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For Immediate Release

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Otsuka Granted Approval in Japan for a New Formulation of ABIILIFY – ABILIFY for Extended–release Injectable Suspension, for Intramuscular Use – Indicated for Schizophrenia

Otsuka Pharmaceutical Co., Ltd., a wholly-owned subsidiary of Otsuka Holdings Co. Ltd., announces as follows.

- ABILIFY extended–release injectable suspension, for intramuscular use, is administered to the patient just once every four weeks. It first became available to patients in the US in March 2013 and is also available in 18 European countries, starting with the UK in 2014.
- The injectable form of Abilify was developed with the aim of preventing relapses by patients with schizophrenia who do not consistently take medicines daily as prescribed. Long-acting formulations, which remain in the body for an extended period, are required to be highly safe. As Abilify is an antipsychotic with confirmed efficacy and an excellent safety profile, development of a once-every-four-weeks injectable form was a highly awaited step.
- With approximately 710,000 people with schizophrenia in Japan, medical costs and costs related to non-employment give rise to annual total cost burdens of approximately 2.8 trillion yen (approximately USD 23 billion) in addition to other societal costs. Patients with schizophrenia need long-term drug treatment to avoid relapse; however 60% of patients reportedly have difficulty continuing to take their medicine. Regulatory approval in Japan of a long-acting injectable form of ABILIFY now provides a new treatment option.

Otsuka Pharmaceutical Co. Ltd.'s ABILIFY (generic name is aripiprazole), is well-established as an efficacious and safe drug, available to patients in 60 countries and regions. Based on its demonstrated efficacy ABILIFY has received regulatory approval in Japan for the manufacture and marketing of ABILIFY in 300 mg and 400 mg vials and in 300 mg and 400 mg dual-chamber syringes. This is the first approval in Japan of a depot formulation of a dopamine D_2 receptor partial agonist agent. Two forms will be available; a vial form (lyophilized powder preparation) for reconstitution with sterile water as well as a kit form containing the lyophilized powder preparation and sterile water for easy reconstitution in a pre-filled, dual-chamber syringe.