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Initiation of US Phase I Clinical Study of Intranasal Zolmitriptan for Migraine

Shin Nippon Biomedical Laboratories, Ltd. (SNBL) is currently developing an intranasal formulation of an anti-migraine drug, zolmitriptan (development code: TRZ). The United States (US) Food and Drug Administration (FDA) reviewed and approved the Investigational New Drug (IND) application for the first-in-man, Phase 1 clinical study of TRZ, and SNBL has initiated the clinical study in the US.

Migraine induces disabling headaches usually in the form of an intense, throbbing pain on one side of the head, which, when severe, can be painful enough to interfere with daily activities. This severe pain is often accompanied by nausea and vomiting. Approximately 28 million patients in the US – almost 10% of the population – and approximately 8.4 million patients in Japan suffer from migraine. Migraine prevalence peaks around patients in their 20s to 40s; these patients are typically in their most productive years, and suffer significant anxiety about the sudden impact of migraine headaches on their daily lives. Patients are thus in need of non-injectable drug formulations that provide reliable relief of migraine and an easy route of administration.

In preclinical studies, the bioavailability[1] of TRZ was as high as 70% of intravenous injection and about 2.3 times higher than the commercially available oral tablet. It is strongly expected that TRZ, combined with a novel user-friendly and pocket-sized intranasal delivery device developed by SNBL, can offer patients a needle-free alternative to injections for reliable relief of migraine.

The FDA reviewed and approved the IND application for the first-in-man, Phase 1 clinical study to assess the safety, tolerability, and pharmacokinetics of TRZ in healthy volunteers. The results from the Phase 1 clinical study is planned to be reported by the end of this year.

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

Notes

1 Bioavailability: the fraction of an administered dose of unchanged drug that reaches the systemic circulation.