

March 28, 2022

Taiho Pharmaceutical Co., Ltd.
Helsinn Group

Taiho Pharmaceutical Obtains Approval to Manufacture and Market NK₁ Receptor Antagonist Arokaris[®] I.V. Infusion 235mg in Japan

Taiho Pharmaceutical Co., Ltd. (hereinafter “Taiho”) and Helsinn Group (hereinafter “Helsinn”), announced today that Taiho has been granted approval from the Japanese Ministry of Health, Labour and Welfare to manufacture and market the NK₁ receptor antagonist antiemetic drug “Arokaris[®] I.V. Infusion 235mg” (generic name: fosnetupitant chloride hydrochloride) for gastrointestinal symptoms (nausea and vomiting, including delayed phase) associated with cancer chemotherapy (cisplatin, etc.).

Arokaris[®] is an NK₁ receptor antagonist antiemetic drug and is a phosphorylated pro-drug preparation (injection) which is converted to netupitant, the active component. Chemotherapy-induced nausea and vomiting can have deleterious effects on patients’ quality-of-life, and may also interfere with chemotherapy administration, therefore guidelines¹⁻⁴ recommend adequate prophylaxis.

Taiho, which acquired exclusive development and marketing rights for Arokaris[®] in Japan under a license agreement with Helsinn in April 2011, has conducted clinical trials in Japan since then, and submitted a new drug application in March 2021.⁵

This approval is based on the results of a Phase III clinical study (CONSOLE⁶) comparing the efficacy and safety of Arokaris[®] versus fosaprepitant in patients receiving highly emetogenic chemotherapy in combination with palonosetron and dexamethasone. The results of this study were published in the *Journal of Clinical Oncology*.⁷

Within Taiho’s mainstay field of oncology, the company is also focusing on cancer supportive care. Under a former distribution and license agreement with Helsinn, effective as of January 2004, Taiho has been marketing the 5-HT₃ receptor antagonist

Aloxi® (generic name: palonosetron hydrochloride) in Japan since April 2010.

Helsinn is pleased to be able to bring this new treatment option for supportive care in cancer to patients in Japan. Taiho will promote the proper use of Arokaris® to ensure that it can make further contributions to patients and healthcare professionals.

Product Information

Product name	Arokaris® I.V. Infusion 235mg
Generic name	Fosnetupitant chloride hydrochloride
Indications	Gastrointestinal symptoms (nausea and vomiting, including delayed phase) associated with cancer chemotherapy (cisplatin, etc.)
Dosage and administration	For intravenous infusion use, the usual dosage of fosnetupitant is 235mg for adults, once on the first day of cancer chemotherapy, combined with other antiemetic drugs.

About Taiho Pharmaceutical Co., Ltd.

Taiho Pharmaceutical, a subsidiary of Otsuka Holdings Co., Ltd., is an R&D-driven specialty pharma focusing on the three fields of oncology, allergy and immunology, and urology. Its corporate philosophy takes the form of a pledge: “We strive to improve human health and contribute to a society enriched by smiles.” In the field of oncology in particular, Taiho Pharmaceutical is known as a leading company in Japan for developing innovative medicines for the treatment of cancer, a reputation that is rapidly expanding through its extensive global R&D efforts. In areas other than oncology, as well, the company creates and markets quality products that effectively treat medical conditions and can help improve people's quality of life. Always putting customers first, Taiho Pharmaceutical also offers consumer healthcare products that support people's efforts to lead fulfilling and rewarding lives. For more information about Taiho Pharmaceutical, please visit: <https://www.taiho.co.jp/en/>.

About the Helsinn Group

Helsinn is a fully integrated, global biopharma company headquartered in Lugano, Switzerland. It is focused on improving the lives of cancer patients all over the world with a leading position in cancer supportive care and an innovative pipeline of cancer therapeutics.

Helsinn is a third-generation family-owned company, that since 1976 has been focused on improving the lives of patients, guided by core values of respect, integrity and quality. It operates a unique licensing business model with integrated drug development and manufacturing capabilities. Helsinn has a commercial presence in 190 countries either directly, with operating subsidiaries in the U.S. and China, or via its network of long-

standing trusted partners. Helsinn also has a fully integrated supply chain and product development through its subsidiary in Ireland, Helsinn Birex Pharmaceuticals Ltd.

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

1. MASCC/ESMO Antiemetic Guideline 2016
2. NCCN clinical practice guidelines in oncology: antiemesis. 2018; Ver.3
3. Hesketh PJ, Kris MG, Basch E, Bohlke K, Barbour SY, Clark-Snow RA, et al. Antiemetics: American Society of Clinical Oncology Clinical Practice Guideline Update. J Clin Oncol. 2017; 35: 3240-3261
4. Aogi K, Takeuchi H, Saeki T, Aiba K, Tamura K, Iino K, et al. Optimizing antiemetic treatment for chemotherapy-induced nausea and vomiting in Japan: Update summary of the 2015 Japan Society of Clinical Oncology Clinical Practice Guidelines for Antiemesis. Int J Clin Oncol. 2021;26:1-17
5. Taiho Pharmaceutical Submits New Drug Application for NK₁ Receptor Antagonist Fosnetupitant for Prevention of Gastrointestinal Symptoms (Nausea and Vomiting) Associated with Cancer Chemotherapy (March 23, 2021, News Release)
<https://www.taiho.co.jp/en/release/2021/20210323.html>
6. A phase III, randomized, double-blind, multicenter, active control study of Pro-NETU for the prevention of chemotherapy induced nausea and vomiting (CINV) in patients receiving Cisplatin based highly emetogenic chemotherapy (HEC) (JapicCTI-194611)
7. Hata A, Okamoto I, Inui N, Okada M, Morise M, Akiyoshi K, et al. Randomized, Double-Blind, Phase III Study of Fosnetupitant Versus Fosaprepitant for Prevention of Highly Emetogenic Chemotherapy-Induced Nausea and Vomiting: CONSOLE. J Clin Oncol. 2022;40:180-188