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**Launch of Phase II Clinical Trial**  
**for Intranasal Granisetron Formulation**

Translational Research, Ltd. (TRL), a 100% subsidiary company of Shin Nippon Biomedical Laboratories, Ltd. (SNBL), is developing an intranasally delivered form of granisetron (TRG), a drug with anti-emetic effects, in the US. TRL announced TRG has been successfully dosed to the first patient in the Phase II clinical trial.

TRL has finished Phase I clinical trial of TRG in the US earlier this year, and TRG has shown excellent results: i) rapid absorption (blood granisetron concentration reached more than 70 percent of  $C_{max}^1$  10 minutes after the administration of TRG), ii) great absorption (absolute bioavailability<sup>2</sup> of TRG was approximately 100%), and iii) excellent safety profile (no irritation was observed upon thorough examination by otolaryngologists). TRL had been further preparing for the Phase II clinical trial through meetings with the US Food and Drug Administration (FDA) to discuss the study design of Phase II clinical trial and the future clinical development plan of TRG, aiming for FDA approval of the New Drug Application.

In the double-blind<sup>3</sup>, multiple-site Phase II clinical trial, TRL plans to evaluate TRG's efficacy in preventing nausea and vomiting, safety profile, and tolerability in cancer patients on chemotherapy (treatment with anti-cancer drugs).

During a treatment of cancer by chemotherapy or radiation therapy, cancer patients often suffer side effects such as severe nausea and vomiting. Granisetron is effective in preventing these side effects and is already available in the market in oral and injectable forms. However, correct dosing of an oral drug can be difficult, when patients are suffering from nausea or vomiting or when the patient's swallowing capability is hindered. Also, injections can be difficult, as they are invasive to patients and need to be performed by either a doctor or a registered nurse. Therefore, the existing oral and injectable forms of granisetron do not fully meet the needs of patients and medical staff, and development of a new delivery method that is easier and more precise is desired. TRG, under development by TRL, allows patients to self-dose precisely and easily, even when swallowing is difficult, using a potable intranasal delivery device, Fit-lizer®, developed by Bioactis, Ltd., which is also an SNBL subsidiary company. Because of these characteristics, TRG is greatly awaited in the

clinics and hospitals.

Currently, TRL is aggressively applying this original intranasal drug delivery technology, used in TRG, to other drugs and has multiple intranasal drugs in the development pipeline. Other than granisetron, the development pipeline of intranasal drug products includes analgesics such as morphine and fentanyl, migraine drugs such as sumatriptan, and insulin.

The effect of this new venture on the earnings of SNBL's current term is minimal. However, the results and findings of this clinical trial will allow TRL to pursue opportunities to license-out the technology or establish joint-development relationships with pharmaceutical companies. As such, TRL will continue to strive to increase the corporate value of SNBL Group.

[Footnote]

1.  $C_{max}$ : Maximum drug concentration in the blood reached after dosing.
2. Absolute bioavailability: The extent (percent) of active drug that reaches systemic circulation after an administration of drug, when compared with intravenous administration.
3. Double-blind: A study design to collect scientific and objective clinical study data, in which neither the patient nor the physician knows whether the patient is receiving which dosages.