

November 21, 2017

Sumitomo Dainippon Pharma Co., Ltd.

Angelini S.p.A.

**Sumitomo Dainippon Pharma and Angelini Announce Partnership for Commercialization of Latuda® (Lurasidone Hydrochloride) in Europe**

Sumitomo Dainippon Pharma Co., Ltd. (Head Office: Osaka, Japan; President: Masayo Tada; hereinafter “**Sumitomo Dainippon Pharma**”) and Angelini S.p.A. (Head Office: Rome, Italy; CEO: Gianluigi Frozzi; hereinafter “**Angelini**”) announced today that the companies have formed a partnership (entering into a license and distribution agreement) with the goal to expand availability in Europe of Latuda® (generic name: lurasidone hydrochloride; hereinafter “LATUDA”), an atypical antipsychotic which was created by Sumitomo Dainippon Pharma.

Under the terms of the agreement, Sunovion Pharmaceuticals Europe Ltd., a subsidiary company of Sumitomo Dainippon Pharma Group, (hereinafter “**Sunovion Europe**”) has granted Angelini exclusive commercialization rights for LATUDA in 29 European countries\* and in Turkey (hereinafter “**Territory**”). Sunovion Europe is transferring the marketing authorization for LATUDA in Europe to Angelini. Furthermore, Sumitomo Dainippon Pharma will supply LATUDA bulk tablets, or final products to Angelini.

Angelini will hold the marketing authorization for LATUDA in Europe and will commercialize it in the Territory. Angelini will begin to distribute LATUDA in Italy to mark the first country in the Territory, by the end of 2017. Sunovion Europe will continue to distribute LATUDA in the United Kingdom, Switzerland, Norway, Finland, Sweden, Denmark and the Netherlands, where it has already been launched.

“Sumitomo Dainippon Pharma has been seeking to establish a partnership for commercialization of LATUDA in Europe after a partnership on LATUDA business in Europe with Takeda Pharmaceutical Company Limited was terminated in 2015. We are pleased to announce the partnership with Angelini,” said Masayo Tada, Representative Director, President and CEO of Sumitomo Dainippon Pharma. “We expect to provide this therapeutic option to a greater number of patients in Europe.

“Central nervous system (CNS) diseases and disorders are one of our focus therapeutic areas, and we are pleased to enhance our already strong product portfolio by introducing LATUDA,” said Gianluigi Frozzi, CEO of Angelini. “We will work closely with Sunovion Europe to make LATUDA available in a greater number of European countries.”

\* Italy, San Marino, Vatican City, Spain, Andorra, Austria, Bulgaria, Croatia, Cyprus, Czechia, Greece, Hungary, Poland, Portugal, Romania, Slovenia, Slovakia, Russia, Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kyrgyzstan, Moldova, Ukraine, Tajikistan, Turkmenistan, Uzbekistan

(References)

### **About Latuda®**

LATUDA is an atypical antipsychotic created originally by Sumitomo Dainippon Pharma, characterized by a unique chemical structure and an affinity for dopamine D<sub>2</sub>, serotonin 5-HT<sub>2A</sub> and serotonin 5-HT<sub>7</sub> receptors where it has antagonist effects. In addition, LATUDA is a partial agonist at the serotonin 5-HT<sub>1A</sub> receptor and has no appreciable affinity for histamine H<sub>1</sub> or muscarinic M<sub>1</sub> receptors.

LATUDA has been available for the treatment of schizophrenia in the United States since 2011, in Canada since 2012, in Switzerland since 2013, in Denmark, Norway and the U.K. since 2014, in the Netherlands, Finland and Australia since 2015, in Sweden since 2016, and in Thailand, Hong Kong and Singapore since 2017. Sumitomo Dainippon Pharma is conducting Phase 3 studies with a view to obtaining approvals of LATUDA for the treatment of schizophrenia, bipolar I depression and bipolar maintenance in Japan and submitted the New Drug Application for the treatment of schizophrenia in China. Similar efforts are ongoing in collaboration with Daiichi Sankyo Company, Limited for four Latin American countries, with Standard Chem. & Pharm. Co., Ltd. for Taiwan, with DKSH (Thailand) Limited for Thailand, Singapore and Hong Kong, with Bukwang Pharmaceutical Co., Ltd. for Korea, with Servier Laboratories Australia Pty Ltd. for Australia and with NewBridge Pharmaceuticals Limited for the six countries of the Gulf Cooperation Council including Saudi Arabia and Kuwait.

### **About Sumitomo Dainippon Pharma Co., Ltd.**

Sumitomo Dainippon Pharma Co., Ltd., defines its corporate mission as "to broadly contribute to society through value creation based on innovative research and development activities for the betterment of healthcare and fuller lives for people worldwide". By pouring all our efforts into the research and development of new drugs, we aim to provide innovative and effective pharmaceutical solutions to people not only in Japan but also around the world

in order to realize our corporate mission. For more details, please visit Sumitomo Dainippon Pharma's website ([www.ds-pharma.com/](http://www.ds-pharma.com/)).

### **About Angelini Group**

Angelini is a privately owned international group. Founded in Italy in the early 20th century, it has branches in 20 countries and employs approximately 6,000 people. The pharmaceutical sector is the core business, representing over 50% of the Angelini group, €1.6 billion 2016 revenue.

Angelini pharmaceutical products are available in over 60 countries through its branches and an extensive network of licensees and strategic agreements with local pharmaceutical companies.

The company portfolio focuses mainly on pain relief, inflammation, CNS, anti-infectives, gynecology and has a strong position in the OTC market. The R&D department is currently working on several projects in the areas of Pain & Inflammation Disorders, Infection Control & Infectious Diseases and Nervous System Diseases & Disorders. In the latter, R&D is active with discovery programs, including private-public projects with New Chemical Entities, as well as clinical studies (phase I and II) and with clinical studies for already marketed products fully developed by Angelini. For more details, please visit Angelini's website ([www.angelinipharma.com](http://www.angelinipharma.com)).

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