

THYRADIN®-S Intravenous Injection 200µg Receives Approval in Japan for the Treatment of Myxoedema coma / Hypothyroidism

ASKA Pharmaceutical Co., Ltd. (Head Office: Minato-ku, Tokyo, President: Takashi Yamaguchi, hereinafter "ASKA") today announced that the thyroid hormone preparation "THYRADIN®-S Intravenous Injection 200µg" (hereafter, "This medicine") has received regulatory approval for its manufacture and sale for Myxoedema coma and Hypothyroidism (limited to cases in which treatment with oral levothyroxine sodium is not appropriate) in Japan.

This medicine is a drug for which ASKA received a request for development by Ministry of Health, Labour and Welfare, as determined by the "Unapproved Medicine / Off-label Medicine Review Committee with High Medical Needs" qualifying to have a high medical need. Myxoedema coma is a life-threatening disease, if appropriate treatment is not started early, but there are no intravenous injections available in the Japanese market. As an alternative or modified method, an oral drug can be administered through the nasogastric tube, but there are problems such as difficulties in predicting and testing the amount absorbed.

ASKA strives to contribute to the treatment of patients by providing this drug as a significant new option for the treatment of thyroid dysfunction.

About THYRADIN®-S Intravenous Injection 200µg

THYRADIN®-S Intravenous Injection 200µg (levothyroxine sodium) is indicated for Myxoedema coma / Hypothyroidism (limited to cases in which treatment with oral levothyroxine sodium is not appropriate). This medicine is diluted with Japanese Pharmacopoeia saline and the initial dose for adults normally, is 50 to 400µg of levothyroxine sodium given slowly administered intravenously once daily, and then the second and subsequent days dose is 50 to 100µg once a day. In addition, a dose may be adjusted appropriately depending on the condition of the patient.

About ASKA

ASKA is a Japanese R&D-oriented company which aims to become a specialty pharma player. The Company is listed in the first section of the Tokyo Stock Exchange and will celebrate its 100th anniversary in 2020. Annual sales were \$425M in 2018. With a state-of-the-art manufacturing site, research and development center as well as sales offices throughout Japan with approximately 800 employees, complete dedication relating to the development and marketing of innovative medicines in Japan is assured.

The Company's therapeutic areas of focus are Women's health, Urology and disorders relating to Gastroenterology and the thyroid gland.

ASKA Corporate Philosophy: *Contribute toward the improvement of people's health and progress in medicine through the development of innovative products*