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Company name Otsuka Holdings Co., Ltd.
 Representative Tatsuo Higuchi
 President and Representative Director, CEO
 Code number 4578 First Section , Tokyo Stock Exchange
 Inquiries Takuma Kimura
 Director, Investors Relations Department

Otsuka Pharmaceutical Submits Marketing Authorization Application in Japan for Abilify Once-Monthly Injectable Form for the Treatment of Schizophrenia

Otsuka Pharmaceutical Co., Ltd., a subsidiary company of Otsuka Holdings Co., Ltd., announced it filed an application with the Pharmaceutical and Medical Devices Agency (PMDA) in Japan to market Aripiprazole Extended Release Injectable, a once-monthly formulation of Abilify, for the treatment of schizophrenia.

The consolidated business forecast of fiscal 2013 announced by Otsuka Holdings on November 13, 2013 will not be changed.

- Aripiprazole Extended Release Injectable, a once-monthly IM depot formulation of Abilify, provide uninterrupted medication coverage for one month, providing schizophrenia patients with stable blood concentration of the active drug that remain at a therapeutic range for an extended period of time, which delays timing to relapse without having to take the treatment on a daily basis. It was launched in the U.S. in March 2013, and approved by the EU in November 2013 to be launched starting in the U.K. in January 2014.
- Depot formulations of antipsychotic drugs must be safe to remain in the body for an extended period of time. Because Abilify has an established efficacy and safety profile, it was developed into a once-monthly formulation, aiming to support schizophrenia patients who experience relapses as a result of not being able to continue taking their daily treatment.
- In Japan, there are an estimated 710,000 schizophrenia patients, giving rise to annual social costs of 2.8 trillion Yen primarily attributable to unemployment and treatment costs. Although schizophrenia patients have to take treatment for a long period of time in order to prevent relapses, it can be difficult to continue treatment on a daily basis. An antipsychotic in a once-monthly formulation will be a welcome treatment option for both patients and their physicians.
- In the U.S., where Abilify Maintena has been available for some six months, encouraging feedback has been received from patients and physicians. The efficacy and safety of aripiprazole in a once-monthly administration of drug treatment can help to stabilize the overall treatment program for patients.

Tokyo, Japan, January 15, 2014 – Otsuka Pharmaceutical Co., Ltd. today announced it filed an application with the Pharmaceutical and Medical Devices Agency (PMDA) in Japan to market Aripiprazole Extended Release Injectable, a once-monthly formulation of Abilify, for the treatment of schizophrenia. This is the first depot formulation of a dopamine partial agonist to be filed for regulatory approval in Japan.