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Development of Nasal Zolmitriptan Product for Migraine

Shin Nippon Biomedical Laboratories, Ltd. (SNBL) has developed a nasal delivery system (“*μcoTM System*”) that enables patients to easily and accurately deliver drugs through the nose. Use of *μcoTM System*, which consists of SNBL’s novel nasal drug carrier and novel nasal drug delivery device, allows efficient drug absorption and faster action in patients.

The effectiveness of *μcoTM System* has already been demonstrated in the development of SNBL’s anti-emetic nasal granisetron product (development code: TRG), which has shown excellent efficacy and safety in a Phase 2 clinical study. As its next pipeline candidate, SNBL has begun the development of nasal zolmitriptan, also utilizing *μcoTM System*. Zolmitriptan, an anti-migraine drug, has enjoyed wide use by migraine patients, and its safety and efficacy are already well established.

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 regular lifestyle of patients. In the US, 28 million people (around 10% of the entire population) suffer from migraine headaches, while there are 8.4 million patients in Japan. The majority of migraine patients are between 20 and 40 years of age – at the height of their professional and personal lives – and these patients live in fear of the next strong migraine attack. According to a study conducted in the US, migraine patients lose 3.8 days for men and 5.6 days for women each year to bed rest as the result of migraine attacks. The economic losses caused by migraine headaches may reach more than US\$10 billion per year (Hu XH, *et al.*, Burden of migraine in the United States. Arch Intern Med 159: 813-818, 1999). With such social and economic impacts, there are currently many types of anti-migraine agents available worldwide, with a global market size as large as US\$3.5 billion. However, unmet needs remain among patients for a migraine drug with quick and consistent action that is also portable and easy to use.

By using SNBL’s *μcoTM System*, a migraine drug that is delivered in the nasal cavity is expected to be absorbed efficiently and consistently, swiftly easing migraine symptoms. Also, nasal administration has the advantage of providing accurate dosing even when migraine is accompanied by nausea or vomiting.

Previously, SNBL examined the first generation triptan drug, sumatriptan, as a product candidate. However, after further evaluation, due to its faster transit to the brain (the intended site of action), longer sustained effect, and higher absorbability through the nasal cavity, SNBL has concluded that zolmitriptan is the most appropriate migraine drug for further development. SNBL’s nasal zolmitriptan is a new powder product which, when compared in animal studies to existing nasal liquid products, has much higher and much faster absorption. Additionally, SNBL’s nasal zolmitriptan product will incorporate SNBL’s newly developed single-use, disposable device to further increase portability.

SNBL aims to rapidly develop its nasal zolmitriptan product until completion of Phase 1 clinical study, at which time SNBL will seek to license-out the product for further development.

The effect of the matters reported above on the earnings of SNBL’s current term is minimal.