Philogen
innovating targeting

PRESS RELEASE

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

THE BOARD OF DIRECTORS APPROVES THE NET FINANCIAL POSITION RELATED TO THE FIRST QUARTER OF 2023, WHICH IS POSITIVE AND AMOUNTS TO 66,731 THOUSAND EUROS, AND NOTES THE PROGRESS OF THE MAIN CLINICAL TRIALS *NIDLEGY*™ AND FIBROMUN IN LINE WITH FORESEEN TIMELINES AND THE DEVELOPMENT OF OTHER INDUSTRIAL ACTIVITIES

THE BOARD OF DIRECTORS ALSO APPROVED, AMONG OTHER THINGS:

- **THE SUSTAINABILITY BUDGET 2022;**
- **THE INITIATION OF A SHARE BUYBACK PROGRAM**

Siena (Italy), May 11, 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 March 31, 2023, noted the progress of the main clinical *trials Nidlegy*™ and Fibromun, as well as the positive development of other industrial activities. At the same meeting, the Board also approved the 2022 Sustainability Report and the launch of a share buyback program.

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

"The Group closes the first quarter of 2023 with a net financial position of € 66.7 million, testifying an efficient and focused management of resources.

The Phase III trial of Nidlegy™ in melanoma has reached 87 of the 95 events required for study read-out. We expect to reach the 95th event in the second half of 2023. An event corresponds to a tumor recurrence or death of a patient. We are extremely excited about the data with Nidlegy™ in high-risk basal cell carcinoma, on which the Group will increase is investment in the coming months with the aim of accelerating patient enrollment.

Fibromun pivotal trials are on track both in soft tissue sarcoma and glioblastoma. Following the completion of the Phase I part of the study in Switzerland in recurrent glioblastoma, the trial will begin the randomized Phase II part in a few weeks."

NET FINANCIAL POSITION AS OF MARCH 31, 2023

Below is a table of the Philogen Group's Net Financial Debt as of March 31, 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			Variations	
Net financial debt	**March 31, 2023**	**December 31, 2022**	**2023 vs. 2022**	**%**
(A) Cash and cash equivalents	3,663	8,436	(4,773)	(56.6)%
(B) Cash equivalents to cash and cash equivalents.	16,000	16,000	-	-
(C) Other current financial assets	62,458	61,764	693	1.1%
(D) Liquidity (A+B+C)	**82,121**	**86,200**	**(4,079)**	**(4.7)%**
(E) Current financial debt	31	29	(2)	(7.1)%
(F) Current part of non-current financial debt	1,744	1,726	18	1.0%
(G) Net current financial debt (E+F)	**1,775**	**1,755**	**20**	**0.9%**
(H) NET CURRENT FINANCIAL DEBT (G-D)	**(80,346)**	**(84,445)**	**4,099**	**(4.8)%**
(I) Non-current financial debt	13,615	14,007	(392)	(2.8)%
(J) Debt instruments	-	-	-	-
(K) Trade and other current payables.	-	-	-	-
(L) Non-current financial debt (I+J+K)	**13,615**	**14,007**	**(392)**	**(2.8)%**
(M) NET FINANCIAL DEBT (H+L)	**(66,731)**	**(70,438)**	**3,707**	**(5.3)%**

(*) 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 first quarter of 2023 with a positive net financial position of 66,731 thousand euros compared to a

positive net financial position of 70,438 thousand euros as of December 31, 2022, showing a percentage decrease of 5.3%.

As of March 31, 2023, the Group closes with liquidity of Euro 82,121 thousand compared to liquidity as of December 31, 2022 of Euro 86,200 thousand, showing a decrease of 4.7%. The latter change is mainly attributable to the net balance between (A) income and expenses related to operations: i) receipts for ongoing research and development contracts in the amount of Euro 2,148 thousand; ii) costs of core operations in the amount of approximately Euro 6.209 thousand; iii) investments for the construction of the new GMP plant in Rosia (Siena) amounting to approximately Euro 384 thousand; (B) income and expenses related to financial operations: i) extinguishment and collection of hedging derivative on loan amounting to Euro 219 thousand; ii) *fair value of* OTC hedging derivative on loans amounting to Euro 35 thousand; iii) collection of coupons on bonds amounting to Euro 143 thousand; iv) net positive change in *fair value of* the securities portfolio amounting to approximately Euro 557 thousand; v) purchase of treasury shares amounting to Euro 588 thousand.

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 Call No. 5/21, the net financial position does not include within it tax credits that can be used to offset future cash outflows from core operations by contributing positively to future cash savings, which, at the end of the first quarter of 2023, are more than 8 million euros.

Current and noncurrent financial indebtedness as of March 31, 2023 amounted to €15,390 thousand compared to €15,763 thousand as of December 31, 2022, showing a decrease of approximately €372 thousand resulting from the progress of existing amortization schedules. It should be noted that financial indebtedness is represented for approximately Euro 11,959 thousand 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 remainder 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 in accordance with the foreseen timelines. As of March 31, 2023:

- Nidlegy™ (a biopharmaceutical product, proprietary to Philogen, designed for the treatment of skin cancer)

The European Phase III study in stage IIIB/C melanoma has reached, in 2022, the enrollment of the 214 patients foreseen by the protocol. Clinical activities associated with the study (e.g., patient monitoring) will continue in 2023 at the 22 centers involved across France, Italy, Germany and Poland. At the date of this press release, the study reports 87 of the 95 events required for study *read-out* (one event corresponds to a disease recurrence or patient death). The 95th event is expected to be reached by the end of 2023.

Patient enrollment in the U.S. Phase III trial in stage IIIB/C melanoma continues in line with company forecasts. At the date of this press release, 31 centers have been opened (including 19 in 2022 and 5 in 2023). Additional centers are being activated in the coming months.

Moreover, two Phase II studies are ongoing in "*High-Risk*" Basal Cell Carcinoma (BCC) and in other non-melanoma skin cancers. The Group is working to accelerate its activities in BCC, in view of the high rate of durable complete remissions (clinical and/or pathological CR) observed in patients treated with Nidlegy ™. More information on CR rate will be reported in 2023. The CR rate of competing products (Odomzo ™, Erivedge™, Libtayo ™) is 5-6%. Clinical activities will also continue in other non-melanoma skin cancers (e.g., squamous cell carcinoma).

- 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 has, as of the date of this press release, 19 active clinical centers (12 in 2022), and 61 of the 118 patients foreseen by the protocol enrolled. The study will continue in 2023 in Germany, Italy, Spain, Poland, and France.

The American Phase IIb study in newly diagnosed leiomyosarcoma in combination with doxorubicin is ongoing at 9 clinical centers in the United States. Leiomyosarcoma is the most common STS subtype.

The European Phase II trial in third-line STS in combination with dacarbazine has, as of the date of this press release, enrolled 26 patients of the 92 planned by protocol, and is ongoing at 11 clinical centers. Additional centers are in the process of being activated.

The Phase I/II trial in glioblastoma at first progression 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, both in terms of survival and durable objective responses (e.g., in some cases lasting for more than 15 months), are to date substantially higher than the ones reported for current standard drugs (e.g., lomustine alone). The Company will continue to update the financial community in 2023 on the progress of this trial. The randomized Phase II part with 158 patients is scheduled to begin in mid-2023. Regulatory activities aimed at opening 18-20 clinical centers in Germany, Italy, Switzerland, France and the United States are underway.

The Phase I/II/IIb trial in newly diagnosed glioblastoma in combination with radiotherapy and temozolomide continues at the University Hospital of Zurich. As of the date of this press release, the third cohort out of five total cohorts for the Phase I part *is ongoing*.

- OncoFAP is a small organic molecule with high affinity for Fibroblast Activation Protein (FAP). FAP is highly expressed in over 90% of epithelial tumours. The Company is currently developing several pharmaceutical derivatives based on the OncoFAP ligand.

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

A Company-sponsored clinical study of the radio-therapeutic derivative ^{177}Lu-OncoFAP-23 is scheduled to start by the end of 2023.

Preclinical experiments with OncoFAP-GlyPro-MMAE (an OncoFAP derivative conjugated to cytotoxic drugs) are ongoing.

- Partnerships

Partnerships continue on (i) Dodekin (Confidential Partner), (ii) Dekavil (Pfizer) and (iii) small organic molecules (Janssen and Bracco).

Publication of a new study with Google has been reported on BioRXiv, which is focused on Machine Learning models applied to DNA-Encoded Chemical Library Technology.

- New GMP plant Rosia (Siena)

The AIFA inspection of the new GMP production plant in Rosia is expected in the second half 2023. The inspection is aimed at approving the new GMP facility for commercial purposes. It should be noted that this facility will join the existing GMP plant in Montarioso (Siena), which was strengthened in 2021 and is dedicated to the production of experimental drugs.

The Group is therefore consolidating its core business by conducting experimental clinical trials with its proprietary drugs, while at the same time planning some industrial activities aimed at the commercialisation of its drugs.

As part of the above industrial activities, the Group is evaluating the possibility of a collaboration with a partner (with a strong track-record in the dermato-oncology sector) for the distribution activities of its Nidlegy ™ product in the European territory, reserving for itself the exclusive rights for exploitation of Nidlegy ™ in the US territory.

SUSTAINABILITY REPORT 2022

The Board of Directors approved the Sustainability Report for the year 2022. The document is available on the Company's website at "https://www.philogen.com/governance/sustainability-esg/".

The Company has prepared the Philogen Group's first Sustainability Report in order to comply with recent regulatory changes (*Corporate Sustainability Reporting Directive*) and to communicate in a structured and organic way the Group's approach to sustainability and its performance in the environmental, social and economic spheres.

The Sustainability Report 2022 was prepared in accordance with the "GRI *Sustainability Reporting Standards*" published by the Global Reporting Initiative (GRI).

INITIATION OF THE SHARE BUYBACK PROGRAM

The Board of Directors of the Company, in implementation of the authorization given by the Shareholders' Meeting on April 28, 2023, approved the launch of a program to purchase treasury shares (the "**Program**"). Details of the Program are provided below, pursuant to Article *144-bis*, paragraph 3, of Consob Regulation adopted by Resolution No. 11971/1999 and Delegated Regulation (EU) 2016/1052.

- Objectives of the Program: the Program is aimed at (i) establishing a securities warehouse to divest, dispose of and/or use treasury shares at any time, in whole or in part, on one or more occasions, as part of agreements with strategic *partners* (including, but not limited to, *licensing* agreements) and/or corporate/financial transactions of an extraordinary nature in connection with which it is necessary or appropriate to assign or otherwise dispose of treasury shares, and (ii) to acquire shares to service existing or future *stock option* plans, *stock grants* or otherwise incentive programs, whether for consideration or free of charge, in favor of corporate officers, employees or collaborators of the Group.

- Maximum number of treasury shares: the purchase of ordinary shares, which may also be carried out in several *tranches*, may concern up to a maximum of No. 270,000 ordinary shares, within the limits of distributable profits and available reserves resulting from the latest approved financial statements at the time each transaction is carried out, as well as in compliance with the provisions of Article 2357, paragraph 3, of the Italian Civil Code.

- Minimum and maximum consideration: purchases will be made at a price that in any case shall not deviate, downward or upward, by more than 20 percent from the price recorded by the Philogen S.p.A. stock in the Euronext Milan market session on the day preceding each individual transaction.

- Maximum countervalue: the total disbursement of purchase deeds may not in any event exceed Euro 4,590,000.

- Duration of the Program: the Program, like the shareholders' authorization to purchase treasury shares, has a duration until the end of October 28, 2024.

Philogen will use an intermediary to execute the share buyback program. The Company will notify the market of the intermediary identified.

It should be noted that the authorization of the shareholders' meeting, as well as the initiation of the Program, does not obligate the Company to make purchases, and the Program may therefore be executed even partially, and its execution may be revoked at any time and promptly communicated to the market.

Any subsequent changes to the Program will be promptly announced to the public.

Purchase transactions will be subject to market disclosure, in detailed and aggregate form, within the terms and in the manner prescribed by applicable laws and regulations.

As of the date of this press release, the Company holds 227,770 ordinary shares (equal to 0.5609% of the share capital), with a total value of 3,306,652.98 euros.

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The manager 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 pharmaceutical products 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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