August 19, 2010
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)

Results of a Meeting with the US Food and Drug Administration (FDA) Concerning the Development of Intranasal Granisetron

Planning for a Phase 3 Study to Improve Patient Quality of Life (QOL)

Shin Nippon Biomedical Laboratories, Ltd. (SNBL) is currently developing an intranasal formulation of the antiemetic drug granisetron (development code: TRG) in the US. On the basis of the results of the completed Phase 2 study, SNBL held an End of Phase 2 Meeting[1] with the US Food and Drug Administration (FDA). At this meeting, the FDA agreed to SNBL's plans to conduct a Phase 3 program aimed at demonstrating the effectiveness of TRG against delayed chemotherapy induced nausea and vomiting (CINV), a common side effect of chemotherapy. The FDA also agreed to SNBL's proposal to use a new, more convenient intranasal delivery device in Phase 3.

Specifically, the FDA agreed to SNBL's plans to confirm the efficacy of TRG in preventing both the acute CINV that patients experience on the day of chemotherapy and the delayed CINV that patients suffer from in the days following chemotherapy. The FDA also agreed to SNBL's proposal to use a newly developed single use device in Phase 3, instead of the multiple use device used in Phases 1 and 2, which required manual loading of a drug capsule before each administration.

SNBL believes that if it can be demonstrated in Phase 3 that, using a convenient single use device, TRG is effective in preventing both acute and delayed CINV, TRG will be able to make a major contribution to improving the quality of life (QOL) of patients suffering from the side effects of chemotherapy.

At the present time, the effect of this matter on the earnings of SNBL's current term is minimal. Going forward, SNBL will continue to proceed with outlicensing activities with pharmaceutical companies.

Notes:

[1] End of Phase 2 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.