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**BRISTOL-MYERS SQUIBB AND OTSUKA PHARMACEUTICAL COMPANY LAUNCH  
NEW RAPIDLY DISINTEGRATING ORAL ANTIPSYCHOTIC MEDICATION  
ABILIFY<sup>®</sup> DISCMELT<sup>™</sup> (aripiprazole)**

*Provides Another ABILIFY Formulation Option for Adults With Schizophrenia  
or Manic Episodes of Bipolar I Disorder*

**PRINCETON, NEW JERSEY AND TOKYO, JAPAN, August 17, 2006** – Bristol-Myers Squibb Company (NYSE: BMY) and Otsuka Pharmaceutical Co., Ltd. today announced the launch of ABILIFY<sup>®</sup> DISCMELT<sup>™</sup> (aripiprazole) Orally Disintegrating Tablets, a new oral form of the antipsychotic medication ABILIFY<sup>®</sup> (aripiprazole) that disintegrates rapidly in the mouth. The U.S. Food and Drug Administration (FDA) approved ABILIFY DISCMELT on June 7, 2006.

ABILIFY DISCMELT provides a convenient alternative for adults with schizophrenia or manic episodes associated with Bipolar I Disorder. Pharmacokinetic studies showed that ABILIFY DISCMELT Orally Disintegrating Tablets are bioequivalent to regular ABILIFY tablets, thereby offering similar efficacy and safety at the same doses as the oral tablets.

“Many adults with schizophrenia or Bipolar I Disorder, both in inpatient and outpatient settings, don’t take their medication as prescribed,” said John Zajecka, M.D., Director, Psychiatry Treatment Research Center and Associate Professor, Department of Psychiatry, Rush University Medical Center in Chicago. “ABILIFY DISCMELT provides healthcare professionals a formulation alternative that may be desirable for some adult patients.”

Some adults with schizophrenia or bipolar mania may have difficulty swallowing tablets or, in institutional settings, may hide pills inside their cheek to later spit them out. ABILIFY DISCMELT tablets are placed on the tongue and disintegrate rapidly upon contact with saliva, providing the convenience of a tablet without the need for liquid.

The vanilla-flavored ABILIFY® DISCMELT™ (aripiprazole) 10 mg and 15 mg Orally Disintegrating Tablets are packaged in blister packs and each dosage form is colored differently with scattered specks. Directions for use of ABILIFY DISCMELT Orally Disintegrating Tablets can be found in the FULL PRESCRIBING INFORMATION and should be shared with patients. Adults with phenylketonuria should be advised that ABILIFY DISCMELT contains phenylalanine.

### **About ABILIFY**

The first and only available dopamine partial agonist,<sup>1</sup> ABILIFY® (aripiprazole) is indicated for the treatment of schizophrenia including maintaining stability in adults who had been symptomatically stable on other antipsychotic medications for periods of three months or longer and observed for relapse during a period of up to 26 weeks. ABILIFY is also indicated for the treatment of acute manic and mixed episodes associated with Bipolar I Disorder, and for maintaining efficacy in adults with Bipolar I Disorder with a recent manic or mixed episode who had been stabilized and then maintained for at least six (6) weeks. Physicians who elect to use ABILIFY for extended periods should periodically re-evaluate the long-term usefulness of the drug for the individual. Since its initial approval in 2002, more than seven million prescriptions have been written in the United States.<sup>2</sup>

ABILIFY is available by prescription only. ABILIFY tablets are available in 2 mg, 5 mg, 10 mg, 15 mg, 20 mg, and 30 mg strengths. The effective dose range is 10-30 mg/day for schizophrenia patients, and 15 or 30 mg/day for Bipolar I Disorder patients. In addition to administration as a tablet, ABILIFY is available in a 1 mg/mL nonrefrigerated oral solution. The safety of doses of ABILIFY above 30 mg/day has not been evaluated in clinical trials.

ABILIFY is taken once daily with or without food. It is important to talk to a healthcare professional for more information about ABILIFY.

- more -

**IMPORTANT SAFETY INFORMATION for ABILIFY® (aripiprazole):**

**Increased Mortality in Elderly Patients With Dementia-Related Psychosis**

**Elderly patients with dementia-related psychosis treated with atypical antipsychotic drugs are at an increased risk of death compared to placebo. Although the causes of death were varied, most of the deaths appeared to be either cardiovascular or infectious in nature. ABILIFY® (aripiprazole) is not approved for the treatment of patients with dementia-related psychosis (see Boxed WARNING).**

ABILIFY is contraindicated in patients with a known **hypersensitivity** to the product.

As with all antipsychotic medications, including ABILIFY, a rare condition referred to as **neuroleptic malignant syndrome (NMS)** has been reported. As with all antipsychotic medications, prescribing should be consistent with the need to minimize the risk of **tardive dyskinesia (TD)**.

**Cerebrovascular adverse events** (eg, stroke, transient ischemic attack), including fatalities, have been reported at an increased incidence in clinical trials of elderly patients with dementia-related psychosis treated with ABILIFY, including a significant dose response relationship in a fixed-dose trial. ABILIFY is not approved for the treatment of patients with dementia-related psychosis.

**Hyperglycemia**, including some serious cases ranging from ketoacidosis, hyperosmolar coma, or death, has been reported in patients treated with atypical antipsychotics. Patients on ABILIFY should be appropriately tested before and monitored during treatment.

ABILIFY may be associated with **orthostatic hypotension** and should be used with caution in patients with known cardiovascular disease, cerebrovascular disease, or conditions which would predispose them to hypotension.

As with other antipsychotic drugs, ABILIFY should be used with caution in patients with a history of **seizures** or with conditions that lower the seizure threshold.

Like other antipsychotics, ABILIFY may have the potential to **impair judgment, thinking, or motor skills**. Patients should not drive or operate hazardous machinery until they are certain ABILIFY does not affect them adversely.

Disruption of the body's ability to reduce **core body temperature** has been attributed to antipsychotics. Appropriate care is advised for patients who may exercise strenuously, be exposed to extreme heat, receive concomitant medication with anticholinergic activity, or be subject to dehydration.

As antipsychotics have been associated with **esophageal dysmotility and aspiration**, ABILIFY should be used cautiously in patients at risk for aspiration pneumonia.

As the possibility of a **suicide** attempt is inherent in psychotic illness and bipolar disorder, close supervision of high-risk patients should accompany drug therapy.

Prescriptions for ABILIFY® (aripiprazole) should be written for the smallest quantity consistent with good patient management to reduce the risk of overdose.

Physicians should determine if a patient is **pregnant** or intends to become pregnant while taking ABILIFY. Patients should be advised not to breast-feed while taking ABILIFY.

Patients should be advised to avoid alcohol while taking ABILIFY.

Both CYP3A4 and CYP2D6 are responsible for ABILIFY metabolism. Agents that induce CYP3A4 (eg, carbamazepine) could cause an increase in ABILIFY clearance and lower blood levels. Inhibitors of CYP3A4 (eg, ketoconazole) or CYP2D6 (eg, quinidine, fluoxetine, or paroxetine) can inhibit ABILIFY elimination and cause increased blood levels.

**Commonly observed adverse events** reported with ABILIFY in 3-week bipolar mania trials at a greater than or equal to 5% incidence for ABILIFY and at a rate at least twice the rate of placebo include, respectively, akathisia (15% vs 4%), constipation (13% vs 6%), and accidental injury (6% vs 3%).

**Treatment-emergent adverse events** reported with ABILIFY in short-term trials at an incidence greater than or equal to 10% and greater than placebo, respectively, include headache (31% vs 26%), agitation (25% vs 24%), anxiety (20% vs 17%), insomnia (20% vs 15%), nausea (16% vs 12%), dyspepsia (15% vs 13%), somnolence (12% vs 8%), akathisia (12% vs 5%), lightheadedness (11% vs 8%), vomiting (11% vs 6%), and constipation (11% vs 7%).

The adverse events reported in a 26-week, double-blind schizophrenia trial comparing ABILIFY and placebo were generally consistent with those reported in the short-term, placebo-controlled schizophrenia trials, except for a higher incidence of tremor: 9% for ABILIFY vs. 1% for placebo.

## **About Bristol-Myers Squibb and Otsuka Pharmaceutical Co., Ltd.**

Bristol-Myers Squibb and Otsuka Pharmaceutical Co., Ltd. are collaborative partners in the development and commercialization of ABILIFY in the United States and major European countries.

ABILIFY® (aripiprazole) was discovered by Otsuka Pharmaceutical Co., Ltd. Founded in 1964, Otsuka Pharmaceutical Co., Ltd. is a healthcare company with the mission statement: "Otsuka - people creating new products for better health worldwide." Otsuka researches, develops, manufactures and markets innovative, original products, focusing its core businesses on pharmaceutical products for the treatment of disease and consumer products for the maintenance of everyday health. The Otsuka Pharmaceutical Group comprises 87 companies and employs approximately 27,000 people in 17 countries and regions worldwide. Otsuka and its consolidated subsidiaries earned US \$6.8 billion in consolidated annual revenues in fiscal 2005.

Bristol-Myers Squibb is a global pharmaceutical and related health care products company whose mission is to extend and enhance human life.

*For more information and FULL PRESCRIBING INFORMATION, including **Boxed***

**WARNING**, visit: [www.abilify.com](http://www.abilify.com)

Visit Bristol-Myers Squibb at: [www.bms.com](http://www.bms.com)

Visit Otsuka Pharmaceutical Co., Ltd. at: [www.otsuka-global.com/](http://www.otsuka-global.com/)

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### References

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<sup>1</sup> Burris KD, Molski TF, XU C, et al. Aripiprazole, a novel antipsychotic, is a high-affinity partial agonist at human dopamine D2 receptors. *J Pharmacol Exp Ther.* 2002;302:381-389.

<sup>2</sup> IMS Auditrac NGPS: Abilify Total Monthly Retail Prescriptions: Data Accessed 04/24/2006.