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Licensing Agreement for Nasal Drug Delivery Technology Platform

–Nasal Progesterone for Treatment of Traumatic Brain Injury–

Shin Nippon Biomedical Laboratories, Ltd. (“SNBL”; President: Ryoichi Nagata; Tokyo, Japan) announces the conclusion of a licensing agreement with Besins Healthcare (CEO, Leslie Grunfeld; Belgium) to use SNBL’s novel nasal delivery technology platform¹⁾ for an intranasal progesterone product.

This agreement grants a license to use the nasal delivery technology platform developed by SNBL, including its international patents, for a nasal progesterone powder formulation (“the Product”). Besins Healthcare and affiliates receives exclusive rights to develop and commercialize the Product under the license. In return, SNBL will receive a one-time payment for the execution of the agreement, payments with respect to certain development milestones and royalties on sales after market.

About 10 million people around the world sustain traumatic brain injury (TBI)¹⁾ annually. In the United States alone, about 1.7 million people sustain a TBI annually; out of which, 52,000 die, 275,000 are hospitalized, and 80,000 experience the long-term disabilities associated with TBI. Most common causes of TBI have been reported as falls and automobile accidents, while there are also many cases where TBI is suffered by soldiers due to explosions or soccer and American football athletes due to impacts to the head.^{A), B)}

Progesterone is one of the endocrine hormones and has traditionally been used in the field of women’s health. On the other hand, recent research suggests that progesterone has neuroprotective effects against brain injuries.^{C)} BHR Pharma, LLC (Virginia, USA; "BHR"), an affiliate company of Besins Healthcare, is engaged in the development of injectable form of progesterone in patients with TBI and is currently conducting a global Phase 3 clinical study program³⁾ to verify the neuroprotective effects and safety.^{D)}

In addition to the injectable form, in order to expand the applicability of the progesterone compound to a wider range of TBI patients, Besins Healthcare has decided to develop a non-injectable form of progesterone which would meet the needs of concussions or mild TBI patients, such as soldiers and athletes. The product is expected to provide quick and easy administration of progesterone, immediately following an incident, providing an effective neuroprotection against TBI. BHR anticipates entering the clinic within this year and to develop the product for timely commercialization.

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, we have conducted clinical trials applying the platform technology to granisetron for anti-emesis and to zolmitriptan for migraine relief. SNBL continues to research its applicability to influenza vaccines (News Release for details). Through the application of the platform technology to progesterone under this agreement, SNBL hopes to make a significant contribution to improving the quality of life for TBI patients. In addition to the core CRO business, SNBL plans to establish its Translational Research (TR) business⁴⁾, which aims to increase revenue through intellectual property, 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 effect of this matter on this year's earnings is planned to be disclosed on May 14, 2013, in the report of this year's budget.

Besins Healthcare is a pharmaceutical company founded in Paris, France in 1885. Currently, the company is registered in Belgium and has the head office functions in Thailand. The company specializes in the development and commercialization of hormonal and nutritional drugs for men and women. Over the years, the company has established a high reputation in especially in the field of women's health, and plays a central role in hormone therapy for women and men. The company's products are distributed through its subsidiary companies and a network of business partners to more than 90 countries around the world. The company has about 650 employees.

[Notes]

- 1) 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. Is a fundamental technology that is versatile can be applied to various drugs. , we have conducted several clinical trials to date, this technology, safety and efficacy in into the conditions of the clinical trials. (<http://www.snbl-nds.co.jp/jp/>).
- 2) Traumatic brain injury (TBI) occurs when an external force traumatically injures the brain, possibly leading to permanent or temporary impairment of the brain function. It can impair cognitive, physical, and psychosocial functions, with an associated diminished or altered state of consciousness. In cases that led to the higher brain dysfunction, the paralysis of limbs or even death may occur. There are also many patients that seemingly appear no different than healthy people, but they lose social adaptability and cannot enjoy a normal livelihood.
- 3) Global Phase 3 clinical study program is a large-scale clinical trial conducted at the end of the

development to obtain approval as a drug, and it is carried out simultaneously across multiple countries. It can incorporate enrollment of several hundreds to several thousands of patients to confirm the efficacy and safety of a drug.

- 4) 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.

[References]

- A) The impact of traumatic brain injuries: a global perspective *NeuroRehabilitation* 2007; 22 (5) 341-53.
- B) *Traumatic Brain Injury in the United States: A Report to Congress* (1999).
- C) Progesterone as a neuroprotective factor in traumatic and ischemic brain injury *Prog Brain Res* 2009;. 175:219-37.
- D) *ClinicalTrials.gov*. US NIH. ([Http://clinicaltrials.gov/ct2/show/NCT01143064](http://clinicaltrials.gov/ct2/show/NCT01143064))