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Development Status of ONO-2506 for Injection/PROGLIA

ONO-2506 for Injection/PROGLIA was discovered by Ono Pharmaceutical Co., Ltd. (“Ono”) and is under joint development by Ono and Merck & Co., Inc., Whitehouse Station, N.J., USA (“Merck”) for acute stroke. With the exception of Japan, Taiwan and Korea, Merck has the worldwide license.

A Phase II clinical study (“RREACT”), which was initiated by Ono, has been under way in the United States and Canada. A planned interim analysis has been conducted by an independent Data Safety Monitoring Board (“DSMB”) with the objective of determining whether it is appropriate to continue the study.

The DSMB has recommended to Ono that the study discontinue. The interim analysis demonstrated it is highly unlikely that ONO-2506 for Injection/PROGLIA will show statistically significant efficacy compared to placebo in the current study design. Ono has accepted this recommendation and decided to discontinue this study after consultation with Merck.

Ono will collect all the data from the study and share them with Merck. After further analysis of the data, Ono will discuss with Merck future development plans for ONO-2506 for Injection/PROGLIA outside Japan, Taiwan and Korea.

In Japan, a Phase II/III clinical study has already been commenced based on the results of the previously completed clinical studies conducted in Japan. This study will continue as previously scheduled.

(Reference)

Interim Analysis by Data Safety Monitoring Board

The DSMB consists of independent experts in medical and statistical fields from universities who are not directly involved in the clinical study. The Board examines the safety and efficacy data from the study and makes a recommendation to the sponsor of the study whether the study should be continued.

RREACT – Rapid Response with an Astrocyte modulating agent in acute Cortical sTroke.