend the reach of their cancer centers.

Ellis, director of community outreach and engagement at the Masonic Cancer Center in Minneapolis, Minnesota, is a founder of the conference, which was created to be tactical and practical for staff in the cancer centers. “[Topics we discuss with colleagues include] how to build our community engagement boards, showcasing successful offices that got high marks in their CCSG,” Ellis said. “Who are those champions, and how did they highlight the wins that their office had in their CCSG to get that high score? We talk

about catchment and connection with our clinical partners, [as well as] marketing and communications and the role [they play] in lifting up the community outreach work that we do.”

The 5-year CCSG has proven to be instrumental for institutions, with the University of California San Francisco Helen Diller Family Comprehensive Cancer Center noting that the grant is a major source of federal funding for the center, equaling approximately \$7 million in total costs per year.¹ Yale Cancer Center in New Haven, Connecticut, also reported that the CCSG provides the resources and infrastructure to aid in the coordination of 6 of the center’s interdisciplinary research programs, which range from basic laboratory research to clinical investigations.²

“[Catchment is] one of those huge and powerful topics because I don’t know that all our outreach staff and faculty are as immersed in geospatial mapping and that data piece [of it]. Catchment informs our work,” Ellis said.

The catchment area of the Masonic Cancer Center encompasses all of Minnesota. According to the center’s website, meeting diverse communities is essential: Minnesota has the largest Somali American population in the US, the largest urban population of Hmong people in the world, and 11 federally recognized American Indian tribes.³

“The work we’ve done has been bringing awareness to our community partners about this amazing resource. [Masonic is] a hidden gem in the Twin Cities; you don’t have to go far for great care, and you don’t have to go far if you’re interested or thinking about clinical research or being involved in it. We’re right in your city. There are ways you can engage with us, and meeting [the] community where they’re at is one of the biggest ways we’ve gone about doing it,” Ellis said.

One of the preconference activities at the 2023 CCCIF meeting included a community tour. “[At] Sylvester [Comprehensive Cancer Center in Miami, Florida,] we got to see their Game Changer mobile unit and how they’re doing screening in the

community,” Ellis said. “They brought the unit [to the community], their staff was there, and we got to talk to them and ask questions focused on that example.”

Sylvester Comprehensive Cancer Center’s 3 customized Game Changer motorhomes have been bringing free cancer screenings to neighborhoods in South Florida since 2018, thanks to support from community organizations and philanthropic donors. Multilingual health care professionals from Sylvester travel to local libraries, businesses, and community events such as health fairs to offer screening for HIV and prostate, colorectal, gastric, and head/neck cancers.⁴

In the first 7 months of 2023, Sylvester officials reported that more than 300 adults had been screened and 33 positive results identified; those with positive results were referred for follow-up care.⁴

“One of the bigger impacts from this conference is [the] connection to NCI, how decisions are made, and [what] future planning is happening for various areas. Community outreach—in any space, not just cancer centers—sometimes is a topic that can be glossed over,” Ellis said. “The way that our groups have come together has shown us how essential these offices are and how supporting that infrastructure can push forward and make a large impact in the communities we serve, which is our goal.” ■

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Tampa General Hospital Cancer Institute Celebrates 2 Years of Growth and Innovation

As Tampa General Hospital (TGH) Cancer Institute in Florida approaches its 3-year anniversary, Eduardo M. Sotomayor, MD, the institute's vice president and executive director, notes that the progress it has achieved was made possible by continually searching for creative solutions to address patients' needs.

"There is a need for [the] cancer institute to provide the best care to the growing population in the Tampa Bay area," Sotomayor, who was named to his current appointments in November 2023,¹ said in an interview with *OncologyLive*. "We are in the process of working through the vision, mission, and our strategic plan, but we are a cancer institute that is highly translational. We are going to be focused on basic science, but basic science that is going to rapidly translate to the bedside. We are committed to the community that we serve [and] we're going to have very strong community outreach, engagement, education, and training." In December 2022, the TGH Cancer Institute, which also serves as the primary teaching hospital for the University of South Florida (USF) Morsani College of Medicine, received a 3-year accreditation from the Commission on Cancer (COC). The COC is a quality program established by the American College of Surgeons; earning accreditation signifies that the TGH Cancer Institute met 34 quality care standards, utilized a multidisciplinary approach, and demonstrated a commitment to improving patient outcomes and quality of life. Institutions that are accredited by the COC diagnose and/or treat more than 70% of all patients with a new cancer diagnosis.²

In June 2023, *Newsweek* selected TGH as one of the top cancer hospitals in the United States. The institute received this distinction by ranking in the top 3% of cancer hospitals based on hospital quality metrics and survey results encompassing replies from both patients and oncology health care professionals.³

Since its establishment in April 2021, the TGH Cancer Institute has experienced remarkable growth, both in terms of attracting talent and expanding its physical footprint. The cancer institute has recruited 22 physicians across surgical, radiation, and hematologic oncology, as well as

more than 20 advanced practice providers, including pharmacists, nurses, managers, and administrators.¹

The TGH Cancer Institute sets itself apart by offering initiatives such as the TGH-USF Health Precision Medicine Biorepository. The biorepository, which is located on the USF Health Morsani College of Medicine campus, collects, catalogs, and stores biologic samples for future research. The biorepository allows the institute to conduct clinical and translational research and to further develop precision medicine approaches that will have an impact on patients in the Tampa area and beyond.⁴

Another program that has led to improved care for patients with cancer is the institute's integration of the CareComm command center. CareComm, which was developed in partnership with GE HealthCare, consists of 20 artificial intelligence apps—video walls made up of 38 large screens, 32 workstations, and multiple computer systems—staffed by a multidisciplinary clinical team. The artificial intelligence apps or "tiles" apply advanced analytics to aid decision-making, help monitor patient flow, and track delays in care, allowing the clinical staff to make better-informed decisions and even predict the needs of patients before they arise.⁵

In October 2020, TGH reported that the integration of the CareComm command center had led to a \$40 million reduction in systemwide inefficiencies since its inception in 2019. TGH noted that CareComm decreased the average length of stay for patients by eliminating 20,000 excess days.⁶

TGH has also invested significant resources into upgrading its radiation oncology program. In January 2023, the cancer institute announced the expansion of the program to include new technologies such as CyberKnife and TrueBeam, as well as high dose rate brachytherapy. CyberKnife is a radiosurgery system that offers a noninvasive alternative to surgery. The TrueBeam linear accelerator allows for fast and precise delivery of image-guided radiation therapy.⁷

"We [have] started developing our clinical translational research program, which is going very well; we are opening innovative phase 1, 2, and 3 clinical trials," Sotomayor

said. "This year, we are going to speed up that effort. Also in 2024, we will be building our basic science company recruitment of top-notch cancer researchers from the nation. Being post COVID[-19 pandemic] will help us recruit talented people. Because of all this growth, the board of TGH and the CEO have made a commitment for the next 5 years to support the cancer institute. This year we are going to apply for Center of Excellence accreditation, but our ultimate goal is to pursue National Cancer Institute designation within the decade." ■



Eduardo M. Sotomayor, MD

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Zhang on the Implications of Findings From the KEYNOTE-564 Trial in RCC



Tian Zhang, MD, MHS, an associate professor in the Department of Internal Medicine at UT Southwestern Medical Center, discusses the implications of findings from subgroup analyses of the phase 3 KEYNOTE-564 trial (NCT03142334) of adjuvant pembrolizumab (Keytruda) in patients with renal cell carcinoma (RCC).

The safety profile of pembrolizumab remains consistent across KEYNOTE-564 patient subgroups and is characterized by immune-mediated adverse effects similar to those observed in the overall population, Zhang notes. These include rashes, colitis, and, less frequently, endocrinopathies such as thyroiditis and hypothyroidism, alongside mild elevations in liver function and occurrences of pneumonitis. Pembrolizumab is being employed in the adjuvant setting, where it is an efficacious treatment option for patients, she says. Pembrolizumab may postpone RCC recurrence and potentially extend patients' overall survival (OS), Zhang notes.

Excitingly, news releases have indicated positive OS outcomes from the KEYNOTE-564 trial, Zhang concludes. Since the presentation of data from the subgroup analyses at the 2023 International Kidney Cancer Symposium, additional data from the trial were presented at the 2024 American Society of Clinical Oncology Genitourinary Cancers Symposium and further validated the efficacy of adjuvant pembrolizumab in this context. ■

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Hagensee on Strategies for Cervical Cancer Prevention



Michael Hagensee, MD, PhD, professor in the Department of Medicine and Department of Microbiology at Louisiana State University Health discusses cervical cancer prevention measures and highlights ongoing research investigating barriers to cervical cancer treatment and care.

Globally, oncologists and researchers are working to eradicate cervical cancer, Hagensee begins. Certain vaccines are designed to fight infection by the human papillomavirus (HPV) strains that cause cervical cancer, and ensuring the widespread availability of these vaccines is crucial because they must be administered before HPV exposure, Hagensee explains. Ideally, individuals aged 9 to 25 years should receive the HPV vaccination to maximize its protective effects, he notes, adding that these vaccines constitute primary cervical cancer prevention.

Additionally, secondary cervical cancer prevention methods exist, he notes. Upon detection of lesions induced by HPV, diagnostic intervention can prevent these lesions from progressing to cancer, according to Hagensee, which involves cervical Papanicolaou tests for lesion identification and testing for the presence of the virus itself. Notably, Hagensee emphasizes that the main message remains clear: Oncologists possess the necessary tools to eliminate cervical cancer. ■

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