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Oncology: Palonosetron approved in Japan, second pharmaceutical market wordwide

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The second generation 5-HT3 receptor antagonist palonosetron available in more than 50 countries worldwide, including US, EU and Japan

Today, Taiho Pharmaceutical Co., Ltd., Japanese licensee of Helsinn's second generation 5-HT3 receptor antagonist palonosetron, gained marketing approval in Japan for this drug indicated for the prevention of chemotherapy-induced nausea and vomiting (CINV) (including delayed phase) in patients with cancer.

Palonosetron will be marketed as Aloxi®. The approval of Aloxi® is based on the compelling results of a large multicenter randomized double-blind clinical trial (PROTECT study) conducted in Japan which demonstrated the superiority of palonosetron versus granisetron in the delayed phase. Palonosetron has been developed by the Helsinn Group in Switzerland, worldwide licensor of the drug. Today the product is approved in 62 countries, including US (since 2003) and EU (approved in 2005).

Aloxi® (palonosetron) is the leading brand in the USA within the CINV Day of Chemo segment, and it is steadily growing in the major European markets. The worldwide sales of palonosetron totalled more than 400 million US dollars in 2008 and continued to increase in 2009.

"The marketing approval granted to palonosetron in Japan, the second largest pharma market worldwide, is a key achievement for our company", Riccardo Braglia, Helsinn's Group Chief Executive Officer, said. "This is the first ever approval we have gained in Japan, and we must acknowledge the essential role played by our partner Taiho, leading oncology firm in this country", he concluded.

"To contribute to the improvement of cancer treatment, Taiho is putting its effort in research and development of not only anticancer agents but also agents to alleviate adverse reactions induced by cancer chemotherapy," commented Toru Usami, President of Taiho Pharmaceutical. "With the marketing approval of Aloxi®, we hope to provide a new treatment option to patients who are suffering from cancer chemotherapy induced nausea and vomiting."

About Palonosetron (Aloxi®, Onicit®, Paloxi®)

Palonosetron (palonosetron hydrochloride) is a second generation 5-HT3 Receptor Antagonist, developed for the prevention of chemotherapy-induced nausea and vomiting (CINV) in patients with cancer, with a long half-life of 40 hours and at least 30 times higher receptor binding affinity than currently available compounds. Palonosetron demonstrates, in clinical trials and clinical practice, a unique long-lasting action in the prevention of CINV. The product has shown to be effective in preventing both acute and delayed CINV in patients receiving Moderately Emetogenic Chemotherapy (MEC). A single intravenous dose of palonosetron provides better protection from CINV than first-generation 5-HT3 receptor antagonists throughout a 5-day post-chemotherapy period*. According to the NCCN (National Comprehensive Cancer Network) Guidelines palonosetron is the

preferred 5-HT3 receptor antagonist to be used in a combined regimen with an NK-1 antagonist and dexamethasone to prevent nausea and vomiting induced by Highly Emetogenic Chemotherapy (HEC).

Palonosetron is contraindicated in patients known to have hypersensitivity to the drug or any of its components. The most commonly reported adverse reactions (incidence more or equal to 2 percent) in CINV trials with palonosetron were headache (9 percent) and constipation (5 percent), and they were similar to the comparators. Palonosetron has been developed by the Helsinn Group in Switzerland and today it is marketed as Aloxi®, Onicit®, and Paloxi® in more than 50 countries world-wide. Palonosetron, marketed as Aloxi®, is the leading brand in the USA within the CINV Day of Chemo segment, and it is steadily growing in the European markets.

For more information about palonosetron, please visit the website: www.aloxi.com

*This sentence refers to Moderately Emetogenic Chemotherapy (MEC) setting

About the Helsinn Group

Helsinn is a privately owned pharmaceutical group with headquarters in Lugano, Switzerland, and subsidiaries in Ireland and USA. Helsinn's unique business model is focused on the licensing of pharmaceuticals and medical devices in therapeutic niche areas. The Group in-licenses early stage new chemical entities, completes their development from the performance of pre-clinical/clinical studies and Chemistry, Manufacturing and Control (CMC) development, to the filing for and attainment of their market approval worldwide.

Helsinn's products are sold directly, through the Group subsidiaries, or eventually out-licensed to its network of local marketing and commercial partners, selected for their deep in-market knowledge and know-how, and assisted and supported with a full range of product and scientific management services, including commercial, regulatory, financial, legal and medical marketing advice.

The active pharmaceutical ingredients and the finished dosage forms are manufactured at Helsinn's cGMP facilities in Switzerland and Ireland, and supplied worldwide to its customers. Helsinn is the worldwide licensor of palonosetron and of the original nimesulide, a non-steroidal anti-inflammatory drug (NSAID) distributed in more than 50 countries worldwide. Helsinn, with a workforce of around 450 employees in Switzerland, Ireland and USA, reported a 2008 turnover of over CHF 280.3 million (about EUR 178 million), covering 75 countries worldwide, with over 20% of this turnover invested in R&D.

For more information about Helsinn Group, please visit the website: www.helsinn.com

About Taiho Pharmaceutical

Taiho Pharmaceutical Co., Ltd. (Taiho) is a company engaged in discovery, development, manufacturing and marketing of pharmaceutical products, with its headquarters in Tokyo, Japan. Taiho is the leading company of oncology field in Japan. For more information about Taiho, please visit the company's Web site at: www.taiho.co.jp/english/index.html

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