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FDA APPROVES ABILIFY® (aripiprazole) FOR TREATMENT OF ACUTE BIPOLAR MANIA, INCLUDING MANIC AND MIXED EPISODES

Approval of New Indication for ABILIFY Brings an Important New Treatment Option For the More than Two Million Americans With Bipolar I Disorder

(PRINCETON, N.J. AND TOKYO, October 1, 2004) – Bristol-Myers Squibb Company (NYSE: BMY) and Otsuka Pharmaceutical Co., Ltd. today announced that the U.S. Food and Drug Administration (FDA) has approved ABILIFY® (aripiprazole) for the treatment of acute bipolar mania, including manic and mixed episodes associated with bipolar disorder.

The FDA approval is based on positive results from two placebo-controlled, three-week trials of 516 hospitalized patients with bipolar I disorder who were experiencing an acute manic or mixed episode. In these studies, ABILIFY demonstrated significant improvement in the symptoms of acute manic or mixed episodes.ⁱ The most common side effects reported in clinical trials ($\geq 5\%$ incidence and occurred at least twice as frequently in the ABILIFY-treated group compared to the placebo or sugar pill group) were akathisia (an inner sense of restlessness and need to move about), constipation and accidental injury.ⁱⁱ The rate of discontinuation due to side effect was low (aripiprazole-treated 11% and placebo-treated 9%). In these clinical trials with ABILIFY, there was no significant difference from placebo with respect to weight gain, blood sugar levels, or lipids. The proportion of patients meeting a weight gain criterion of $\geq 7\%$ of body weight was ABILIFY (3%) compared to placebo (2%).ⁱⁱⁱ

“The approval of ABILIFY for the treatment of acute bipolar mania is important news for the millions of people in this country who suffer from bipolar I disorder,” said Paul Keck, M.D., professor of psychiatry, pharmacology and neuroscience, and vice chairman for research, Department of Psychiatry, University of Cincinnati College of Medicine. “ABILIFY provides symptom improvement for acute mania, with a low incidence of somnolence.” In short-term, placebo-controlled trials of bipolar mania,

somnolence was reported in 14% of patients on ABILIFY® (aripiprazole) compared to 7% of patients on placebo.^{iv}

“We are pleased that ABILIFY has reached another significant medical milestone. We are committed to educating patients and their doctors about ABILIFY and the important role it can play in improving mental health,” said Peter R. Dolan, chairman and chief executive officer, Bristol-Myers Squibb. “This approval underscores our commitment to delivering innovative solutions that address unmet needs for a broad spectrum of patients with mental illness, as well as their families and healthcare providers.”

"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. “As the first and only dopamine partial agonist^{v,vi}, ABILIFY represents an important option in the treatment of bipolar I disorder.”

Bipolar I disorder affects more than two million Americans, and onset generally occurs before the age of 30. Bipolar I disorder can include manic, depressive, or mixed phases, or episodes. During the manic phase of the illness, the person’s mood is elated and judgment impaired, and they are likely to deny that they are ill and need help. During the depressive phase, the patient may feel so hopeless that they are incapable of seeking or accepting help, and they may believe that they cannot be helped. Mixed episodes involve the simultaneous occurrence of depressive and manic symptoms. People with bipolar I disorder may also experience some psychotic symptoms, including hallucinations and paranoia. The duration of mood episodes range from hours or days to many months. Bipolar I disorder can be difficult to recognize, and even after a diagnosis is made, it is often extremely challenging to convince a person with bipolar I disorder to seek and maintain treatment.

About ABILIFY

ABILIFY 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 controlled trials. Since its approval, over 2.4 million prescriptions have been written in the United States.^{vii} ABILIFY is indicated for the treatment of schizophrenia and acute manic and mixed episodes associated with bipolar disorder.

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

A rare but potentially fatal complex of symptoms referred to as neuroleptic malignant syndrome (NMS) has been reported with antipsychotic medicines, including ABILIFY® (aripiprazole). Another condition associated with these medicines is called tardive dyskinesia (TD), a condition that can cause potentially irreversible involuntary movements.

Increases in blood sugar levels (hyperglycemia) have been reported in patients treated with these medicines, including ABILIFY. Hyperglycemia, in some cases extreme and associated with coma or death, has been reported in patients treated with atypical antipsychotics. It is important that patients tell their healthcare provider if they are diabetic, have risk factors for diabetes (e.g., obesity, family history of diabetes), or if they are experiencing unexpected increases in thirst, urination, or hunger. Before starting treatment with atypical antipsychotics, patients should have their glucose tested and also be monitored during treatment.

Lightheadedness or faintness (orthostatic hypotension), caused by rising too quickly from a sitting or lying position, has been reported with these medicines. ABILIFY should be used cautiously if a patient has a history of seizures.

Patients should not drive or operate heavy machinery until they know how ABILIFY affects them.

Patients should talk to their healthcare provider if they are pregnant or intend to become pregnant. Patients should also discuss with their healthcare provider all prescription and non-prescription medicines they are taking or plan to take.

Other common side effects are: headache, agitation, anxiety, insomnia, nausea, upset stomach, sleepiness, an inner sense of restlessness and need to move about (akathisia), lightheadedness, vomiting, constipation, and tremors.

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 diversified healthcare company with a philosophy: “Otsuka - people creating new products for better health worldwide.” Known for its bold originality, Otsuka has built its business through leadership in two fields: pharmaceutical products for the treatment of disease, and consumer products for the promotion of everyday health. The Otsuka Pharmaceutical Group includes 73 enterprises 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>

This press release includes certain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 regarding, among other things, statements relating to goals, plans and projections regarding the company's financial position, product development and business strategy. These statements may be identified by the fact that they use words such as "anticipate," "estimate," "expect," "intend," "plan," "believe," and other words and terms of similar meaning in connection with any discussion of future operating or financial performance. Such forward-looking statements are based on current expectations and involve inherent risks and uncertainties, including factors that could delay, divert or change any of them, and could cause actual outcomes and results to differ materially from current expectations. These factors include, among other things, market factors, competitive product development, governmental regulations and legislation, changes to wholesaler inventory levels, the results of the planned financial statement restatement process and the audit of such restated financial statements patent positions and litigation. For further details and a discussion of these and other risks and uncertainties, see Bristol-Myers Squibb Company's Securities and Exchange Commission filings, including the company's 2003 annual report on Form 10-K. The company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise.

ⁱ Abilify Product Labeling, p.2

ⁱⁱ Abilify Product Labeling, p. 4

ⁱⁱⁱ Abilify Product Labeling, p. 5

^{iv} Abilify Product Labeling, p. 3

^v 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.

^{vi} 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.

^{vii} IMS Weekly NPA Plus, Verispan longitudinal database as of August 20, 2004.