

February 14, 2017

Ohara Pharmaceutical Co., Ltd.

## Postponement of the NHI Drug Price Listing and Launch of “ERWINASE® for Intramuscular Injection 10000”

On December 19, 2016, Ohara Pharmaceutical Co., Ltd. (Head Office: Shiga, CEO: Seiji Ohara) received the manufacturing and marketing approval of “ERWINASE® for intramuscular injection 10000” from the Ministry of Health, Labour and Welfare for the indications of “acute leukemia (including patients with blast crisis in chronic leukemia) and malignant lymphoma. However, ERWINASE should be used only for patients who experienced hypersensitivity to L-asparaginase preparations.” At the present time, global supply of ERWINASE is restricted due to a lack of manufacturing capacity at our manufacturing partner; therefore we have decided to postpone the procedures for the NHI drug price listing and the launch of ERWINASE until planned capacity improvement measures have been implemented and a stable supply has been established.

As the company that has obtained manufacturing and marketing approval for ERWINASE in Japan, we take the major effects of this delay in supply seriously, and we will make every effort to obtain a stable supply of ERWINASE as soon as possible, for the benefit of the patients who require it and their families.

### <Product outline>

Brand name	ERWINASE® for intramuscular injection 10000
Generic name	Crisantaspase
Indications	Acute leukemia (including patients with blast crisis in chronic leukemia) and malignant lymphoma However, ERWINASE should be used only for patients who experienced hypersensitivity to L-asparaginase preparations
Dosage and administration	The usual dosage of ERWINASE is 25,000 U/m <sup>2</sup> of body surface area administered intramuscularly once daily three times a week in combination with other antineoplastic agents.