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DSP and Takeda Sign Development and Commercialization Agreement for an Atypical Antipsychotic Agent Lurasidone in Europe

Dainippon Sumitomo Pharma Co., Ltd. (“DSP”) (Headquarters: Osaka, Japan: President: Masayo Tada) and Takeda Pharmaceutical Company Limited. (“Takeda”) (Headquarters: Osaka, Japan: President & CEO: Yasuchika Hasegawa) today announced that they have entered into a license agreement for the joint development and exclusive commercialization of the oral formulation of lurasidone hydrochloride (generic name, “lurasidone”), an atypical antipsychotic agent developed originally by DSP, for the treatment of schizophrenia and bipolar disorder in 26 member states of the European Union (“EU”) except the United Kingdom (“UK”), Switzerland, Norway, Turkey and Russia (“Territory”). Takeda will have exclusive commercialization right in the Territory. The UK is excluded from this transaction and the right will be reserved for DSP. Lurasidone was approved for the treatment of schizophrenia in adult patients in the United States by the Food and Drug Administration in October 2010.

Under terms of the agreement, Takeda will make an upfront payment of 10 Billion Japanese Yen and milestone payments up to approximately US$180 million in the event of a Marketing Authorization Application (“MAA”) filing and MAA approval for targeted indications: schizophrenia and bipolar disorder. Upon commercialization, Takeda will pay royalty to DSP based on net sales in the Territory, and DSP will supply the product to Takeda. In addition, after the execution of this agreement, future development costs necessary for MAA filing and its approval in the Territory will be shared between DSP and Takeda at a certain fixed ratio. Further details of the economic conditions are not disclosed.

The two companies will aim for the earliest possible MAA filing of lurasidone in the Territory with joint development based on the global studies carried out by DSP. In regard to a future MAA filing, consultation is on-going to determine whether additional clinical studies are necessary before the MAA for either of the two targeted indications can be submitted to the European Medicines Agency.

“Lurasidone is the core overseas development product of the DSP group and with respect to Europe we have focused our progress on executing a mutually-beneficial license agreement.” said Masayo Tada, president and chief executive officer, Dainippon Sumitomo Pharma Co., Ltd. “I am very pleased to enter into an agreement with Takeda Pharmaceutical Company, with a sales network in the leading countries of Europe. Because the Central Nervous System field is one of Takeda’s core therapeutic areas, they understand the potential of lurasidone. Both companies will coordinate to accelerate development in Europe and we aim to deliver the medicine faster to more patients. ”

“We are very pleased to enter into this agreement as the Central Nervous System field is one of Takeda’s core therapeutic areas,” said Yasuchika Hasegawa, president & CEO, Takeda Pharmaceutical Company Limited. “With lurasidone already approved in the U.S. and in late stage development in other regions, we will work vigorously in close cooperation with DSP to achieve the earliest possible launch of lurasidone in our agreement territories to maximize the product’s potential.”

With respect to DSP’s financials, the upfront will be added to net sales and operating income this quarter (Jan 1 - Mar 31, 2011). Revisions to the financial forecast for this fiscal year in regards to other license agreements and recent achievement trends are announced today. Takeda will record the upfront payment in this fiscal year ending March 31, 2011, and will not revise its financial forecast for this fiscal year.

（Reference）

Lurasidone is an atypical antipsychotic agent, developed originally by DSP with an affinity for dopamine D2, serotonin 5-HT2A and serotonin 5-HT7 receptors where it has antagonist effects. In addition, lurasidone is a partial agonist at the serotonin 5-HT1A receptor and has no appreciable affinity for histamine or muscarinic receptors.

On October 28, 2010 (U.S. Time) lurasidone HCl (brand name LATUDA®) was approved for the treatment of schizophrenia in adult patients in the United States by the Food and Drug Administration. LATUDA was launched in the United States for the treatment of schizophrenia on February 4, 2011 (US time) through DSP’s subsidiary Sunovion Pharmaceuticals Inc.
In the U.S., the recommended starting dose for LATUDA is 40mg/day taken with food (at least 350 calories) with no initial dose titration required. The maximum recommended dose is 80 mg/day. The efficacy of LATUDA for the treatment of schizophrenia was established in four, short-term (6-week), placebo-controlled clinical studies in adult patients who met DSM-IV criteria for schizophrenia. In these studies, LATUDA demonstrated significantly greater improvement versus placebo on the primary efficacy measures [the Positive and Negative Syndrome Scale (PANSS) total score and the Brief Psychiatric Rating Scale-derived from PANSS (BPRSd)] at study endpoint. A total of five clinical trials contributed to the understanding of the tolerability and safety profile of LATUDA. The most commonly observed adverse

reactions (≥5% and at least twice that for placebo) in patients treated with LATUDA in short-term clinical studies were somnolence, akathisia, nausea, parkinsonism, and agitation.

Development stage:

Schizophrenia: Phase III as Pan-Asia study (Japan, Korea and Taiwan)

Bipolar Disorder: Phase III in the U.S. and Europe, etc.

About DSP

Located in Osaka, Japan, Dainippon Sumitomo Pharma (DSP) is a pharmaceutical company with a diverse portfolio of pharmaceutical, animal health, food and specialty products. DSP aims to produce innovative pharmaceutical products in the Central Nervous System (CNS) field, designated as a key therapeutic area, and other specialty areas. DSP is based on the merger in 2005 between Dainippon Pharmaceutical Co., Ltd., and Sumitomo Pharmaceuticals Co., Ltd. Additional information about DSP is available through its corporate website, www.ds-pharma.com.

About Takeda

Located in Osaka, Japan, Takeda is a research-based global company with its main focus on pharmaceuticals. As the largest pharmaceutical company in Japan and one of the global leaders of the industry, Takeda is committed to strive towards better health for patients worldwide through leading innovation in medicine. Additional information about Takeda is available through its corporate website, www.takeda.com.

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