Helsinn Group and Italfarmaco announce oral presentation of NEPA (netupitant and palonosetron) data at ESMO Virtual Congress 2020

- A Phase 3 study concludes that a simplified regimen of one dose of NEPA and dexamethasone (DEX) has comparable anti-emetic efficacy to regimens with greater frequency and dosage of DEX.

Lugano, Switzerland, and Milan, Italy, September 18, 2020 – Helsinn, a Swiss pharmaceutical group focused on building quality cancer care and rare disease products, and Italfarmaco, an Italy-based multinational pharmaceutical group committed to safeguard people's health, today announce an abstract has been accepted for oral presentation at the ESMO Virtual Congress 2020 taking place from September 19-21. Full details of the presentation are below.

Dexamethasone (DEX) has traditionally played an integral role in the management of Chemotherapy-induced Nausea and Vomiting (CINV). Whilst generally considered safe, even short-term use of DEX is associated with various side effects, including transient elevations in glucose, insomnia, anxiety, and gastric upset. There is also evidence to suggest that DEX may reduce the efficacy of most immunotherapies and cellular therapies if used concurrently.

To evaluate the potential impact of a reduction of DEX as component of the antiemetic regimen a randomized, open-label, three-arm, multicenter non-inferiority Phase III study was conducted by the Italian LUNG-NEPA study group, led by the responsible medical officer of the study Prof Emilio Bria of the Cattolica-Gemelli University Hospital in Rome and sponsored by the Oncotech Consortium in Naples, Italy. Dr. Luigi Celio of the National Cancer Institute of Milan was the author of the research protocol and served as a scientific advisor for this investigator-initiated study.

In this study two DEX-sparing treatment groups were compared to a standard DEX regimen (reference group), all in combination with NEPA as antiemetic prophylaxis in chemotherapy-naïve patients with non-small cell lung cancer (NSCLC) receiving cisplatin-based HEC was designed.

A total of 222 patients (76% male), 74 in each arm, were evaluated. CR rates during the overall and delayed phases were 77.0% in Arms DEX1 and DEX3 and 74.3% in Arm DEX4 (95% CI, -11.1% to 16.5%). No significant differences were observed between groups in proportions of

patients who reported no impact on daily life due to nausea, vomiting, or both during the 5-day observation period after cisplatin administration.

This study shows for the first time a comparable anti-emetic control during the 5-day period and no impact on patient functioning with the simplified three-drug regimen of NEPA plus single-dose DEX and standard dosing of DEX in the setting of cisplatin.

These results are in line with recent ESMO management and treatment recommendation for supportive care in the COVID-19 era, that advise to consider a single dose of dexamethasone on day 1 without additional use on the following days even in highly emetogenic chemotherapy.

The safety profile for NEPA is consistent with that expected for these drug classes with the type and incidence of adverse events also being typical for a diverse cancer population receiving cytotoxic chemotherapy[1].

Dr Silvia Sebastiani, Helsinn Head of Medical Affairs, commented: "Our aim is to always improve the quality of life for cancer patients. Based on these important new data, we are glad that a simplified, NEPA based, antiemetic regimen which reflects recent recommendation of ESMO guidelines, could potentially be available for patients undergoing highly emetogenic chemotherapy."

Dr Mario Mangrella, Italfarmaco Medical Affairs' Director, commented: "Proper management of side effects related to chemotherapy is key to ensure the best curative treatment for oncological patients. These results show that it is possible to reduce the amount of dexamethasone given in a NEPA-based antiemetic prophylaxis without compromising on its efficacy"

Dr Luigi Celio, National Cancer Institute of Milan, stated: "As a single agent, NEPA inhibits 2 anti-emetic pathways with one dose, given with DEX. These data suggest that DEX reduction

[1] A Review of **NEPA**, a Novel Fixed Antiemetic Combination with the Potential for Enhancing Guideline Adherence and Improving Control of Chemotherapy-Induced Nausea and Vomiting
Paul J. Hesketh, Matti Aapro, Karin Jordan, Lee Schwartzberg, Snezana Bosnjak, Hope Rugo
Biomed Res Int. 2015; 2015: 651879. Published online 2015 Sep 3. doi: 10.1155/2015/651879

would be possible with NEPA in both cisplatin and anthracycline based setting, simplifying the 3-drug regimen to day 1 of chemotherapy."

Prof Emilio Bria, Cattolica-Gemelli University Hospital of Rome, stated: "This study strongly supports NEPA and DEX as an effective combination in preventing CINV when administered on day one, thus allowing to reduce the pills burden for patients also in cisplatin-based chemotherapy."

Presentation Details:

Title: Two simplified dexamethasone (DEX)-sparing regimens with NEPA for the prevention of emesis caused by cisplatin (DDP): a phase III, controlled, non-inferiority trial

Session: Session: On-demand mini oral session (Supportive and palliative care)

Date: Friday, **18.09.2020**

Time: 09:36-09:41

Presenter: Luigi Celio (Italy)

About NEPA (netupitant/palonosetron)

In the EU:

AKYNZEO® (netupitant 300mg/palonosetron 0.5mg) capsules for oral use was approved in May 2015 in the EU. A line extension to introduce the IV formulation AKYNZEO® (fosnetupitant 235mg/palonosetron 0.25mg) powder for concentrate for solution for infusion was approved in March 2020 in the EU. Fosnetupitant is a netupitant prodrug, which converts into netupitant once administered intravenously. Akynzeo® (oral and IV) is indicated in the EU for adults for the

prevention of acute and delayed nausea and vomiting associated with highly emetogenic cisplatin-based cancer chemotherapy and moderately emetogenic cancer chemotherapy.

For additional information please see the EU Summary of Product Characteristics.

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 acquisition to address unmet medical needs. Helsinn operates a unique integrated licensing business model, achieving success with over 80 long-standing partners in 190 countries, who share our 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). 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 Italfarmaco

Italfarmaco SpA is a private Italian multinational company located in Milan, operating in Italy and abroad in both the pharmaceutical and fine chemical industries through its controlled and/or participated companies. Italfarmaco was establish in 1938. Today Italfarmaco Group markets ethical products in Italy, Switzerland, France, Spain, Germany, Portugal, Greece, Russia, Turkey,

Chile, Peru, Morocco and also for its subsidiary company Chemi Spa in USA and Brazil, where it employs over 3000 people with an annual sales turnover over 700 million euros. Its products, always with high therapeutic content, are mainly oriented towards the cardiovascular, immuno-oncologic, gynecological, osteoporosis and neurological area.

Italfarmaco group's mission is to research, produce and market new and innovative drugs while being committed to improve quality of life and extend life span globally for the benefit and health of patients.

To learn more about Italfarmaco Group please visit www.italfarmaco.com

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