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For Immediate Release

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**A New Choice of Therapy for the Treatment of Depression:
ABILIFY[®] Granted Additional Approval as Adjunctive Therapy for the
Treatment of Depression in Japan**

Otsuka Pharmaceutical Co., Ltd. (Otsuka), a subsidiary company of Otsuka Holdings Co., Ltd., announced that Otsuka has received new regulatory approval in Japan for the antipsychotic agent ABILIFY[®] (aripiprazole). Specifically, the new approval is for the additional indication “the adjunctive treatment in major depressive disorder” (only in patients who have had an inadequate response to conventional therapy).

The consolidated business forecast of fiscal 2013 announced by Otsuka Holdings on May 14, 2013 will not be changed.

- Approximately 1 million people are estimated to suffer from depression in Japan, and about one-third of patients who take treatments such as serotonergic or noradrenergic antidepressants still have unresolved depression symptoms. In countries such as the U.S., ABILIFY[®] (aripiprazole) has become an important choice as adjunctive therapy for the treatment of depression, because it may adjust the imbalance of dopamine, which is one of the chemicals thought to play a role in causing depression.
- ABILIFY was launched in the U.S. in 2002 as the world’s first dopamine D2 receptor partial agonist, and it has become a global product sold in over 60 countries and regions. Otsuka Pharmaceutical has worked tirelessly to innovate new categories by obtaining multiple indications for ABILIFY, an antipsychotic drug with unique mechanism of action and superior safety profile.
- ABILIFY was discovered and developed by Otsuka Pharmaceutical, and this one single antipsychotic drug now owns 13 indications around the world, an unprecedented number. ABILIFY for depression/depressive state is the third indication approved in Japan. In May 2013, ABILIFY was awarded the Japanese *Imperial Invention Prize*, a national prize awarded to outstanding inventions created through strenuous efforts.

(Tokyo, Japan, June 14, 2013) – Otsuka Pharmaceutical Co., Ltd. today obtained regulatory approval from the Japanese Ministry of Health, Labor and Welfare (MHLW) for ABILIFY as the first antipsychotic drug in Japan to treat depression/depressive state as an adjunct therapy in patients who showed an inadequate response to existing antidepressant therapy.

1 in 15 Japanese people are said to experience depression (major depressive disorder) during their lifetime. There are approximately 1 million Japanese people with depression, and the number of diagnosed patients has increased 2.4-fold over the last twelve years. Research shows that men are more prone to depression by the time they reach their forties, in the prime of their careers, and women are more to depression after reaching age thirty or older. There are more women depressed than men across all age categories. Only 30% to 40% patients who take antidepressants get full relief from depression symptoms, and therefore different choices of therapies are much needed to satisfy those with unresolved conditions.

Otsuka Pharmaceutical conducted a Phase-III clinical trial as support for this regulatory approval for ABILIFY as adjunctive therapy for depression. The primary efficacy endpoint for the trial was the mean change, from baseline to the completion of this randomized, double-blinded treatment phase, in a standard measure called MADRS (Montgomery-Asberg Depression Rating Scale) of patients diagnosed with depression. Patients taking ABILIFY showed significant improvements in terms of MADRS total score reduction, compared to those taking placebo. The most frequently observed adverse reactions were akathisia, tremor, constipation, and adipsia. In a long-term, 52-week clinical trial extending from this Phase-III clinical trial, the average MADRS score remained stable and with no safety issues.

In Japan, ABILIFY was approved as an antipsychotic for the treatment of schizophrenia in 2006, followed by approval of an additional indication for the improvement of manic episodes associated with bipolar disorder in 2012. ABILIFY for depression/depressive state is the third indication approved in Japan

In May 2013, ABILIFY was awarded the Japanese *Imperial Invention Prize*, a national prize awarded to outstanding inventions created through strenuous efforts. Otsuka's team of researchers who created aripiprazole was honored for discovering an effective treatment for schizophrenia with fewer side effects than conventional treatments.

Otsuka Pharmaceutical will continue its passionate, longstanding commitment to CNS drug research and development to address unmet medical needs of patients with mental disorders.