

May 15, 2002

Public Relations  
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### **Announcement of Manufacturing Approval for Elaspol<sup>®</sup> 100 for Injection, the World's First Drug for Acute Lung Injury**

Ono Pharmaceutical Co., Ltd. (Headquarters: Osaka City, President: Kimiichiro Matsumoto) announces that manufacturing of Elaspol<sup>®</sup> 100 for injection, the world's first drug for acute lung injury associated with systemic inflammatory response syndrome (SIRS), was approved on April 11, 2002.

SIRS is a systemic inflammatory reaction caused not only by infections, but also by extensive surgical invasion, burn, trauma, pancreatitis, etc. In serious cases, SIRS may cause failures in the lungs, liver, kidneys, and other organs having no direct relations with the local inflammatory lesion, with the possibility of death.

Lung injury is one of the most intractable organ failures associated with SIRS. Elastase, an enzyme released from neutrophils (specialized white blood cells) responsible for the inflammatory response, is believed to attack lung tissue, leading to rapid deterioration of respiratory function.

Patients with lung injury must be confined to the intensive care unit (ICU), where their respiratory function is maintained by continuous mechanical ventilation via a tube inserted into the trachea. Until now, no effective treatments have been available for such patients, other than the treatment of symptoms of the underlying disease.

By selectively inhibiting neutrophil elastase, and thereby improving the patient's respiratory function, Elaspol<sup>®</sup> 100 for injection can shorten the period for which patients with lung injury need mechanical ventilation. This reduces serious patient stresses and ventilator-associated pneumonia caused by mechanical ventilation.

In addition, early removal from mechanical ventilation will shorten the period of the patients' stay in ICU, resulting in reduction of medical costs. With these features, Elaspol<sup>®</sup> 100 for injection is attracting worldwide attention as an innovative drug.

#### **Product Profile of Elaspol<sup>®</sup> 100 for Injection**

Nonproprietary : sivelestat sodium hydrate  
name

Active : 100 mg sivelestat sodium hydrate per vial  
ingredient

Indications : Acute lung injury associated with systemic inflammatory response syndrome (SIRS)

Dosage and : Usually, after dissolving in physiological saline, a daily dose of 4.8 mg/kg body weight  
administration of sivelestat sodium hydrate should be diluted with 250 - 500 mL of fluid infusion for 24-hour continuous intravenous administration (at 0.2 mg/kg/hr). Dosing period should not be more than 14 days.

Manufactured : Ono Pharmaceutical Co., Ltd.  
and distributed  
by