
Submission of Nidlegly™ Marketing Authorization Application Validated by EMA

The first marketing authorization application of Nidlegly™ for the treatment of locally advanced fully resectable melanoma was submitted on June 3rd and validated by EMA on June 20

The assessment period of the dossier by the authorities has started on June 20th

Siena, Italy, and Mumbai, India, 4 July, 2024 - Philogen S.p.A. (BIT:PHIL) and Sun Pharmaceutical Industries Limited (Reuters: SUN.BO, Bloomberg: SUNP IN, NSE: SUNPHARMA, BSE: 524715 (together with its subsidiaries and/or associated companies, “Sun Pharma”) announces that on June 20th the European Medicines Agency (EMA) validated the submission of the Marketing Authorization Application (MAA) for Nidlegly™, which was finalized on June 3rd.

"The validation of the dossier by EMA represents the first important milestone for the MAA review process," **commented Dario Neri, chief executive officer and chief scientific officer at Philogen.** "Our group is committed to working with EMA throughout the review process with the goal of making Nidlegly™ available to patients in need."

Nidlegly™ is partnered with Sun Pharma for the treatment of Skin Cancers in Europe, New Zealand and Australia. Both companies jointly made the following announcements:

- October 23, 2023 - Phase III PIVOTAL trial met the primary endpoint ([link](#))
- May 31, 2024 – Primary results of PIVOTAL presented at ASCO ([link](#))
- June 4, 2024 – MAA submission to EMA ([link](#))

The data of the Phase III Nidlegly™ trial are expected to be published in a peer-reviewed scientific journal in 2024.

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About Nidlegly™ (Daromun)

Nidlegly™ is a biopharmaceutical product, proprietary to Philogen, designed for the treatment of skin cancer. It consists of two active ingredients, L19IL2 and L19TNF. The two ingredients are manufactured independently and mixed prior to intralesional administration. The L19 antibody is specific to the Extra Domain B of Fibronectin, a protein expressed in tumors (and other diseases) but absent in most healthy tissues. Interleukin 2 (IL2) and Tumor Necrosis Factor (TNF) are pro-inflammatory cytokines with a potent anti-tumor activity. Nidlegly™ is currently being investigated in two Phase III clinical trials for the treatment of locally advanced melanoma, and in Phase II clinical trials for the treatment of High-Risk Basal Cell Carcinoma and other non-melanoma skin cancers.

About the PIVOTAL Phase III study

PIVOTAL is a phase III, international, multi-center, randomized, comparator-controlled, parallel-group study evaluating the efficacy and safety of intratumoral injections of Nidlegly™ as a neoadjuvant treatment, followed by standard-of-care treatment (surgery), as opposed to standard-of-care treatment (i.e., surgery alone), in melanoma patients with locally advanced, fully resectable cutaneous, sub-cutaneous (including satellite/in transit metastases), or nodal metastases accessible to intratumoral injection. For both arms, adjuvant treatment with approved drugs was allowed. Nidlegly™ was injected intralesionally up to four times, once a week, before surgery. The trial enrolled 256 patients in Europe across 22 clinical centers in Germany, Italy, France and Poland.

About locally advanced fully resectable melanoma

Melanoma is a skin tumor which begins when melanocytes start growing without control. Melanocytes are found in the basal layer of the epidermis at the boundary with the next layer (the dermis). Locally advanced melanoma is a metastatic cancer in which neoplastic lesions have spread to drainage areas of regional lymph nodes and can appear as micrometastases, satellite/in transit metastases, and/or lymph node metastases. To date, patients with resectable disease receive surgery, possibly followed by approved adjuvant systemic therapies. There is no approved drug for the treatment of locally advanced fully resectable melanoma in the neoadjuvant setting.

About Philogen

Philogen (<https://www.philogen.com>) is an Italian-Swiss biotechnology company specialized in the research and development of innovative pharmaceuticals for the treatment of cancer. The Group's main therapeutic strategy is based on the use of ligands capable to selectively deliver potent payloads (such as pro-inflammatory cytokines, drugs or radionuclides) to the tumor mass, sparing healthy tissues. Over the years, Philogen has discovered and developed monoclonal antibody and small molecule based ligands with high affinity to numerous tumor-associated antigens. The Group is headquartered in Siena, Italy, with a subsidiary and research center in Zurich, Switzerland. In addition to its main oncology focus, Philogen is also active in the development of novel pharmaceuticals for the treatment of chronic and debilitating conditions.

About Sun Pharmaceutical Industries Ltd. (CIN - L24230GJ1993PLC019050)



Sun Pharma is the world’s leading specialty generics company with presence in Specialty, Generics and Consumer Healthcare products. It is the largest pharmaceutical company in India and is a leading generic company in the US as well as Global Emerging Markets. Sun’s high growth Global Specialty portfolio spans innovative products in dermatology, ophthalmology, and onco-dermatology and accounts for over 18% of company sales. The company’s vertically integrated operations deliver high-quality medicines, trusted by physicians and consumers in over 100 countries. Its manufacturing facilities are spread across six continents. Sun Pharma is proud of its multi-cultural workforce drawn from over 50 nations. For further information, please visit www.sunpharma.com and follow us on “X” @SunPharma_Live

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Forward-Looking Statements

The forward-looking statements contained in this press release may be identified by words such as “aims,” “anticipates,” “believes,” “could,” “estimates,” “expects,” “forecasts,” “goal,” “intends,” “may,” “plans,” “possible,” “potential,” “seeks,” “will” and variations of these words or similar expressions that are intended to identify forward-looking statements, although not all forward-looking statements contain these words. Forward-looking statements in this press release include, but are not limited to, statements regarding anticipated advancement of preclinical development efforts and initiation and progression of clinical trials; anticipated enrollment in and progression of Philogen’s clinical trials; the availability of data from clinical trials and preclinical studies; anticipated regulatory filings; the therapeutic potential of Philogen’s product candidates; Philogen’s ability to achieve planned milestones. Philogen may not actually achieve the plans, intentions or expectations disclosed in these forward-looking statements, and you should not place undue

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