Launch of Netupitant-Palonosetron Fixed Combination (Akynzeo®) in the UK by Chugai Pharma UK Ltd.

TOKYO and LUGANO, September 10, 2015 -- Chugai Pharmaceutical Co., Ltd. [Head Office: Chuo-ku, Tokyo; Chairman and CEO: Osamu Nagayama] (Chugai) (TOKYO: 4519) and a wholly owned subsidiary of Chugai, Chugai Pharma Marketing Ltd. [Head Office: London, the UK; Managing Director: John Halls] (CPM) and Helsinn Group [Head Office: Lugano, Switzerland; CEO: Riccardo Braglia], the Swiss Group focused on building quality cancer care, today announced that Akynzeo®, an oral fixed-dose combination of netupitant (highly-selective NK_1 receptor antagonist) and palonosetron (clinically and pharmacologically distinct 5-HT_3 receptor antagonist) indicated for the prevention of chemotherapy-induced nausea and vomiting (CINV), has been launched by a wholly owned subsidiary of CPM, Chugai Pharma UK Ltd. [Head Office: London, the UK; Managing Director: Ruth Currie] (CPU), in the UK as from September 1, 2015. CPM has been granted the exclusive right of Akynzeo for sales and marketing from Helsinn Healthcare S.A.

“Following the launch of Aloxi® starting January this year, we are pleased to deliver a novel new product for the treatment of CINV to patients by CPU.” said John Halls, Managing Director of CPM. “With strong collaboration and partnership with our license partners, including Helsinn, we are confident that CPM will improve our presence in the oncology supportive care in the European market.”

“Helsinn has a great relationship with Chugai and we are delighted that they are our partner in the launch of Akynzeo in the UK.” said Riccardo Braglia, CEO of Helsinn Group. “We believe that Akynzeo can play a significant role in preventing nausea and vomiting in both the acute and delayed phases following chemotherapy treatment, which could lead to more treatment options for the patient.”

CINV is one of the most common side effects of cancer chemotherapy. The prevention of CINV has been refined in treatment guidelines over the past several decades. Currently the combination treatment of antiemetic medicines with different mechanisms of actions are recommended for the prevention of CINV.

Akynzeo provides a combination of two antiemetics in a single oral capsule. A scheme of an NK_1 receptor antagonist, a 5-HT_3 receptor antagonist and dexamethasone meets the guidelines’ recommendation for optimal antiemetic therapy following highly emetogenic and anthracycline cyclophosphamide based chemotherapy.

As stated in the CHMP Summary of opinion*, the “simplification of therapy by decreasing the number of individual dose units to be taken by the patient may furthermore improve patient compliance.”

Chugai and CPM strongly believe that Akynzeo as a novel new treatment option will deliver great contribution to patients in the UK suffering from CINV.

*http://www.ema.europa.eu/docs/en_GB/document_library/Summary_of_opinion/human/003728/WC500184907.pdf

Product name：	Akynzeo®
Generic name：	Netupitant-Palonosetron
Formulation:	Capsule containing Netupitant 300mg / Palonosetron 0.5mg
Indication:	- Prevention of acute and delayed nausea and vomiting associated with highly emetogenic cisplatin-based cancer chemotherapy - Prevention of acute and delayed nausea and vomiting associated with moderately emetogenic cancer chemotherapy
Dosage:	Adults One 300 mg / 0.5 mg capsule should be administered approximately one hour prior to the start of each chemotherapy cycle
EMA approval:	May 27, 2015
Marketing authorization holder:	Helsinn Healthcare S.A.
Sales and marketing responsibility:	Chugai Pharma UK Ltd.
Territory:	the UK, Republic of Ireland
Launch date:	September 1, 2015 (the UK) / to be confirmed (Ireland)

About Chugai Pharma Marketing

Chugai Pharma Marketing Ltd. is the headquarters of all Chugai's clinical development, regulatory affairs, medical affairs, import, sales and marketing of pharmaceutical products in Europe and coordinates the European marketing operations through subsidiaries located in the UK, France, and Germany. Products which are currently marketed in those countries include "RoActemra® (tocilizumab)", a humanized anti-human IL-6 receptor monoclonal antibody, "Granocyte® (lenograstim)", a G-CSF preparation, "Antepsin® (sucralfate)", an antiulcer agent (marketed in the UK and Ireland), and Aloxi (palonosetron), an antiemetic agent (marketed in the UK). Furthermore, CPM is conducting the clinical development of SA237, anti-IL-6 receptor humanized monoclonal antibody for the treatment of neuromyelitis optica, and CIM331, anti-IL-31 receptor humanized monoclonal antibody for the treatment of Atopic dermatitis.

About Chugai

Chugai Pharmaceutical is one of Japan's leading research-based pharmaceutical companies with strengths in biotechnology products. Chugai, based in Tokyo, specializes in prescription pharmaceuticals and is listed on the 1st section of the Tokyo Stock Exchange. As an important member of the Roche Group, Chugai is actively involved in R&D activities in Japan and abroad. Specifically, Chugai is working to develop innovative products which may satisfy the unmet medical needs, mainly focusing on the oncology area.

In Japan, Chugai's research facilities in Gotemba and Kamakura are collaborating to develop new pharmaceuticals and laboratories in Ukima are conducting research for technology development for industrial production. Overseas, Chugai Pharmabody Research based in Singapore is engaged in research focusing on the generation of novel antibody drugs by utilizing Chugai's proprietary innovative antibody engineering technologies. Chugai Pharma USA and Chugai Pharma Marketing are engaged in clinical development activities in the United States and Europe.

The consolidated revenue in 2014 of Chugai totaled 461.1 billion yen and the operating income was 77.3 billion yen (IFRS Core basis).

Additional information is available on the internet at http://www.chugai-pharm.co.jp/english

About the Helsinn Group

Helsinn is a family run, privately owned pharmaceutical group focused on building quality cancer care with a large portfolio of products. Founded in 1976 with headquarters in Lugano, Switzerland, Helsinn also has operating subsidiaries in Ireland, the United States and a representative office in China. Helsinn's business model is focused on the licensing of pharmaceuticals, medical devices and nutritional supplement products in the therapeutic area of cancer care.

Helsinn Group in-licenses early-to-late stage new chemical entities, completing their development by performing preclinical and clinical studies and associated manufacturing activities. Helsinn then prepares necessary regulatory filings in order to achieve marketing approvals worldwide. Helsinn's products are out-licensed to its global network of marketing and commercial partners that have been selected for their local market knowledge and high ethical standards. Helsinn supports these partners by providing a full range of product and scientific management services, including commercial, regulatory, and medical marketing advice. In March 2013, Helsinn established a new commercial organization within its subsidiary, Helsinn Therapeutics (U.S.), Inc., in order to conduct direct sales and marketing activities within the U.S. market. Helsinn's products are manufactured according to the highest quality, safety, and environmental standards at Helsinn's GMP facilities in Switzerland and Ireland from where they are then supplied worldwide to customers.

Further information on Helsinn Group is available at www.helsinn.com.

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