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US FDA's New View on Development of Intranasal Granisetron

– Simplified Clinical Development Requirements Will Quicken NDA Submission –

Shin Nippon Biomedical Laboratories, Ltd. (SNBL) is developing an intranasal form of the antiemetic drug granisetron (development code: TRG) in the US. TRG has completed its evaluation of safety and efficacy in a Phase II study. SNBL today announces the receipt of a formal notice from the US Food and Drug Administration (FDA) regarding the clinical development requirements for submission of a New Drug Application (NDA).

The notice states that an NDA filing will be possible via a new development pathway based on pharmacokinetic (PK) comparison of TRG to the existing granisetron product. This new development pathway will contribute greatly to the early submission of an NDA.

Previously, the clinical development agreed with the FDA at an End-of-Phase II Meeting[1] required Phase III clinical studies to confirm the safety and efficacy of TRG against an existing product; however, the recent notice allows NDA submission based on an abbreviated development program involving PK comparison with the existing granisetron product. This will contribute greatly to early NDA submission and decrease the total cost of development.

TRG shows a comparable absorption profile to injections. Paired with SNBL's novel nasal delivery device, Fit-lizer®, that enables easy and reliable self-administration, TRG is expected to contribute significantly to improvements in patients' quality of life.

The effect of the FDA notice on the earnings of SNBL's current term is minimal.

Notes

[1] End-of-Phase II Meeting:
A type of meeting held between a sponsor and the FDA, on the request of the sponsor after the completion of Phase 2. The aim of the meeting is to confirm the safety of planned Phase 3 studies by considering the results of Phase 2 studies, to assess Phase 3 study plans and designs, and to establish any additional information required for submission for approval.