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FDA APPROVES ORAL SOLUTION FORMULATION OF ABILIFY® (aripiprazole)

New Formulation Offers Effective Treatment Option to Address Special Needs of Patients

PRINCETON, N.J. AND TOKYO, Japan, January 4, 2005 – Bristol-Myers Squibb Company (NYSE: BMY) and Otsuka Pharmaceutical Co., Ltd. today announced that the companies received approval from the U.S. Food and Drug Administration (FDA) for an oral solution formulation of ABILIFY® (aripiprazole). ABILIFY Oral Solution will provide an important new option for adult patients who are unable to swallow or have difficulty swallowing tablets, providing a greater measure of flexibility in addressing individual patient needs. The oral solution formulation will be available in pharmacies in February, 2005.

ABILIFY is indicated for the treatment of schizophrenia and acute manic and mixed episodes associated with bipolar disorder. ABILIFY is the first and only dopamine partial agonist.ⁱ Since its introduction in 2002, ABILIFY has been prescribed to more than 700,000 patients.ⁱⁱ

“The FDA approval of this new oral formulation of ABILIFY underscores Bristol-Myers Squibb’s and Otsuka’s ongoing commitment to addressing the special needs of patients,” said Anthony Hooper, president, U.S. Pharmaceuticals, Bristol-Myers Squibb Company. “We are pleased to provide another effective treatment option, helping physicians manage patients for whom the oral tablet may not be appropriate.”

“We are very proud to have discovered ABILIFY, a unique pharmacological agent that represents our strong focus on pharmaceutical innovation,” said Tatsuo Higuchi, president and representative director, Otsuka Pharmaceutical Co., Ltd. “It is very encouraging that this medication is now approved in two formulations to allow greater flexibility in supporting the management of patients requiring different options.”

About ABILIFY

ABILIFY® (aripiprazole) was approved by the FDA in 2002 for the treatment of schizophrenia. The efficacy and tolerability of ABILIFY in schizophrenia was established by short-term and longer-term placebo-controlled trials. In September 2004, ABILIFY was approved for the treatment of acute bipolar mania, including manic and mixed episodes associated with bipolar disorder. Since its approval, more than 2.9 million prescriptions have been written in the United States.ⁱⁱⁱ

ABILIFY is available by prescription only. Patients should talk to their healthcare provider for more information. To learn more about ABILIFY and for full product information, please visit www.ABILIFY.com.

Important Safety Information

As with all antipsychotic medications, 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).

Hyperglycemia, including some serious cases ranging from ketoacidosis, hyperosmolar coma, or death, has been reported in patients treated with atypical antipsychotics. ABILIFY was not included in epidemiologic studies suggesting this risk; therefore the risk of hyperglycemia with ABILIFY is not known. However, there have been few reports of hyperglycemia in patients treated with ABILIFY. Patients 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. Seizures occurred in 0.3% of bipolar patients treated with ABILIFY in placebo-controlled trials.

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 anticholinergic medications, or be subject to dehydration.

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

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

While taking ABILIFY® (aripiprazole), patients should not:

- Drink alcohol
- Breast-feed an infant

Patients on ABILIFY should notify their physician:

- If they become pregnant or intend to become pregnant
- Of all medications they are taking

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. In this study the majority of the cases of tremor were of mild intensity (9/13 mild and 4/13 moderate), occurred early in therapy (9/13 less than or equal to 49 days), and were of limited duration (9/13 less than or equal to 10 days). Tremor infrequently led to discontinuation (less than 1%) of ABILIFY. In addition, in a long-term (52-week), active-controlled study, the incidence of tremor for ABILIFY was 4%.

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

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

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 products, focusing its core businesses on pharmaceutical products for the treatment of disease and consumer products for the promotion of everyday health. The Otsuka Pharmaceutical Group includes 73 companies around the world, employs 23,000 people, and has total annual revenues of \$4.4 billion.

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

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For more information and full prescribing information, visit: www.ABILIFY.com

Visit Bristol-Myers Squibb on the World Wide Web at: <http://www.bms.com>

Visit Otsuka Pharmaceutical Co., Ltd. at: <http://www.otsuka.co.jp>

ⁱ 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.

ⁱⁱ Kikuchi T, Tottori K, Uwahodo Y, et al. 7-{4-[4-(2,3-dichlorophenyl)-1-piperazinyl]butyloxy}-3,4-dihydro-2 (1H)-quinolinone (OPC-14597), a new putative antipsychotic drug with both presynaptic dopamine autoreceptor agonistic activity and postsynaptic D₂ receptor antagonistic activity. *J Pharmacol Exp Ther.* 1995;274:329-336.

ⁱⁱⁱ IMS Weekly NPA Plus, Verispan longitudinal database as of November 26, 2004.