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Public Relations
Ono Pharmaceutical Co., Ltd.

Announcement of Termination of Exclusive License Agreement on Sivelestat (Elaspol® 100 for Injection) with Eli Lilly and Company

Ono Pharmaceutical Co., Ltd. announced today that Ono and Eli Lilly and Company (Indianapolis, USA) terminated, effective May 26, 2003, the worldwide exclusive license agreement on development, manufacturing and marketing of Sivelestat (excluding Japan, South Korea and Taiwan), which the parties signed on June 16, 2000.

Sivelestat (Elaspol® for Injection), a novel therapeutic agent for acute lung injury developed by Ono, was approved in Japan in April and its marketing started on June 17, 2002 for the indication of acute lung injury associated with systemic inflammatory response syndrome.

Outside Japan, Lilly had been conducting since August 2001 a Western Phase II double-blind clinical study in patients with acute lung injury (ALI) and acute respiratory distress syndrome (ARDS). While this study failed to demonstrate the efficacy of Sivelestat, there were significant differences in the study protocols between the Western study and the Phase III double-blind study conducted by Ono in Japan. Differences were such that the target diseases in the Western study were not exactly same as the approved indication in Japan, and that the Western study included broader patient population who were excluded from the Japanese study (such as elderly patients of 76 years old or more and patients with 4 or more multiple organ failure). Furthermore based on the patient background analysis it was found that the Western study included a greater proportion of severe patients of ALI than the Japanese study.

However, according to the principal investigator speaking at the 23rd International Society for Intensive Care and Emergency Medicine held from 18th to 21st March, 2003 in Belgium, a similar tendency in efficacy to the results seen in the Japanese study was observed in the subgroup analysis of the Western study focusing on the patient population similar to the Japanese study.

Given the result of the Western Phase II study, Lilly looked into the possibility of development targeting alternative patient populations, but finally decided that further investment for this project was not justified based on limited market potential and sales projection due to narrower target patient population and shorter remaining patent life after the launch by performing additional clinical studies.

Recognizing issues such as market and patent factors*, we plan to develop sivelestat globally through clinical studies conducted either by ourselves or a potential new partner because a similar tendency in efficacy to the results seen in the Japanese study was observed in the subgroup analysis of the Western study.

* Patent life in the US is up until 2012 plus patent restoration period.