

Helsinn Integrative Care Announces 510(K) FDA Clearance for Medical Device Xonrid® Gel

Lugano, Switzerland, December 1, 2016: Helsinn Integrative Care, Helsinn's business unit focused on evidence-based, non-pharmaceutical cancer supportive care products, today announces that Xonrid® Gel, a topical gel for radiotherapy-induced dermatitis, already classified as a medical device in the EU, has received 510(K) FDA clearance in the US.

This now allows Xonrid® Gel to be marketed in the US for the management and relief of the burning and itching experienced by patients with radiation dermatitis.

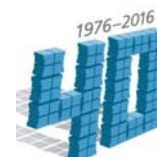
Riccardo Braglia, Helsinn Group Vice Chairman and CEO, commented: *"Helsinn Integrative Care aims to respond to the growing demand from patients for non-pharmaceutical approaches for the management of cancer symptoms solutions backed by robust, evidence-based data. We hope to be able to support both patients and healthcare providers to make informed choices about cancer management."*

"Clearance from the FDA for Xonrid® Gel will allow wider access to cancer patients experiencing dermatitis as a painful side effect of radiation, and is a validation of our approach to this new and under-served market."

About Xonrid® Gel

Xonrid® Gel is a multi-component prescription medical device product. It is a non-sterile topical water-based gel that forms a protective barrier on skin to increase moisture and reduce water loss.

Xonrid® Gel contains numerous ingredients that are grouped into several common ingredient classes, including emollients; preservatives; skin conditioning agents; viscosity-increasing agents; emulsifying agents; and binders. Each ingredient is a well-recognized component of



topical cosmetic products that primarily provide the skin conditioning and emollient features of Xonrid® Gel.

Xonrid® Gel is applied three times per day or as needed. The product is packaged in a 75 mL bottle equipped with an airless dispensing system and a cap. The product is intended to be used for less than 30 days, and has a 36-month shelf life.

Indications for use:

The FDA has granted the following indications for use: Under the supervision of a healthcare professional, Xonrid® Gel is indicated to manage and relieve the burning and itching experienced with radiation dermatitis. Xonrid® Gel helps to relieve dry waxy skin by maintaining a moist wound and skin environment, which is beneficial to the healing process. Not intended to be used on open wounds.

About Radiation Induced Dermatitis

Ionizing radiation is a widely recognized therapeutic approach in the oncology field, for cancer manifestations of different aetiology and localization. In spite of all the advances in medical technology, radiation therapy still causes severe early and late skin effects: among them, RID occurs in approximately 90% of patients.

Important consequences of Radiation Induced Dermatitis include impairment of the quality of a patient's life due to local pain, and premature interruption of radiation treatment can occur.

Radiation Induced Dermatitis frequently appears within the first four weeks of treatment, with epidermal regeneration, healing and resolution occurring within three-four weeks following end of treatment. Complete healing can take up to three months.

About Helsinn Integrative Care

Helsinn Integrative Care is a business unit of the Helsinn Group which seeks to address a growing demand among people with cancer for evidence-based, non-pharmaceutical cancer supportive care products. Helsinn Integrative Care aims to develop and bring to market products supported by robust clinical data which will support both patients and healthcare providers in



making informed choices about cancer management. People with cancer, and cancer survivors, are increasingly looking to self-manage their symptoms and optimise their health by accessing a growing market for medical devices, herbal extracts and medical foods. However, many of these treatments are not supported by clinical evidence and more than two thirds of oncologists are unaware that their patients are using them. Helsinn Integrative Care's Marketed products include Gelclair[®], an oral gel to relieve the pain of oral mucositis. The company is also developing a range of products to treat a wide range of cancer side effects.

For more information, please visit www.helsinn-integrative.com

About the Helsinn Group

Helsinn is a privately owned cancer care pharmaceutical group with an extensive portfolio of marketed products and a broad development pipeline. Since 1976, Helsinn has been improving the everyday lives of patients, guided by core family values of respect, integrity and quality, through a unique integrated licensing business model working with long standing partners in pharmaceuticals, medical devices and nutritional supplement products. Helsinn is headquartered in Lugano, Switzerland, with operating subsidiaries in Ireland and the US, a representative office in China, as well as a product presence in about 90 countries globally.

For more information, please visit www.helsinn.com.

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