Philogen S.p.A. announces receipt of the Good Manufacturing Practice Certificate for its new Production facility in Rosia (Siena, Italy) by Competent Authorities

Siena, Italy, 5 December, 2023 - Philogen S.p.A. (BIT:PHIL) is pleased to announce that its new GMP facility located in Rosia Siena, is now GMP certified. The certification was granted by the GMP MED office of the *Agenzia Italiana del Farmaco* (AIFA) following an inspection occurred in July 2023. AIFA confirmed that Philogen new facility complies with the requirements and guidelines of Good Manufacturing Practice outlined in the Directive 2003/94/EC issued by the European Parliament.

In the European Union, national competent authorities - AIFA in Italy - are responsible for inspecting manufacturing sites based within their own territories. Sites located in one European Member State also benefit from mutual recognition agreements (MRAs) that the European Commission has signed with the authorities of the United States, Switzerland, Canada, Israel, Australia, Japan and New Zealand concerning the conformity assessment of medicinal products.

Philogen plant in Rosia was designed in accordance with the new Annex 1 of the Rules Governing Medicinal Products in the European Union for Good Manufacturing Practice of Medicinal Products for Human Use. The site plans to produce therapeutic proteins in mammalian cells, with a focus on the company's immunocytokines such as Nidlegy™, for both clinical trials and commercial purposes. The completion of the facility required an investment of over 15 million Euros.

On 16 October 2023, Philogen had announced positive topline results from the Phase III trial of Nidlegy™ in patients with locally advanced fully resectable melanoma (NCT02938299). The Rosia facility will manufacture commercial supplies of Nidlegy™ and has been structured to address a global distribution of the product.

Prof. Dario Neri, **co-founder, CEO and CSO of Philogen, commented:** *"Following the positive readout of* Nidlegy™ *Phase III trial, we are very pleased that our new manufacturing site in Rosia has received the GMP Certificate by AIFA. This represents an additional important milestone toward turning Philogen from a research to a commercial company."*

Dr, Duccio Neri, **co-founder and Executive Chairman of Philogen, commented:** *"We are excited that our new manufacturing facility is now poised for supplying life-saving medicines to patients who are in need. This achievement has been possible thanks to multi-million euros investments to construct the new state-of-the-art GMP facility. The new facility in Rosia is among the very few ones in Italy that is planned and equipped to manufacture GMP-grade therapeutic proteins in mammalian cells. We are proud that Philogen has, over the last few years, devoted significant efforts and resources to expand its production capacity and has hired a high number of new talented people in the Italian territory."*

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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 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.

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