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**NEW DATA AND ANALYSES DEMONSTRATE ABILIFY® (aripiprazole) EFFECTIVE AT
TREATING PATIENTS WITH ACUTE MANIC AND MIXED EPISODES OF BIPOLAR
DISORDER**

Maintenance of Effect Also Observed with ABILIFY

(NEW YORK, May 5, 2003) – ABILIFY® (aripiprazole) was demonstrated to be effective in treating acute manic and mixed episodes in patients with bipolar disorder, and maintenance of effect for up to 26 weeks was demonstrated, according to new studies and pooled analyses of data from previous studies presented today at the 157th Annual Meeting of the American Psychiatric Association. In addition, the data show that ABILIFY is generally well-tolerated in patients across the studies presented.

“These results provide evidence that ABILIFY is effective in various aspects of bipolar 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. “Consistent with previous studies, these data show that patients taking ABILIFY experience some side effects at rates that are similar to patients taking placebo. Because ABILIFY is associated with this profile, it could be an important addition to the treatment options available for bipolar disorder.”

Study Evaluating ABILIFY Safety And Efficacy In Short-Term Setting For Bipolar Disorder

A Phase III multicenter, double-blind, placebo-controlled study demonstrated the efficacy and safety of ABILIFY 30 mg/day (doses could be reduced to 15 mg for tolerability) over a three-week period in patients with bipolar I disorder (n=272) experiencing an acute manic or mixed episode. Key outcome measures included the Young Mania Rating Scale (Y-MRS) Total Score, Clinical Global Impression Scale –

Bipolar Disorder (CGI-BP), and Positive and Negative Syndrome Scale (PANSS) Hostility subscale. In this study, ABILIFY® (aripiprazole) produced significant improvements on Y-MRS by day four compared with placebo (-12.5 vs. -7.2, $p \leq 0.01$), and improvement continued throughout the duration of the three-week study. Patients in both treatment groups showed a slight difference in mean body weight from baseline (placebo 0.4 lb; ABILIFY 1.17 lbs); there was no statistically significant difference in the incidence of weight gain between ABILIFY and placebo. The adverse events ($\geq 10\%$ incidence) at least twice as frequent in the ABILIFY group compared to the placebo group (dyspepsia, constipation, akathisia and pain extremity) were generally mild to moderate in intensity. In addition, discontinuation rates due to adverse events were similar (9% ABILIFY, 7% placebo) and there were fewer discontinuations on ABILIFY vs. placebo (9% vs. 21%) due to lack of efficacy.

Pooled Analyses of Data from Multiple Studies Evaluating ABILIFY Safety and Efficacy in Short-Term Settings for Bipolar Disorder

Efficacy Data

Data were pooled from two, three-week, double-blind multicenter studies in 513 patients with acute mania who were randomized to ABILIFY (n=259) or placebo (n=254). The key outcome measures included change from baseline in the Y-MRS Total Score response rate (based on $\geq 50\%$ decreases in Y-MRS) and remission rate (based on Y-MRS Total Score ≤ 12). Results demonstrated that treatment with ABILIFY led to significantly greater total score reduction, response rate, and remission rate compared to placebo, as early as day four and were maintained throughout the three-week studies. Y-MRS Total Score reduction for ABILIFY vs. placebo was -7.26 vs. -4.27 ($p < 0.001$) at day four and continued to improve over three weeks to study endpoint (-10.76 vs. -5.52, $p < 0.001$). Significantly more patients responded with ABILIFY as compared to placebo (47% vs. 26%, $p = 0.001$) and significantly more patients attained remission by study endpoint (42% vs. 24%, $p = 0.001$).

Safety Data

A pooled analysis from four, three-week, double-blind, randomized, multicenter studies of ABILIFY vs. placebo (n=977) demonstrated the comprehensive safety and tolerability profiles of ABILIFY. In this analysis, incidence of clinically significant weight gain ($\geq 7\%$ from baseline weight) with ABILIFY was comparable to placebo (2.9%, 2.4%), and there was zero mean weight change with ABILIFY and a change of -0.44 lb with placebo. ABILIFY also did not produce dose-dependent differences in extrapyramidal adverse events and the study showed that the most frequently reported adverse events with ABILIFY in at least 15% of patients and vs. placebo included headache, nausea, dyspepsia, agitation and akathisia.

Discontinuations due to adverse events were similar in the ABILIFY® (aripiprazole) and placebo groups (10.2% vs. 8.6%).

Long-Term Clinical Findings Summary

In a 26-week, double-blind, randomized, relapse-prevention study of patients with bipolar I disorder, patients receiving ABILIFY showed significantly prolonged time to relapse of symptoms vs. placebo. Patients who had recently experienced a manic or mixed episode were first stabilized with open-label ABILIFY (starting dose of 30 mg/day, with possible reduction to 15 mg/day at clinician's discretion) for six to 18 weeks. After meeting stabilization criteria [Y-MRS \leq 10 and Montgomery-Asberg Depression Rating Scale (MADRS) \leq 13 for six consecutive visits or six weeks], 161 patients were randomized to ABILIFY or placebo for the 26-week maintenance phase. The primary endpoint was time to relapse of manic, mixed, or depressive symptoms. Results showed that time to relapse of symptoms was significantly prolonged with ABILIFY compared to placebo (p=0.020). In addition, total number of relapses (manic, mixed or depressive symptoms) were significantly fewer in patients treated with ABILIFY than placebo (25% vs. 43%, p=0.013). Few patients in the ABILIFY group reported somnolence (5.2% vs. placebo 7.2%). The only adverse events (\geq 10% incidence) more common than placebo were anxiety and nervousness.

About Bipolar Disorder

Bipolar disorder, also known as manic-depressive disorder, affects nearly two million Americans, and onset generally occurs before the age of 30. Mixed episodes involve the simultaneous occurrence of depressive and manic symptoms. The duration of mood episodes range from hours or days to many months. Bipolar disorder can be difficult to recognize, and even after a diagnosis is made, it is often extremely challenging to convince a person with bipolar disorder to seek and maintain treatment. 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.

About ABILIFY

ABILIFY® (aripiprazole) was approved by the FDA in 2002 for the treatment of schizophrenia. The efficacy of ABILIFY in schizophrenia was established by short-term and longer-term controlled trials. Since its approval, over 1.5 million prescriptions have been written in the United States. ABILIFY is available in 5 mg, 10 mg, 15 mg, 20 mg and 30 mg tablets.

Serious side effects can occur with any antipsychotic medicine, including ABILIFY. A rare but potentially fatal complex of symptoms referred to as neuroleptic malignant syndrome (NMS) has been

reported. Another condition associated with antipsychotic medicines is called tardive dyskinesia (TD), a condition which can cause potentially irreversible involuntary movements.

Hyperglycemia, including some serious cases ranging from ketoacidosis to death, has been reported in patients treated with atypical antipsychotics. ABILIFY® (aripiprazole) 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 monitored.

Some people taking antipsychotics have experienced orthostatic hypotension (lightheadedness or faintness caused by rising too quickly from a sitting or lying position).

As with other antipsychotic drugs, ABILIFY should be used cautiously if the patient has a history of seizures. Patients should not drive or operate heavy machinery until they are certain ABILIFY does not affect them adversely.

Before starting ABILIFY, patients should talk to their healthcare provider about any health problems and other prescription or nonprescription medicines they are taking.

In short-term clinical trials, the most commonly reported side effects compared to placebo (sugar pill) were: headache (32% vs. 25%), anxiety (25% vs. 24%), insomnia (24% vs. 19%), nausea (14% vs. 10%), vomiting (12% vs. 7%), sleepiness (11% vs. 8%), lightheadedness (11% vs. 7%), restlessness (10% vs. 7%) and constipation (10% vs. 8%).

The adverse events reported in a 26-week, double-blind trial comparing ABILIFY and placebo were generally consistent with those reported in the short-term, placebo-controlled 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, occurred early in therapy (≤ 49 days) and were of limited duration (≤ 10 days). Tremor infrequently led to discontinuation ($<1\%$) of ABILIFY. In addition, in a long-term (52-week) active controlled study, the incidence of tremor for ABILIFY was 4%.

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

ABILIFY® is a registered trademark of Otsuka Pharmaceutical Co., Ltd.

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 is a diversified health care company guided by its philosophy “Otsuka, people creating new products for better health

worldwide” and dedicated to the research and development of innovative medical, pharmaceutical, and nutritional consumer products to improve the quality of human life. Otsuka has a diverse portfolio including central nervous system, cardiovascular, circulatory, gastro-intestinal, respiratory, dermatological, ophthalmologic, anti-cancer therapies, and is pursuing research in genomics and protein function. The Otsuka Pharmaceutical Group is comprised of 51 businesses and 22,000 employees around the world, earning total revenues of \$4.3 billion annually.

Bristol-Myers Squibb is a global pharmaceutical and related health care product 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 2000 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.