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Conclusion of Licensing Agreement with Pastorus Pharma, LLC.

Intranasal Oxytocin for the Treatment of Autism

Shin Nippon Biomedical Laboratories, Ltd. (SNBL) today announces the conclusion of a licensing agreement with Pastorus Pharma, LLC. (Wyoming, US) for the development and marketing of intranasal oxytocin as a potential treatment for autism.

Under the terms of the licensing agreement, in addition to an upfront payment and payments on the achievement of certain development milestones, SNBL will also receive royalties on sales of oxytocin once the product has been launched. Furthermore, it is planned that SNBL will perform certain preclinical and clinical studies required for the approval of oxytocin under contract from Pastorus.

Oxytocin, a hormone secreted by the posterior pituitary gland, has long been known for its peripheral role in uterine contraction, and has been used for many years in the field of obstetrics and gynecology. Recent research, however, has begun to characterize oxytocin's function in the central nervous system, including modulation of neurotransmitter release, modification of synaptic architecture and activation of specific brain regions involved in social cognition. A recently-published clinical study of oxytocin has demonstrated its efficacy in improving social cognition in patients with autism spectrum disorders[1] (Andari E *et al.*, *PNAS*, 2010). Focusing on this new use for oxytocin, in its development of this drug for the treatment of autism, Pastorus has chosen to use SNBL's proprietary intranasal drug delivery system, μco™ system[2] (muco system), which is expected to provide high efficacy and safety with pain free delivery.

According to a report from the US Centers for Disease Control and Prevention, one in 110 children in the US suffers from autism spectrum disorders (*Prevalence of the Autism Spectrum Disorders (ASDs) in Multiple Areas of the United States, 2004 and 2006: Community Report from the Autism and Developmental Disabilities Monitoring (ADDM) Network*, 2009). The same report states that individuals with an autism spectrum disorder had average medical expenditures that exceeded those of individuals without such a disorder by between $4,110 and $6,200 a year. However, at the current time, there are no treatments approved to treat the core symptoms of autism. SNBL hopes that the development of Pastorus' intranasal oxytocin product candidate will be good news for patients with developmental disorders and their families.

At the present time, the effect of this matter on the earnings of SNBL's current term is minimal. Going forward, if an effect on the earnings of SNBL is expected, this will be reported in a timely manner.

Notes

[1] Autism spectrum disorders: as autistic patients display diverse symptoms, this term is employed to reflect the diversity of these symptoms and the ambiguous boundaries between them, and refers to cerebral dysfunction which has a pervasive cerebral developmental disorder as a common element.

[2] μco™ system (muco system): developed independently by SNBL, μco™ system is an intranasal drug delivery system consisting of a formulation technology that allows safe and efficient absorption of powder formulations from the nasal mucosa, plus a device technology that provides pocket sized portability and ease of use. μco™ system has been positively evaluated as a platform technology with broad utility that can be applied to a wide range of pharmaceutical products.