

Helsinn Advanced Synthesis opens its largest dedicated Anticancer bay



Biasca, Switzerland, July 30, 2020 – Helsinn, a Swiss pharmaceutical group focused on building quality cancer care and rare disease products, announces that its manufacturing subsidiary, Helsinn Advanced Synthesis SA (HAS), which develops and manufactures Active Pharmaceutical Ingredients (APIs), cGMP Advanced Intermediates, High Potency APIs (HPAPIs) and anticancer compounds, has opened its largest dedicated Anticancer bay at its manufacturing plant in Biasca, Switzerland. The new Anticancer bay will be used for the development, analysis, and manufacturing of clinical and commercial anticancer APIs.

In 2012, HAS built its first dedicated Anticancer plant that could manufacture compounds with an OEL down to 50 ng/m³ and had a small, medium and large-scale bay. Due to the success of this Anticancer plant, in 2016 a new expansion was proposed to build a larger scale bay. After receiving positive results from a feasibility study, a detailed engineering plan was put together in 2017 while procurement began. The project spanned three years and involved more than 100 external suppliers, resulting in the largest Anticancer bay at HAS.

The new bay includes three reactor units: 800 L Hastelloy; 1000 L glass lined; and 1200 L Hastelloy allowing for production scale up to ~50 kg; a conic reactor (150 L capacity) for loading operations in a closed system; one Hastelloy filter dryer (0.5 m² filtering surface); and 1 mill. In addition, there are five glove boxes for product handling in a safe way. The Anticancer facility can handle reaction temperatures from -80°C to +140°C and has a dedicated warehouse.

The Swiss Agency for Therapeutic Products (SwissMedic) inspected the new facility in June 2020 and approved manufacturing to start. The first project was initiated in late June. This new Anticancer bay will allow the Company to continue their innovative and critical work.

Waldo Mossi, Local General Manager, Helsinn Advanced Synthesis S.A., commented: “We are delighted to open our new Anticancer Bay after years of hard work and development. HAS is always looking to stay at the cutting edge of technology and to be able to better serve our clients and their important projects. The new facility will allow us to expand our development, analysis and manufacturing capabilities and will be central to the manufacture and delivery of new anticancer compounds into clinics and then on to patients.”

About Helsinn Advanced Synthesis SA

Helsinn Advanced Synthesis SA is the manufacturing division of the Helsinn Group and develops and manufactures Active Pharmaceutical Ingredients (APIs), cGMP Advanced Intermediates, High Potency APIs (HPAPIs) and anticancer compounds for third parties from clinical phase to commercial supply, on an exclusive basis. The production plant is located in Biasca, Switzerland and was established in 1984. The Biasca site is routinely inspected by the FDA, SwissMedic, and other global regulatory agencies. Production scale ranges from grams to tens of kilograms (HPAPIs with an OEL down to 1 ug/m³ and anticancer compounds with an OEL down to 50 ng/m³) and from kilograms up to tens of tons (APIs) in plants fully dedicated to cGMP manufacturing.

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

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