

26 September 2013

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**Licensing Agreement for Nasal Drug Delivery Technology Platform**

**–Nasal Dihydroergotamine for Treatment of Migraine Headache–**

Shin Nippon Biomedical Laboratories, Ltd. (“SNBL”; President: Ryoichi Nagata; Tokyo, Japan) announces the conclusion of a licensing agreement with Transcept Pharmaceuticals, Inc. (“Transcept”; CEO, Glenn A. Oclassen; California, USA; NASDAQ, TSPT) to use SNBL’s novel nasal delivery technology platform<sup>1)</sup> for an intranasal dihydroergotamine (DHE) product.

This agreement grants a license to use the nasal delivery technology platform developed by SNBL, including its international patents, for a nasal DHE powder formulation (“the Product”). Transcept receives exclusive worldwide rights to develop and commercialize the Product under the license. In return, SNBL will receive one-time payments, totaling up to \$42.5 million, for the execution of the agreement and for reaching certain development and commercial milestones, plus low double digit royalties on net sales after market.

Migraine headache is characterized by a thrusting pain that occurs on either side at the temple; it can also be accompanied by nausea. In severe cases, the pain is sufficient to have a significant impact on the normal lifestyle of patients. Migraine is among the most common of neurological disorders, with over 30 million migraine cases each year in the U.S. and 8.4 million patients in Japan each year who suffer from migraine. The Global market for prescription migraine treatments is reported to exceed \$3 billion. The majority of migraine patients are between 20 and 40 years of age, leading active professional and personal lives, and these patients live in fear of the next strong migraine attack. Unmet needs remain among patients for a migraine drug with quick action that can be self-administered. DHE has already been marketed as a migraine drug, and in the US, injectable and liquid nasal spray formulations have been approved; however, the existing liquid nasal spray formulation is absorbed relatively slowly and an unmet need still remains for a fast-acting, self-administered formulation.

Upon confirming a faster absorption of the Product compared to the existing liquid nasal spray formulation in a preclinical feasibility study, Transcept decided to develop the product that would meet the unmet needs of migraine patients. Development of the Product is expected to enable a fast-acting and reliable treatment of migraine that can be self-administered without needles. Transcept aims to market the Product quickly and

plans to initiate the first clinical study of the Product in 2014. The parties anticipate entering into further agreements under which SNBL would supply Transcept with nasal powder spray delivery device components and would provide Transcept with certain preclinical and clinical services to support the development of the Product.

In addition to DHE, Transcept and SNBL are evaluating further potential opportunities for new neuroscience products incorporating the SNBL technology that would deliver meaningful clinical benefits to patients.

SNBL has continued to research and develop the novel intranasal drug delivery technology since 1998 and has succeeded in establishing a versatile platform technology that can be applied to various drugs. To date, SNBL has conducted clinical trials applying the platform technology to insulin for diabetes treatment, granisetron for anti-emesis and to zolmitriptan for migraine relief. As signified by the successful licensing of the technology to Pastorus Pharma, LLC for nasal oxytocin to treat autism spectrum disorder in February, 2011, to Besins Healthcare Group for nasal progesterone to treat traumatic brain injury in April, 2013, and, this time, to Transcept, the overall awareness and evaluation of the technology has been continuously increasing. In addition to the core CRO business, SNBL aims to increase revenue through intellectual property thorough its Translational Research (TR) business<sup>3)</sup>, as typified by this agreement. Development of TR business will supplement the CRO business in providing our pharmaceutical customers with value-adding technology and high-quality services.

The upfront payment for this agreement has been included in the estimated earnings reported on May 14, 2013; therefore, impact on the estimated earnings as a result of this agreement is minimal.

Transcept Pharmaceuticals, Inc. is a specialty pharmaceutical company focused on the development and commercialization of proprietary products to address important therapeutic needs in the field of neuroscience. The company's management team developed Intermezzo<sup>®</sup> from concept to its approval by the FDA in 2011<sup>3</sup>. Purdue holds commercialization and development rights for Intermezzo in the United States. For further information about Transcept, please visit [www.transcept.com](http://www.transcept.com). For information about Intermezzo, please visit [www.MyIntermezzo.com](http://www.MyIntermezzo.com).

#### [Notes]

<sup>1)</sup> Nasal delivery technology platform is SNBL's novel technology, covered by international patents, which significantly enhance the absorption of powder nasal drugs from the nasal mucosa. The technology has

been shown in several clinical trials to be safe and effective under the clinically tested conditions. It is a fundamental technology that is versatile and can be applied to various drugs. Multiple clinical trials conducted to date have demonstrated this technology, safety and efficacy in into the conditions of the clinical trials. (<http://www.snbl-nds.co.jp/en/>).

- <sup>2)</sup> Translational Research Business is SNBL's business unit that takes a medical technology from basic research to a clinical application. SNBL utilizes its own preclinical and clinical facilities to incubate early technologies by value-adding research or conducting development and licensing the technology to biopharmaceutical companies.
  - <sup>3)</sup> Intermezzo® (zolpidem tartrate sublingual tablet) C-IV is indicated for use as needed for the treatment of insomnia when a middle-of-the-night awakening is followed by difficulty returning to sleep. Intermezzo is not indicated for the treatment of middle-of-the-night insomnia when the patient has fewer than 4 hours of bedtime remaining before the planned time of waking.
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