

# PRODUCT PROFILE

## **ABILIFY ASIMTUFII®** *Aripiprazole injection, suspension, extended release*

### Manufacturer

Otsuka America Pharmaceutical, Inc

### Indication

- ABILIFY ASIMTUFII is indicated for the treatment of schizophrenia in adults and for maintenance monotherapy treatment of bipolar I disorder in adults.<sup>1</sup>

### Dosing and Administration

- ABILIFY ASIMTUFII must be administered as an intramuscular (IM) gluteal injection by a health care professional. Any other route of administration, such as IM deltoid injection, is not recommended.<sup>1</sup>
- The recommended dosage of ABILIFY ASIMTUFII is 960 mg via IM gluteal injection once every 2 months (56 days after previous injection).<sup>1</sup>
- Tolerability establishment with oral aripiprazole prior to initiating treatment with ABILIFY ASIMTUFII is recommended for patients who have never taken aripiprazole. It may take up to 2 weeks to establish tolerability because of the half-life of aripiprazole.<sup>1</sup>

### Storage and Handling

- ABILIFY ASIMTUFII is available as a white to off-white, sterile, aqueous, extended-release injectable suspension in single-dose, prefilled syringes containing 720 mg/2.4 mL or 960 mg/3.2 mL.<sup>1</sup>
- ABILIFY ASIMTUFII is recommended to be stored at 25°C (77°F); however, variability between 15 °C and 30 °C (59-86°F) is acceptable.<sup>1</sup>

### Safety/Warnings

- ABILIFY ASIMTUFII is contraindicated in patients with known hypersensitivity to aripiprazole or any component of the injectable suspension. Hypersensitivity reactions including pruritus/urticaria and anaphylaxis have been reported in patients receiving aripiprazole.<sup>1</sup>
- **BOXED WARNING:** Elderly patients with dementia-related psychosis who are treated with antipsychotic drugs are at an increased risk of death. ABILIFY ASIMTUFII is not approved for the treatment of patients with dementia-related psychosis.<sup>1</sup>
- The safety data of ABILIFY ASIMTUFII for the treatment of schizophrenia in adults and maintenance monotherapy treatment of bipolar I disorder in adults is based on studies of Abilify Maintena.<sup>1</sup>
- Based on a 12-week double-blind placebo-controlled study of Abilify Maintena in schizophrenia, the most commonly observed adverse reactions associated with the use of Abilify Maintena in patients (incidence of 5% or greater and aripiprazole incidence at least twice that for placebo) were increased weight (16.8% vs. 7.0%), akathisia (11.4% vs. 3.5%), injection site pain (5.4% vs. 0.6%) and sedation (5.4% vs. 1.2%).<sup>1</sup>

### Disease State Background

- Schizophrenia is a serious mental disorder that can considerably affect a person's emotions, thoughts, perceptions of reality, behaviors and social interactions.<sup>2,3</sup> Although its course and the degree to which it affects individuals can vary, schizophrenia can be debilitating, and it is often a chronic illness.<sup>3</sup> Patients with schizophrenia can experience symptoms such as disordered thoughts, hallucinations, delusions, and cognitive or motor impairment, all of which can severely impair their ability to function.<sup>2,3</sup> The prevalence of schizophrenia and related mental disorders in the United States is estimated to be 0.25% to 0.64%.<sup>3</sup> Despite the low prevalence, schizophrenia is one of the top 15 leading causes of disability worldwide, and it is associated with disproportionately high financial costs when compared with those of other chronic health conditions.<sup>3</sup> Approximately 4.9% of people with schizophrenia die from suicide, a rate much greater than that found in the general population. This contributes to an increased risk of premature mortality; for patients with schizophrenia, the estimated average potential life lost is 28.5 years.<sup>3</sup>
- Bipolar disorder (previously known as manic-depressive illness or manic depression) is a mental illness that causes drastic shifts in a person's energy/activity levels, mood, and concentration, possibly impairing the ability to perform routine daily tasks.<sup>4</sup> Bipolar I disorder, one of the 3 types of bipolar disorder, is defined by manic or hyperactive episodes lasting at least 7 days for most of each consecutive

day or by severe manic symptoms to the degree of requiring immediate medical attention.<sup>4</sup> The overall prevalence of bipolar disorder is estimated to be 2.8% in US adults, with approximately 4.4% of US adults experiencing bipolar disorder at some point in their lives.<sup>5</sup>

## Place in Therapy

- In 2020, the American Psychiatric Association (APA) released a clinical practice guideline for the treatment of patients with schizophrenia that recommended use of antipsychotic medication plus monitoring for effectiveness and adverse events; it also recommended treatment with long-acting injectable antipsychotics for patients who prefer them.<sup>6,7</sup> Schizophrenia, one of the leading causes of disability, is associated with increased rates of premature mortality and suicide.<sup>3,7</sup> Aripiprazole was effective in the treatment of schizophrenia in clinical studies; use of this medication can help alleviate the debilitating social, motor, cognitive and perceptual symptoms of schizophrenia, and it may reduce indirect financial costs related to loss of productivity, social service needs, and criminal justice involvement.<sup>3</sup>
- The APA has not released an updated guideline for the treatment of patients with bipolar disorder since 2002.<sup>8,9</sup> However, aripiprazole use is effective as maintenance monotherapy of bipolar I disorder in adults; it greatly decreases the proportion of patients who relapse compared with use of placebo.<sup>1</sup> Treatment with aripiprazole can allow patients to go about their daily lives without the interruption of unpredictable manic episodes.

## Managed Care Considerations

- The debilitating effects of schizophrenia and bipolar disorder on patients' quality of life, social life, and physical and cognitive abilities necessitate the use of effective, long-acting antipsychotic medication such as ABILIFY ASIMTUFII which can help alleviate symptoms and allow patients to resume their daily normal activities. The Otsuka Patient Assistance Foundation can help patients who do not have health insurance or cannot afford their prescription to get the medication at no cost. Applicants must meet specific eligibility criteria prior to their approval for assistance.<sup>10</sup>

## Market Insights

- ABILIFY ASIMTUFII is the first long-acting injectable (LAI) given every 2 months that is indicated for the treatment of schizophrenia or for maintenance monotherapy of bipolar disorder I in adults.<sup>11</sup>
- The recommended dosage of ABILIFY ASIMTUFII is 960 mg, which must be administered by a healthcare professional once every 2 months (56 days after previous injection) as an intramuscular gluteal injection.<sup>1</sup>
- A leading cause of relapse for patients with mental illness is poor adherence to oral antipsychotics, including in patients with schizophrenia. Poor medication adherence may occur due to a variety of factors, including cognitive dysfunction, adverse effects, and poor social support.<sup>12</sup> Long-acting medications used to treat debilitating mental illnesses are crucial in helping patients to resume their daily activities and in improving their quality of life. Because long-acting injectable medications must be administered by a provider, medication adherence is more accurately assessed than self-administered medications.<sup>12</sup> The APA recommends use of long-acting injectable antipsychotics for patients who prefer them and monitoring for effectiveness and adverse events. Incorporation of ABILIFY ASIMTUFII into managed care plans can help address symptoms of schizophrenia, one of the major causes of disability and premature mortality, ultimately reducing indirect financial costs of the disease such as loss of productivity.

## REFERENCES

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