

Taiho Pharmaceutical Obtains Approval for an Additional Dosage and Administration of 5-HT₃ Receptor Antagonist Aloxi® for Pediatric Patients in Japan

May 27, 2021 - Taiho Pharmaceutical Co., Ltd. and Helsinn Healthcare SA, which is headquartered in Lugano, Switzerland, announced today that Taiho has acquired approval from the Japanese Ministry of Health, Labour and Welfare for an additional dosage and administration in pediatric patients of its 5-HT₃ receptor antagonist Aloxi® I.V. injection 0.75mg and Aloxi® I.V. infusion bag 0.75mg (generic name: Palonosetron Hydrochloride).

Aloxi® was developed for the prevention of chemotherapy-induced nausea and vomiting, and, in adults, has demonstrated its efficacy in delayed nausea and vomiting where other conventional 5-HT₃ receptor antagonists have hitherto provided insufficient effects. The additional indication announced today is based on the results of a Phase III clinical study conducted in Japan with pediatric patients aged 28 days to 18 years. The primary endpoint of the study was complete response (i.e., no emetic event and no rescue medication) from 0 to 120 hours after initiation of highly emetogenic or moderately emetogenic antineoplastic agents on course 1. The complete response rate was 58.6% (95% confidence interval: 44.9% to 71.4%), and the lower limit of the 95% confidence interval was above the pre-specified threshold of 30%, thus verifying the clinical benefit of this agent for pediatric patients. No new safety concerns have been raised respect the known safety profile of palonosetron agent.

Under the license agreement signed in January 2004 with Helsinn Healthcare SA, Taiho Pharmaceutical acquired clinical development and marketing rights in Japan, and manufacturing and marketing approval was obtained for Aloxi® I.V. injection 0.75mg in January 2010 and for Aloxi® I.V. infusion bag 0.75mg in August 2012. Aloxi® is approved for the indication of prevention of chemotherapy-induced nausea and vomiting for adult patients in more than 80 countries and regions, and for pediatric patients in more than 60 countries and regions.

Within Taiho's mainstay field of oncology, the company is also focusing on cancer supportive care. It is expected that Aloxi® will contribute to preventing chemotherapy-induced nausea and vomiting in pediatric patients.

Product Information

Product name	Aloxi® I.V. injection 0.75mg and Aloxi® I.V. infusion bag 0.75mg
Indication and usage	Gastrointestinal symptoms (nausea and vomiting, including delayed phase) resulting from the administration of anticancer agents (cisplatin, etc.)
Dosage and administration	For intravenous and drip infusion use, the usual dosage of palonosetron is 0.75mg per body once daily. <u>For patients aged 18 years old or younger, the usual dosage of palonosetron is 20 µg/kg once per day for intravenous administration and drip infusion and the upper dose limit is 1.5 mg.</u> (Newly approved indication is underlined.)

About the Helsinn Group

Helsinn is a privately-owned Swiss Pharma Company which, since 1976, has been improving the lives of patients, guided by core family values of respect, integrity and quality. The Group has an extensive portfolio of marketed innovative cancer and rare disease therapies, a robust drug development pipeline and ambitions to further accelerate its growth through in-licensing and acquisitions to address unmet medical needs. Helsinn operates a unique integrated licensing business model, achieving success with long-standing partners in 190 countries, who share its values. The Group's pharmaceutical business (Helsinn Healthcare) is headquartered in Lugano, Switzerland with operating subsidiaries in the U.S. (Helsinn Therapeutics US) and China (Helsinn Pharmaceuticals China) which market the Group's products directly in these countries. The Group has additional operating subsidiaries in Switzerland (Helsinn Advanced Synthesis, an active pharmaceutical ingredient manufacturer) and Ireland (Helsinn Birex Pharmaceuticals, a drug product manufacturer). 3B Future Health Fund (formerly known as Helsinn Investment Fund) was created to enhance the future of healthcare by providing funding and strategic support to innovative companies.

Helsinn Group plays an active and central role in promoting social transformation in favor of people and the environment. Corporate social responsibility is at the heart of everything we do which is reinforced in the company's strategic plan by a commitment to sustainable growth.

To learn more about Helsinn Group please visit www.helsinn.com

About Taiho Pharmaceutical Co., Ltd. (Japan)

Taiho Pharmaceutical, a subsidiary of Otsuka Holdings Co., Ltd., is an R&D-driven specialty pharma company with a focus on oncology. Taiho Pharmaceutical also has development programs in allergy and immunology, urology and consumer healthcare products. Our corporate philosophy is simple: “We strive to improve human health and contribute to a society enriched by smiles.”

For more information about, please visit: <https://www.taiho.co.jp/en/>

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