



## H. Lundbeck A/S

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## Corporate Release

### U.S. FDA accepts for review a supplemental New Drug Application to expand labeling of Abilify Maintena® (aripiprazole) for the treatment of Bipolar I disorder

- *Application seeks to expand Abilify Maintena label to include maintenance treatment for Bipolar I disorder*
- *If the label expansion is approved, Abilify Maintena would offer prescribers a once-monthly long-acting injectable option in the maintenance treatment of Bipolar I disorder in adults*

**Valby, Denmark and Tokyo, Japan, 30 November 2016** - H. Lundbeck A/S (Lundbeck) and Otsuka Pharmaceutical Co., Ltd. (Otsuka) today announced the U.S. Food and Drug Administration (FDA) has determined that the supplemental New Drug Application (sNDA) for the expanded labeling of Abilify Maintena® for the maintenance treatment of Bipolar I disorder in adult patients is sufficiently complete to permit a substantive review and is considered filed. Under the Prescription Drug User Fee Act (PDUFA), the FDA has set a target date of 28 July 2017, to complete its review.

#### About Abilify Maintena

Abilify Maintena is an extended-release injectable suspension, for intramuscular use developed by Otsuka in Japan and is co-commercialized by the alliance between Otsuka and Lundbeck. Abilify Maintena was approved in the U.S. in 2013 for the treatment of adults with schizophrenia<sup>i</sup> and is available in a number of countries including the U.S. Europe, Canada and Australia. Efficacy and safety for Abilify Maintena is supported by a short-term (12-week), randomized, double-blind, placebo-controlled trial in acutely relapsed adults, as well as a longer term (52-week) placebo-controlled, double-blind, randomized-withdrawal study for the maintenance treatment of schizophrenia<sup>ii</sup>.

Abilify Maintena, an atypical antipsychotic, is an intramuscular depot formulation of aripiprazole. It is a sterile lyophilized powder that, when reconstituted with sterile water for injection, forms an injectable suspension that can be administered monthly. After an initial injection of Abilify Maintena along with an overlapping 14-day dosing of oral antipsychotic treatment, subsequent injections of Abilify Maintena provide uninterrupted medication coverage for 30 days at a time. It provides a treatment option to address two of the most important considerations in the management of schizophrenia – improving symptoms in patients with an acute relapse of their disease and reducing the risk of relapse or the re-



emergence of worsening of symptoms. Depot formulations of antipsychotic agents provide patients with concentrations of active drug that remain at a therapeutic range for an extended period of time<sup>iii</sup>.

### About Bipolar I disorder

Bipolar I disorder (BP-I) is a chronic mental illness<sup>iv</sup>. People with BP-I experience one or more episodes of mania, and may have episodes of both mania and depression; however, an episode of depression is not necessary for a BP-I diagnosis. The lifetime prevalence of BP-I in the U.S. population is 2.6% with 89% of these cases categorized as severe<sup>v</sup>. If left untreated, the manic and depressive symptoms may get worse.

### Lundbeck contacts

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### About H. Lundbeck A/S

H. Lundbeck A/S (LUN.CO, LUN DC, HLUYY) is a global pharmaceutical company specialized in psychiatric and neurological disorders. For more than 70 years, we have been at the forefront of research within neuroscience. Our key areas of focus are depression, schizophrenia, Parkinson's disease and Alzheimer's disease.

An estimated 700 million people worldwide are living with psychiatric and neurological disorders and far too many suffer due to inadequate treatment, discrimination, a reduced number of working days, early retirement and other unnecessary consequences. Every day, we strive for improved treatment and a better life for people living with psychiatric and neurological disorders – we call this Progress in Mind.

Our approximately 5,000 employees in 55 countries are engaged in the entire value chain throughout research, development, manufacturing, marketing and sales. Our pipeline consists of several late-stage development programmes and our products are available in more than 100 countries. We have research centres in China and Denmark and production facilities in China, Denmark, France and Italy. Lundbeck generated core revenue of DKK 14.6 billion in 2015 (EUR 2 billion; USD 2.2 billion).

For additional information, we encourage you to visit our corporate site [www.lundbeck.com](http://www.lundbeck.com) and connect with us on Twitter at @Lundbeck.



## About Otsuka Pharmaceutical Co., Ltd.

Otsuka Pharmaceutical is a global healthcare company with the corporate philosophy: “Otsuka – people creating new products for better health worldwide.” Otsuka researches, develops, manufactures and markets innovative and original products, with a focus on pharmaceutical products for the treatment of diseases and nutraceutical products for the maintenance of everyday health.

In pharmaceuticals, Otsuka is a leader in the challenging area of mental health and also has research programs on several under-addressed diseases including tuberculosis, a significant global public health issue. These commitments illustrate how Otsuka is a “big venture” company at heart, applying a youthful spirit of creativity in everything it does.

Otsuka Pharmaceutical and related companies, which employ approximately 31,000 people worldwide, is a wholly owned subsidiary of Otsuka Holdings Co., Ltd., the holding company for the Otsuka Group that is headquartered in Tokyo, Japan. The Otsuka Group has business operations in 28 countries and regions around the world, with consolidated sales of approximately 1.45 trillion yen (or USD 11.9 billion or EUR 10.8 billion) in 2015. Otsuka welcomes you to visit its global website at <https://www.otsuka.co.jp/en>.

## Safe Harbor/Forward-Looking Statements

**The above information contains forward-looking statements that provide our expectations or forecasts of future events such as new product introductions, product approvals and financial performance.**

**Such forward-looking statements are subject to risks, uncertainties and inaccurate assumptions. This may cause actual results to differ materially from expectations and it may cause any or all of our forward-looking statements here or in other publications to be wrong. Factors that may affect future results include interest rate and currency exchange rate fluctuations, delay or failure of development projects, production problems, unexpected contract breaches or terminations, government-mandated or market-driven price decreases for Lundbeck's products, introduction of competing products, Lundbeck's ability to successfully market both new and existing products, exposure to product liability and other lawsuits, changes in reimbursement rules and governmental laws and related interpretation thereof, and unexpected growth in costs and expenses.**

**Certain assumptions made by Lundbeck are required by Danish Securities Law for full disclosure of material corporate information. Some assumptions, including assumptions relating to sales associated with product that is prescribed for unapproved uses, are made taking into account past performances of other similar drugs for similar disease states or past performance of the same drug in other regions where the product is currently marketed. It is important to note that although physicians may, as part of their freedom to practice medicine in the US, prescribe approved drugs for any use they deem appropriate, including unapproved uses, at Lundbeck, promotion of unapproved uses is strictly prohibited.**

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<sup>i</sup> Drug Approval Reports. U.S. Food and Drug Administration (FDA). 2013. Available at: <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Reports.MonthlyApprovalsAll>. Accessed 11 November 2014.

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<sup>ii</sup> ABILIFY MAINTENA US (aripiprazole) 2016 Full prescribing information. Tokyo: Otsuka Pharmaceutical Co., Ltd.

<sup>iii</sup> Kane JM, Sanchez R, Perry PP, et al. Aripiprazole intramuscular depot as maintenance treatment in patients with schizophrenia: a 52-week, multicenter, randomized, double-blind, placebo-controlled study. *Journal of Clinical Psychiatry*. 2012; 73(5): 617-624.

<sup>iv</sup> Bipolar Disorder. National Alliance on Mental Illness website. <http://www.nami.org/Learn-More/Mental-Health-Conditions/Bipolar-Disorder>. Accessed 27 September 2016.

<sup>v</sup> Kessler RC, Chiu WT, Demler O, Walters EE. Prevalence, severity, and comorbidity of twelve-month DSM-IV disorders in the National Comorbidity Survey Replication (NCS-R). *Archives of General Psychiatry*, 2005 Jun;62(6):617-27.