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SUPPLEMENTAL NEW DRUG APPLICATION (sNDA) FOR LONG-TERM SCHIZOPHRENIA TREATMENT SUBMITTED FOR ABILIFY? (aripiprazole)

Placebo-controlled 26-week study of recently approved antipsychotic examines efficacy and safety in long-term use

PRINCETON, NJ and TOKYO (February 25, 2003) – Bristol-Myers Squibb Company (NYSE: BMY) and Otsuka Pharmaceutical Co., Ltd. announced today that a Supplemental New Drug Application (sNDA) for the long-term treatment of schizophrenia has been submitted for ABILIFY? (aripiprazole) to the U.S. Food and Drug Administration (US FDA). The FDA approved ABILIFY for the treatment of schizophrenia in November 2002 based on a New Drug Application (NDA) that included a number of short-term (4-6 week) clinical trials.

“The efficacy, safety and tolerability of ABILIFY have been demonstrated in short-term clinical trials,” said Jeffrey Lieberman, M.D., vice chairman of psychiatry, professor of psychiatry and pharmacology, University of North Carolina at Chapel Hill. “Because schizophrenia is a chronic illness, it is important to have studies examining the long-term use of schizophrenia treatments such as ABILIFY.”

The sNDA is based on results from a placebo-controlled 26-week trial involving 310 patients with stable, chronic schizophrenia who were randomized to receive either placebo or ABILIFY (15 mg/daily). The study compared ABILIFY to placebo in time to relapse and rate of relapse, defined in this study as impending decompensation. In this study, treatment with ABILIFY resulted in significantly fewer patients relapsing after 26 weeks versus placebo; the relative risk of relapse for aripiprazole-treated patients was half that of placebo-treated patients (relative risk of relapse for aripiprazole:placebo = 0.503, $p < 0.001$).

Rates of discontinuation due to an adverse event were 8% for placebo compared to 10% for ABILIFY. Spontaneously reported adverse events with ABILIFY in this study occurring with an incidence of greater than 5% and greater than that of the placebo group were: insomnia (40% placebo vs. 43% aripiprazole), tremor (placebo 1% vs. aripiprazole 9%), akathisia (7% placebo vs. 8% aripiprazole), vomiting (3% placebo vs. 6% aripiprazole), and nausea (3% placebo vs. 5% aripiprazole). Mean change in weight in patients receiving ABILIFY over the course of the 26-week study was –1.3 kg compared to –0.9 kg for placebo-treated patients.

In short-term (4- and 6-week) placebo-controlled trials, there was no difference in the incidence of discontinuation due to adverse events between patients treated with ABILIFY (7%) and placebo (9%) or incidence of extrapyramidal syndrome (6% vs. 6%). In addition, studies showed that ABILIFY was associated with a moderate difference in sedation (11% vs. 8% for placebo), and did not cause significant QT_c interval changes.

ABILIFY is available in 10 mg, 15 mg, 20 mg and 30 mg tablets. For more information, please see full prescribing information.

About Schizophrenia

Schizophrenia affects more than two million Americans, and about one percent of the population worldwide. Schizophrenia interferes with a person's ability to think clearly, manage emotions, make decisions and relate to others. This illness tends to manifest itself in early adulthood and is characterized by positive symptoms, such as hallucinations, delusions, and paranoia, as well as negative symptoms, such as social withdrawal and emotional flatness. While there is no cure for schizophrenia, it is a treatable illness.

About Bristol-Myers Squibb and Otsuka

Bristol-Myers Squibb and Otsuka are collaborative partners in the development and commercialization of aripiprazole in the United States and major European countries. ABILIFY 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, and is pursuing research in genomics and protein function. The Otsuka Group is comprised of 32 businesses around the world, earning total revenues of \$4.5 billion annually.

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