PHILOGEN S.p.A. (Courtesy English Translation)

THE BOARD OF DIRECTORS APPROVES THE NET FINANCIAL POSITION FOR THE THIRD QUARTER OF 2023, WHICH IS POSITIVE AND AMOUNTS TO 68,622 THOUSAND EUROS, AND NOTES THE PROGRESS OF THE MAIN TRIALS *NIDLEGY*™ AND FIBROMUN IN LINE WITH EXPECTED TIMELINES AND THE EVOLUTION OF OTHER INDUSTRIAL ACTIVITIES

Siena (Italy), Nov. 7, 2023 - In compliance with the disclosure commitments made by the Company as part of the listing process, the Company announces that the Board of Directors of Philogen S.p.A. (the "**Company**" or "**Philogen**" and, together with its Swiss subsidiary Philochem, the "**Group**"), which met today, approved the Group's net financial position as of Sept. 30, 2023, and noted the progress of the main trials *Nidlegy*™ and Fibromun, as well as the positive development of other industrial activities.

Dario Neri, CEO and Chief Scientific Officer of Philogen S.p.A., commented:

"The Group has achieved significant results in these first 9 months of 2023 that confirm the Group's scientific soundness, the value of the conducted clinical trials, and the excellence of the core business, motivitaing the company to plan industrial activities aimed at commercializing drugs and undertake a transformation from an R&D company to a product company.

Regarding the cash position, the group continues with a focused and efficient management, closing the third quarter 2023 with a positive net financial position amounting to € 68,622 thousand, in line with the position at the beginning of the year.

Numerous goals have been achieved on the scientific and regulatory fronts.

On October 16, we announced the achievement of the primary objective of the Phase III clinical trial of Nidlegy™ in fully resectable locally advanced melanoma. This achievement makes us very proud since Nidlegy™ represents the first drug of its kind, i.e., an immunocytokine, to reach this milestone. As of today, the Group is working on finalizing the electronic common technical document (eCTD) to be submitted to the relevant authorities in order to apply for Marketing Authorization. We are also proud of the progress of Nidlegy™ in basal cell carcinoma and Fibromun in Soft Tissue Sarcoma and Glioblastoma, where Philogen is conducting additional clinical trials with registration potential. Promising data observed in patients with Glioblastoma at first progression in the so-called GLIOSTAR study with Fibromun provided the motivation to launch a new Phase II clinical trial in the United States, which has already been approved by the U.S. Food and Drug Administration.

The new GMP manufacturing facility in Rosia received the two scheduled inspections by the GMP MED and GMP API offices of the Italian Medicines Agency (AIFA) in July and October 2023, respectively. We expect to receive Commercial authorization from both offices in the coming months. The GMP authorization for production of experimental drugs not intended for commercialization at the other production site in Montarioso, has already been renewed. Therefore, once the GMP authorization process for the Rosia site is completed, the Group will be independent and fully integrated for the production of drugs for both clinical trials and commercial sale, including for third parties.

In addition to the radiopharmaceutical ^{177}Lu-OncoFAP-23, Philogen is also planning a First-in-Human trial with the non-radioactive derivative OncoFAP-GlyPro-MMAE. In addition, the Group has begun a new collaboration with the University of Milan to offer OncoFAP-GlyPro-MMAE to dogs with tumors in the context of a clinical trial. The aim is to provide this innovative drug, which has shown great efficacy in murine tumor models, to sick dogs that have no therapeutic alternatives.

Since the IPO in March 2021, we have completed the Phase III PIVOTAL study of Nidlegy™ in melanoma and made great progress both in opening centers, and in patient enrollment, in the Fibromun studies in Soft Tissue Sarcoma. We have also launched new programs in basal cell carcinoma with Nidlegy™, in first- and second-line Glioblastoma with Fibromun, with ^{68}Ga-OncoFAP, with ^{177}Lu-OncoFAP-23, and with OncoFAP-GlyPro-MMAE. Our Swiss subsidiary Philochem recently discovered a new molecule against ACP-3, an ideal target for prostate cancer, for which we have filed a patent application. These will be just some of the new drugs of the future, and this gives an idea of the Philogen Group's ability to innovate.

This is in addition to the agreements we announced with Bracco, Google, Sun Pharma, Merck Sharp & Dohme, and IBSA, in 2022 and 2023."

NET FINANCIAL POSITION AS OF SEPTEMBER 30, 2023

The following is a table of the Philogen Group's Net Financial Debt as of September 30, 2023, prepared in accordance with ESMA Guideline 32-382-1138 of March 4, 2021 and Consob's Attention Call No. 5/21:

Figures in thousands of euros **Net financial debt**	**September 30, 2023**	**June 30, 2023**	**March 31, 2023**	**December 31, 2022**
(A) Cash on hand	12,636	20,592	3,663	8,436
(B) Equivalents to cash on hand	15,000	16,000	16,000	16,000
(C) Other current financial assets	56,119	57,710	62,458	61,764
(D) Liquidity (A+B+C)	**83,755**	**94,302**	**82,121**	**86,200**
(E) Current financial debt	41	23	31	29
(F) Current part of non-current financial debt	1,827	1,786	1,744	1,726
(G) Net current financial debt (E+F)	**1,868**	**1,809**	**1,775**	**1,755**
(H) NET CURRENT FINANCIAL DEBT (G-D)	**(81,887)**	**(92,494)**	**(80,346)**	**(84,445)**
(I) Non-current financial debt	13,265	13,424	13,615	14,007
(J) Debt instruments	-	-	-	-
(K) Trade and other current payables.	-	-	-	-
(L) Non-current financial debt (I+J+K)	**13,265**	**13,424**	**13,615**	**14,007**
(M) NET FINANCIAL DEBT (H+L)	**(68,622)**	**(79,069)**	**(66,731)**	**(70,438)**

(*) Net financial debt is an alternative performance indicator, not identified as an accounting measure under IFRS, and therefore, should not be considered an alternative measure to those provided by the Group's financial statements for assessing the Group's financial position.

The Group ended the third quarter of 2023 with a positive net financial position of 68,622 thousand euros compared to a positive net financial position of 79,069 thousand euros as of June 30, 2023, showing a percentage decrease of 13.2 percent.

As of September 30, 2023, the Group closes with liquidity of 83,755 thousand euros compared to liquidity of 94,302 thousand euros as of June 30, 2023, showing a decrease of 11.2%. The change, amounting to 10,547 thousand euros, is attributable to the net change in cash flows generated by (i) collections from contracts with customers for 858 thousand euros, (ii) outflows for core operations for approximately 8,006 thousand euros, (iii) outflows for the purchase of a building adjacent to the Montarioso (Siena) plant for a total of 2.300 thousand euros; (iv) outlays for investments related to the construction of the new office building at the Rosia (Siena) site totaling approximately 686 thousand euros; (v) outlays for the purchase of treasury shares totaling 762 thousand euros; and (vi) net positive change in financial operations totaling approximately 349 thousand euros, given by 164 thousand euros related to the collection of coupons that took place in the third quarter of 2023, by 189 thousand euros relating to the net positive change in the *fair value* of the securities portfolio held and by 4 thousand euros relating to the negative change in the *market to market* of the hedging derivative on outstanding loans. It should also be noted that part of the liquidity, amounting to €15,000 thousand as of September 2023, is invested in short-term time deposits, remunerated at market rates on maturity.

For clarity, it should be noted that in compliance with the outline provided by ESMA Guideline 32-382-1138 of March 4, 2021 and Attention Reminder No. 5/21, the net financial position does not include tax credits that can be used to offset future cash outflows from core operations. At the end of the third quarter of 2023, the related residual credits are approximately 4 million euros.

Current and noncurrent financial debt as of September 30, 2023 amounted to 15,133 thousand euros compared to 15,223 thousand euros as of June 30, 2023, showing a decrease of approximately 100 thousand euros resulting from the progress of existing amortization schedules. It should be noted that financial indebtedness is represented for approximately 12,094 thousand euros by the notional debt inherent in the real estate leases, for the three company sites, represented in accordance with international accounting standards (IFRS 16). The remaining portion relates to the loan taken out to finance part of the project to expand the Rosia (Siena) production site.

UPDATE ON THE GROUP'S INDUSTRIAL PROGRAMS

The most advanced programs are on schedule. Specifically, as of September 30, 2023:

- For Nidlegy™ (a biopharmaceutical product, proprietary to Philogen, designed to treat skin cancer):

As announced in a press release on October 16, the European Phase III study in locally advanced melanoma has achieved its primary objective by demonstrating a statistically and clinically significant improvement in Recurrence-Free Survival in patients with fully resectable locally advanced melanoma. The Group is currently working on finalizing the *electronic common technical document* (eCTD) to be submitted to the relevant authorities in order to apply for Marketing Authorization. Some clinical activities associated with the European study (e.g., patient monitoring) will continue at the 22 centers involved in France, Italy, Germany and Poland.

Patient enrollment in the U.S. Phase III trial in stage IIIB/C melanoma continues in line with company expectations. As of today's date, 33 centers have been opened. Additional centers will be opened during 2023.

Two Phase II studies are ongoing in "*High-Risk*" *locally advanced* Basal Cell Carcinoma (LaBCC) and other non-melanoma skin cancers. The Group is working to accelerate activities in BCC, based on the high rate of durable complete remissions (clinical and/or pathological CR) observed in patients treated with Nidlegy™. More information on the CR rate will be reported in the coming months. The CR rate of competing products (Odomzo™, Erivedge™, Libtayo™) is 5-6%. Clinical activities will also continue on other non-melanoma skin cancers (e.g., squamous cell carcinoma).

- For Fibromun (a biopharmaceutical product, proprietary to Philogen, designed for the treatment of soft tissue sarcoma (STS) and Glioblastoma):

The European Phase III study in first-line STS in combination with doxorubicin continues in line with company plans. As of the date of this press release, 23 clinical centers have been opened (16 in 2022) and 83 patients of the 118 planned in the protocol have been enrolled. The study will continue during 2024 in Germany, Italy, Spain, Poland, and France.

The U.S. Phase IIB study in first-line leiomyosarcoma in combination with doxorubicin is ongoing at 9 clinical centers in the United States. Note that leiomyosarcoma is the most common subtype of STS.

The randomized phase of the European Phase II trial in the third-line STS in combination with dacarbazine continues. As of the date of this press release, the trial has enrolled 46 patients of the 92 patients foreseen in the protocol, and is ongoing at 18 clinical centers. Additional centers are in the process of being activated.

The Phase I/II trial in first line Glioblastoma in combination with lomustine has completed the so-called Phase I *Dose Escalation* after enrolling 15 patients in 3 cohorts. The benefits of the investigational therapy seen to date, both in terms of survival and lasting objective responses (e.g., in some cases for more than 15 months), are substantially higher than those reported with standard drugs (e.g., lomustine alone). The Company will continue to update the financial community on the progress of the Phase I patients. The randomized Phase II trial with 158 patients began in June 2023. Regulatory activities aimed at opening 18-20 clinical centers in Germany, Italy, Switzerland, and France, are ongoing.

The Group is also launching a new Phase II study in the United States with Fibromun in combination with lomustine for the treatment of patients with Glioblastoma with one or more progressions. This study has already been approved by the U.S. Food and Drug Administration.

The Phase I/II/IIB trial in first-line Glioblastoma in combination with radiotherapy and temozolomide continues at the University Hospital of Zurich. As of the date of this press release, cohort 4 of the 5 foreseen in the Phase I trial, is ongoing.

- For OncoFAP (small organic molecule with high affinity for *Fibroblast Activation Protein* (FAP):

FAP is highly expressed in more than 90% of epithelial tumors. The Company is to date developing several pharmaceutical derivatives based on the OncoFAP ligand.

The derivative ^{68}Ga-OncoFAP (radio-diagnostic derivative) is being studied in a Phase I clinical trial in patients with solid tumors. The study has been approved by AIFA and is conducted in Italy.

The *company-sponsored* clinical trial of the ^{177} Lu-OncoFAP-23 derivative (radio-therapeutic derivative) is scheduled to begin in early 2024.

A clinical trial with OncoFAP-GlyPro-MMAE (OncoFAP derivative conjugated to cytotoxic drugs) in dogs with cancer is ongoing at the University of Milan. The "First-in-Human" study is scheduled to begin by the end of 2024.

- For OncoACP-3 (small organic molecule with high affinity for *Acid phosphatase 3* (ACP-3)):

The research team in Switzerland has discovered a new molecule with very high affinity for ACP-3. ACP-3 is a protein highly expressed by prostate cancer but not expressed in healthy tissues. The group has submitted a patent application on the new product.

- *Partnerships*

Partnerships continue on (i) Dodekin, (ii) Dekavil (with Pfizer), (iii) small organic molecules (with Janssen and Bracco), and (iv) Nidlegy™ (with Sun Pharma in Europe, Australia and New Zealand; in the context of a U.S. Phase II study with Merck Sharpe & Dohme).

- For the new GMP Rosia (Siena) plant.

The new GMP manufacturing facility in Rosia has had two inspections by the GMP MED and GMP API offices of the Italian Medicines Agency (AIFA) in July and October 2023, respectively. The Group expects to receive Commercial approval from both offices in the coming months. This facility will complement the existing GMP facility in Montarioso, Siena, which was strengthened in 2021 and is dedicated to the production of investigational drugs.

Therefore, the Group is consolidating its *core business* by conducting experimental clinical trials with its proprietary drugs and at the same time planning some industrial activities aimed at the commercialization of its drugs.

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The director in charge of preparing corporate accounting documents, Laura Baldi, declares pursuant to paragraph 2 Article 154 bis of the Consolidated Law on Finance that the accounting information contained in this press release corresponds to the documentary results, books and accounting records.

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Philogen Group Description.

Philogen is an Italian-Swiss company active in the biotechnology sector, specializing in the research and development of pharmaceuticals for the treatment of highly lethal diseases. The Group mainly discovers and develops targeted anticancer drugs by exploiting high-affinity ligands for tumor markers (also called tumor antigens). These ligands - human monoclonal antibodies or small organic molecules - are identified using *Antibody Phage Display Libraries* and *DNA-Encoded Chemical Libraries* technologies.

The Group's main therapeutic strategy for the treatment of such diseases is the so-called *tumor targeting.* This approach is based on the use of ligands capable of selectively delivering very potent therapeutic active ingredients (such as, for example, pro-inflammatory cytokines) at the tumor mass, sparing healthy tissues. Over the years, Philogen has mainly developed monoclonal antibody-based ligands that are specific for antigens expressed in tumor-associated blood vessels but not expressed in blood vessels associated with healthy tissues. These antigens are usually more abundant and more stable than those expressed directly on the surface of tumor cells. This approach, so-called *vascular targeting*, is used for most of the projects pursued by the Group.

The Group's goal is to generate, develop, and commercialize innovative products for the treatment of diseases for which medical science has not yet identified satisfactory therapies. This is achieved by leveraging (i) proprietary technologies for the isolation of ligands that react with antigens present in specific diseases, (ii) experience in developing products targeted to the tissues affected by the disease, (iii) experience in drug manufacturing and development, and (iv) the Group's extensive portfolio of patents and intellectual property rights.

Although the Group's drugs are primarily oncology applications, the *targeting* approach is also potentially applicable to other diseases, such as some chronic inflammatory diseases.

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FOR MORE INFORMATION:

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