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Shin Nippon Biomedical Laboratories, Ltd.

CEO and President: Ryoichi Nagata

Tokyo Stock Exchange, First Section: Code # 2395

Contact Information: CFO and Executive Vice President, Toshihiko Seki (Tel: +81-(0)3-5565-5001)

First Report on Results of US Phase 2 Clinical Study of Intranasal Granisetron

Shin Nippon Biomedical Laboratories, Ltd. (SNBL) is developing an intranasal form of the antiemetic drug granisetron (development code: TRG) in the US. SNBL today announces the first report on the results of the Phase 2 clinical study of TRG.

The study, which was conducted at 14 specialist cancer treatment centers in the US, was a double-blind study¹ to compare the preventive efficacy and safety of three doses of TRG (0.5 mg, 1.0 mg, 2.0 mg) in cancer patients (total 68 patients) at risk of chemotherapy-induced nausea and vomiting (CINV) associated with the administration of highly emetogenic chemotherapy.²

According to the results of the study, 71.4%, 76.0%, and 90.9% of patients achieved complete control of CINV in the 24 hours post-chemotherapy in the TRG 0.5 mg, 1.0 mg, and 2.0 mg groups, respectively. The TRG 2.0 mg dose in particular demonstrated outstanding efficacy. Furthermore, in the global satisfaction assessment conducted in patients who were treated, patients rated their satisfaction with the TRG 0.5 mg, 1.0 mg, and 2.0 mg doses at 87.7%, 79.8%, and 96.6%, respectively, reflecting high levels of global satisfaction. In particular, those patients dosed with TRG 2.0 mg expressed extremely high levels of global satisfaction.

Concerning safety, of the adverse events³ observed, the majority were caused by chemotherapy; no adverse events of particular note to TRG itself were observed. Furthermore, from the perspective of potential local irritation of the nose from use of an intranasal formulation, patients in the study performed self assessments of nasal irritation, including the subjective symptoms of nasal discomfort, nasal burning, nasal itching, and bad taste. At 30 minutes, 4 hours, and 24 hours after dosing, almost no nasal irritation was observed. The favorable safety profile of TRG was thus confirmed.

Patients undergoing chemotherapy for cancer suffer significantly from nausea and vomiting caused by chemotherapy. Currently, patients often refuse to continue treatment due to the heavy burden of nausea and vomiting, posing a problem in the treatment of cancer. TRG, with its excellent efficacy in swiftly controlling nausea and vomiting, high patient global satisfaction, and favorable safety profile, is in future certain to make a significant contribution to reducing the suffering caused by chemotherapy, and to improving patients' quality of life.

This Phase 2 study serves as a successful proof of concept⁴ for TRG's utility in cancer patients receiving highly emetogenic chemotherapy, and justifies further investigation of TRG in Phase 3. The results of this Phase 2 study raise the added value of TRG and are expected to make a significant contribution to the smooth progress of out-licensing activities in future.

The effect of the matters reported above on the earnings of SNBL's current term will be reported in a timely manner upon any progress made in activities such as out-licensing.

Notes

- 1: Double-blind study: a study in which the subjects, the study physicians, the study physicians' staff involved in treatment, clinical assessments, etc., and the study sponsor do not know which treatment has been assigned to be administered to each subject.
- 2: Highly emetogenic chemotherapy: chemotherapy causing emesis in more than 90% of patients.
- 3: Adverse event: an undesirable medical event that occurs in a patient administered a drug. Adverse events are not necessarily causally related to the drug administered.
- 4: Proof of concept: the demonstration of the efficacy and safety, etc. of a study drug in humans; this must be established before advancing to Phase 3 studies.