PHILOGEN S.p.A.

THE BOARD OF DIRECTORS APPROVES THE NET FINANCIAL POSITION RELATED TO THE FIRST QUARTER OF 2024, WHICH IS POSITIVE AND AMOUNTS TO 54,748 THOUSAND EUROS AND NOTES THE PROGRESS OF THE MAIN TRIALS *NIDLEGY*™ AND FIBROMUN IN LINE WITH THE EXPECTED TIMELINE AND THE EVOLUTION OF OTHER INDUSTRIAL ACTIVITIES

THE BOARD OF STATUTORY AUDITORS ASCERTAINS THAT THE MEMBERS OF THE BOARD OF STATUTORY AUDITORS MEET THE REQUIREMENTS OF PROFESSIONALISM, HONOUR AND INDEPENDENCE

Siena (Italy), May 7, 2024 - In fulfillment of 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**"), meeting today, approved the Group's net financial position as of March 31, 2024 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:

"We are proud to announce that the Phase III clinical data of Nidlegy™ in melanoma has been selected for an oral presentation at ASCO on May 31, 2024. ASCO is the most relevant conference in oncology and will allow the results to be presented to a specialist audience for the first time. The event precedes the submission of the marketing authorization application to the European Medicines Agency (EMA) scheduled for June 3, 2024.

Fibromun registrational trials continue on schedule in both soft tissue sarcoma (STS) and glioblastoma. The Phase III trial in first-line STS successfully passed the interim analysis, in which the efficacy and tolerability of the drug were reviewed by an independent committee. The trial is progressing toward completion of patient enrollment scheduled for the summer of this year. We are looking forward to being able to announce the final data from the study which, if positive, would enable the Group to have a second investigational drug that could be brought to registration."

NET FINANCIAL POSITION AS OF MARCH 31, 2024

The following is a table of Philogen Group's Net Financial Debt as of March 31, 2024, prepared in accordance with ESMA Guideline 32-382-1138 of March 4, 2021 and Consob's Attention Reminder No. 5/21:

Figures in thousands of euros			Variations	
Net financial debt	**March 31, 2024**	**December 31, 2023**	**2024 vs. 2023**	**%**
(A) Cash and cash equivalents	6,960	10,635	(3,675)	(34.6)%
(B) Cash equivalents to cash and cash equivalents.	5,000	5,000	-	-
(C) Other current financial assets	57,040	59,709	(2,669)	(4.5)%
(D) Liquidity (A+B+C)	**69,000**	**75,344**	**(6,344)**	**(8.4)%**
(E) Current financial debt	60	22	38	175.7%
(F) Current part of non-current financial debt	1,865	1,868	(3)	(0.2)%
(G) Net current financial debt (E+F)	**1,925**	**1,890**	**35**	**1.9%**
(H) NET CURRENT FINANCIAL DEBT (G-D)	**(67,075)**	**(73,455)**	**6,380**	**(8.7)%**
(I) Non-current financial debt	12,327	13,025	(698)	(5.4)%
(J) Debt instruments	-	-	-	-
(K) Trade and other current payables.	-	-	-	-
(L) Non-current financial debt (I+J+K)	**12,327**	**13,025**	**(698)**	**(5.4)%**
(M) NET FINANCIAL DEBT (H+L)	**(54,748)**	**(60,430)**	**5,682**	**(9.4)%**

(*) 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 statement formats for assessing the Group's financial position.

The Group ended the first quarter of 2024 with a positive net financial position of 54,748 thousand euros compared to a net financial position, also positive, of 60,430 thousand euros as of December 31, 2023, showing a percentage decrease of 9.4 percent.

As of March 31, 2024, the Group's liquidity amounted to Euro 69,000 thousand, a decrease of 8.4% compared to the liquidity as of December 31, 2023 of Euro 75,344 thousand. The latter change is mainly attributable to the net balance between (i) cash receipts for ongoing research and development contracts in the amount of Euro 1,242 thousand; (ii) costs

of core operations in the amount of approximately Euro 7,253 thousand; (iii) capex in the amount of approximately Euro 1.319 thousand, of which Euro 666 thousand for the construction of the new office building at the Rosia (Siena) site, Euro 453 thousand for investments in new machinery and equipment and Euro 200 thousand relating to specific facilities; (iv) net positive change in financial management of approximately Euro 987 thousand, given by coupon collections of Euro 256 thousand and Euro 731 thousand relating to the net positive change in the *fair value of* the portfolio. It should also be noted that part of the liquidity, amounting to Euro 5,000 thousand as of March 31, 2024, is invested in short-term *time deposits*, which are remunerated at market rates on maturity.

Current and non-current financial debt decreased from Euro 14,915 thousand as of December 31, 2023 to Euro 14,252 thousand as of March 31, 2024, showing a decrease of approximately 4.4%, resulting from the progress of the existing amortization schedules. It should be noted that financial debt is represented by (i) approximately Euro 11,606 thousand from the debt inherent in the leases of the three corporate sites, represented according to the international accounting standard (IFRS 16), (ii) Euro 2.586 thousand from the medium-long term loan signed with the Banca Intesa Group (formerly Ubi Banca S.p.A.) in January 2021, executed in order to partially finance the construction and equipment installations of the new GMP plant at the Rosia (Siena) site, and (iii) for Euro 66 thousand from the balance of credit cards as of March 31, 2024.

UPDATE ON THE GROUP'S INDUSTRIAL PROGRAMS

During the first quarter of 2024, the Company reports the following scientific updates.

- Nidlegy™ - a biopharmaceutical product designed for the treatment of skin cancers

Following the achievement of the primary objective of the Phase III study in locally advanced melanoma, the Company is working on the finalization of the *Marketing Authorization Application* documentation, which is expected to be submitted to the *European Medicines Agency* (EMA) in the first half of 2024.

Patient enrollment in the U.S. Phase III trial in stage IIIB/C melanoma continues in line with company expectations. To date, 33 centers have been opened.

Two Phase II studies are ongoing in "*High-Risk Locally Advanced*" Basal Cell Carcinoma (BCC) and other non-melanoma skin cancers. The Group has accelerated activities in BCC based on the high rate of durable complete remissions (clinical and/or pathological CR) observed in patients treated with Nidlegy™. As of the date of this press release, 70 patients have been enrolled in the ongoing Duncan study in Switzerland, Poland and Germany. The two clinical trials also allow Nidlegy™ to be tested in other non-melanoma skin cancers (e.g., squamous cell carcinoma, *Merkel Cell Carcinoma).* Discussions are underway with regulatory authorities to finalize an industrial development plan to bring the drug to registration.

As disclosed on May 30, 2023, Nidlegy™ was the subject of an exclusive marketing, licensing, and supply agreement with Sun Pharma for Europe, Australia, and New Zealand. Philogen is the exclusive rights holder for all other territories and for all indications other than skin cancer.

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

In the European Phase III study in first-line STS in combination with doxorubicin, 104 patients of the 118 foreseen the protocol have been enrolled. The study is continuing in Germany, Italy, Spain, Poland and France. Patients are randomized 1:1. Fifty percent of patients are treated with doxorubicin (control arm) and the other 50 percent of patients are treated with doxorubicin in combination with Fibromun (experimental arm). The study, whose primary *endpoint* is *Progression Free Survival* (PFS), *was* designed to observe at least 80% improvement in the experimental arm versus the control arm. Based on historical data, the *median* PFS of doxorubicin alone is expected to be around 4.6 months. An *Independent Data and Safety Monitoring Board* meeting on Feb. 19, 2024 recommended the continuation of the study as per the protocol, based on the evaluation of interim efficacy and *safety* data.

The U.S. Phase IIb study in first-line leiomyosarcoma in combination with doxorubicin is ongoing at 7 clinical centers in the United States. Please note that leiomyosarcoma is the most common subtype of STS.

The randomized phase of the European Phase II trial in third-line STS in combination with dacarbazine continues. The *trial* has enrolled 65 patients of the 92 planned foreseen by protocol.

Regarding the Phase I/II trial in second-line Glioblastoma in combination with lomustine, Phase I is completed with 15 patients divided into 3 cohorts and Phase II is ongoing. As of the date of this press release, 67 of the 158 patients scheduled for Phase II of the study have been enrolled. The study is currently ongoing in Switzerland, Italy and Germany. Philogen is working with the aim of opening additional centers in major European countries.

The Phase I/II/IIb trial in first-line Glioblastoma in combination with radiotherapy and temozolomide continues at the University Hospital of Zurich. Cohort 4 of the 5 planned in the Phase I trial is currently underway.

- OncoFAP-small organic molecule with high affinity for *Fibroblast Activation Protein* (FAP). FAP is highly expressed in more than 90% of epithelial tumors. The Group is to date developing several pharmaceutical derivatives based on the OncoFAP ligand

68Ga-OncoFAP (radio-diagnostic derivative) has completed enrollment in the Phase I clinical trial (FAPrimo) in patients with solid tumors. The Group is working to take the drug into Phase II.

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

Experimental data obtained in several preclinical models with OncoFAP-GlyPro-MMAE (a nonradioactive derivative of OncoFAP conjugated to cytotoxic drugs) have shown an excellent ability to block the growth of several tumor types. To date, the drug is undergoing a clinical trial in dogs with spontaneous neoplasia at University of Milan. It is also planned to begin GMP production of OncoFAP-GlyPro-MMAE, preparatory to starting clinical trials in human patients.

- Products in *partnership*

Partnerships continue on (i) Dodekin (confidential partner), (ii) Dekavil (Pfizer) and (iii) Nidlegy™ (Sun Pharma and MSD), and (iv) on small organic molecules (Janssen and Bracco).

- New GMP Plant Rosia (Siena)

The first inspection of the new GMP manufacturing facility in Rosia, Siena, by AIFA's GMP MED office was successful in July 2023. A second inspection by AIFA's GMP API office was carried out in October 2023. The latter was aimed at approving the new GMP facility for commercial purposes. It should be noted that this facility will complement the existing GMP plant at the Montarioso (Siena) site, which is dedicated to the production of experimental drugs.

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

Specifically, the Rosia production site currently has the following approvals from AIFA following the above inspections:

- MED GMP Authorization 09.11.2023 No.aM- 149/2023):

  1. Production Authorization for Commercial Products (Filling in asepsis);
  2. Production Authorization for Clinical Products (Filling in asepsis)
  3. Recognition and appointment of the relevant "Qualified Person" (*QP*) of site.

- API GMP Authorization 05.01.2024 N°API- 10/2024)

  1. Authorization for the Production of Active Substances for Commercial Use;
  2. Recognition and appointment of the relevant "Qualified Person" (QP) of site.

- Montarioso production site

  1. Renewal of Authorization for the Production of Active Substances for Experimental Use (GMP API 28.08.2023 N°aAPI- 100/2023);
  2. Recognition and appointment of the relevant "Qualified Person" (QP) of site.

VERIFICATION OF THE REQUIREMENTS OF THE MEMBERS OF THE BOARD OF STATUTORY AUDITORS

Philogen's Board of Statutory Auditors, which took office today following its appointment by the Shareholders' Meeting of 29 April 2024, verified, inter alia, that its members met the requirements of professionalism, honour and independence set forth by current legislation and the Articles of Association, as well as the Corporate Governance Code. With regard to Mr. Pierluigi Matteoni, who has held the position of Standing Auditor for more than nine consecutive financial years, the Board of Statutory Auditors has deemed that, in this specific case, the autonomy of judgement and free appreciation of the work of the directors and company management are not compromised in any way; therefore, the Board of Statutory Auditors, notwithstanding Recommendation 7, letter e), of the Corporate Governance Code, has verified that the independence of the Board of Statutory Auditors is not compromised in any way and that the existence of the independence requirements for Mr Matteoni are satisfied, and reserve the right to review the opinion if these circumstances should turn out to be unfulfilled during his term of office. The results of the checks carried out were announced today to the Company's Board of Directors.

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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 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:

Philogen - Investor Relations

IR@philogen.com - Emanuele Puca | *Investor Relations*