

**PHILOGEN S.p.A.**

**THE BOARD OF DIRECTORS APPROVES THE NET FINANCIAL POSITION FOR THE FIRST QUARTER OF 2022, EQUAL TO POSITIVE 76,352 THOUSAND EURO AND ACKNOWLEDGES THE PROGRESS OF THE MAIN TRIALS NIDLEGY™ AND FIBROMUN IN LINE WITH THE EXPECTED TIMING AND THE EVOLUTION OF THE OTHER BUSINESS ACTIVITIES**

**Siena (Italy), May 12, 2022** - In compliance with the disclosure commitments undertaken by the Company as part of the recent 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, 2022, and acknowledged the progress of the main trials *Nidlegly™* and *Fibromun*, and progress across the other business activities.

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

*"The Philogen Group closed the first quarter of 2022 with very positive results thanks to important collaborations that generated cash in the second quarter of 2022. Financially, the company expects to not burn cash in 2022 (at least for operational management, despite the projected increase in spending on clinical trials), thanks to both new and existing partnerships.*

*Additionally, we are pleased to provide the first 2022 update on the progress of our products in advanced clinical trials.*

*To date, the speed of patient enrollment in the *Nidlegly™* and *Fibromun* trials remains in line with the expectations outlined in the Business Plan.*

*For *Nidlegly™*, we expect to complete recruitment of the 214 planned patients in Q2 2022 for the European Phase III study in Stage IIIB,C melanoma. We are waiting to reach the 95 protocol-required events for the study read-out.*

*Emerging results for the use of *Fibromun* in combination with lomustine in recurrent glioblastoma continue to be very promising. Patients with the disease usually do not benefit from standard treatments (e.g., those based on lomustine alone). It was possible to evaluate the safety and efficacy of the combination of *Fibromun* with lomustine, which showed, in addition to an excellent tolerability of the drug, a strong reduction of tumor mass in 2 patients out of 6 (-98% and -82% at 12 months and 9 months, respectively) and stabilization for 3 of the other 4 patients. The only patient who did not benefit from the treatment tested positive for COVID-19 soon after entry into the study, received only one dose of *Fibromun*, and showed rapid disease progression, as expected for the conventional evolution of glioblastoma lesions. The trial is progressing with the dose escalation part of the study as per the protocol.*

*We are also obtaining extremely encouraging results for the OncoFAP platform, both OncoFAP-radioconjugated and OncoFAP-conjugated to cytotoxics. It has been possible to observe cures in experimental models of aggressive tumors with both OncoFAP-labeled lutetium-177 and OncoFAP-MMAE (a cytotoxic drug) conjugates. These results have facilitated the selection of products to move into clinical trials.*

*Philogen has also made progress in the field of radiopharmaceuticals for diagnostic imaging. The company's technological excellence has enabled it to discover and patent innovative tracers that localize to tumor sites with excellent selectivity, enabling more accurate staging of the disease. Philogen also announced a new imaging partnership with Bracco, a leading clinical imaging company.*

*Finally, we would like to report the results recently published in the journal *Blood Advances* of our interleukin 2 vehicle, for which complete and durable responses have been recorded in last-line patients with acute myeloid leukemia (AML) in combination with an anti-CD33 antibody from Boehringer Ingelheim. These results, in a disease that to date is often incurable, represent an excellent basis for a registration trial in patients without a therapeutic alternative. "*

**NET FINANCIAL POSITION AS OF 31 MARCH 2022**

The following table sets forth Philogen Group's Net Financial Debt as of March 31, 2022, prepared in accordance with ESMA Guidance 32-382-1138 dated March 4, 2021 and Consob's Attention Reminder No. 5/21:

<i>Figures in thousands of euros</i>	<b>March 31, 2022</b>	<b>December 31, 2021</b>	<b>Variations</b>	
<b>Net financial debt</b>			<b>2022 vs 2021</b>	<b>%</b>
(A) Cash and cash equivalents	2,852	8,880	(6,028)	(67.9)%
(B) Equivalents to cash and cash equivalents	-	-	-	-
(C) Other current financial assets	89,741	92,797	(3,056)	(3.3)%
<b>(D) Liquidity (A+B+C)</b>	<b>92,593</b>	<b>101,677</b>	<b>(9,084)</b>	<b>(8.9)%</b>

(E) Current financial debt	12	9	2	24.6%
(F) Current portion of non-current financial debt	1,816	1,799	17	0.9%
<b>(G) Net current financial debt (E+F)</b>	<b>1,827</b>	<b>1,808</b>	<b>19</b>	<b>1.0%</b>
<b>(H) NET CURRENT FINANCIAL INDEBTEDNESS (G-D)</b>	<b>(90,766)</b>	<b>(99,870)</b>	<b>9,104</b>	<b>(9.1)%</b>
(I) Non-current financial debt	14,421	14,685	(264)	(1.8)%
(J) Debt instruments	-	-	-	-
(K) Trade payables and other current payables	-	-	-	-
<b>(L) Non-current financial debt (I+J+K)</b>	<b>14,421</b>	<b>14,685</b>	<b>(264)</b>	<b>(1.8)%</b>
<b>(M) NET FINANCIAL DEBT (H+L)</b>	<b>(76,345)</b>	<b>(85,184)</b>	<b>8,839</b>	<b>(10.4)%</b>

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

The Group closed the first quarter of 2022 with liquidity amounting to Euro 92,593 thousand compared to Euro 101,677 thousand as of December 31, 2021, and a positive net financial position as of March 31, 2022 amounting to Euro 76,345 thousand compared to a net financial position, also positive, of Euro 85,184 thousand as of December 31, 2021 (showing a percentage decrease of approximately 10.4% compared to December 31, 2021). In compliance with the ESMA Guideline 32-382-1138 of 4 March 2021 and Consob recommendations, the net financial position does not include receivables from customers and tax credits, which, at the end of the first quarter of 2022, should be reported to be in excess of €15,000 thousand.

The change in cash and cash equivalents in the first quarter of 2022 is mainly due to (i) the costs of ordinary operations of approximately Euro 6,000 thousand, (ii) the purchase of treasury shares of approximately Euro 1,181 thousand, and (iii) investments for the new GMP facility at the Rosia site of Euro 1,507 thousand.

Current and non-current financial debt decreased from €16,493 thousand as of December 31, 2021 to €16,248 thousand as of March 31, 2022, showing a decrease of approximately €245 thousand resulting from the progress of the existing amortization plans. It should be noted that financial indebtedness is represented for approximately Euro 11,715 thousand by the notional debt inherent in the real estate leases for the three company sites, represented in accordance with international accounting standards. 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. Specifically, as of March 31, 2022:

- Nidlegly™, the product currently at the most advanced stage of development, is progressing according to the expected timeline for the European Phase III study in Stage IIIB,C melanoma. 207 patients have been treated as of March 31, 2022 (210 patients as of May 12, 2022) of the 214 patients planned in the protocol. Recruitment of the 214 patients is expected to be achieved in Q2 2022, as outlined in the prospectus published in March 2021. As of the date of this release, the 95 events, which according to the protocol will allow for the final data read-out (an event consists of disease progression or death of a patient), have not yet accrued. Clinical trials in melanoma in the United States also continue, as does a study in non-melanoma skin cancers in Europe;
- Fibromun, the second most advanced product in development status after Nidlegly™, is progressing according to the expected timeline for trials in soft tissue sarcoma and the most lethal brain tumor (*i.e.*, glioblastoma). The results observed for the treatment of patients with recurrent glioblastoma using Fibromun in combination with lomustine, which led to stabilizations or durable objective responses in 5/6 patients in the first cohort evaluated in the current study, have motivated the Group to further intensify clinical development activities in this indication. The number of clinical centers and countries involved in the trial is increasing, also in light of the promising clinical data recently published [Weiss et al. (2020) *Sci. Transl. Med.*, 12, eabb2311; Schliemann et al. (2021) *Eur. J. Cancer*, 150, 143].
- On March 22, 2022, a new partnership was announced with Bracco, a global leader in diagnostic imaging, to develop and commercialize, for the purpose of diagnostic applications, a small organic molecule discovered and validated by the Philogen Group.
- Investment continues with vehicle-delivered interleukin-2. New clinical data were recently published in collaboration with Boehringer Ingelheim in last-line patients with acute myeloid leukemia (Berdel et al., *Blood Advances* 2022, 2021006909). Complete and sustained remissions of disease were observed in patients treated with F16-IL2 (drug from Philogen) in combination with an anti-CD33 antibody (drug from Boehringer Ingelheim).

These patients had previously failed all available therapies, including bone marrow transplantation. This study follows an article previously published by the Group in *Science Translational Medicine* and lays the groundwork for a registration trial in this indication with vehicle-delivered interleukin-2. To date, the Group is evaluating whether to conduct these developments with F16-IL2 or L19-IL2 (Darleukin).

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The manager responsible for preparing the company's financial reports, Laura Baldi, hereby declares, pursuant to paragraph 2 of Article 154-bis of the Consolidated Law on Finance, that the accounting information contained in this press release corresponds to the documented results, books and accounting records.

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### **Philogen Group Description**

Philogen is an Italian-Swiss company active in the biotechnology sector, specialized 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 main therapeutic strategy of the Group for the treatment of these 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) to the tumor mass, sparing healthy tissues. Over the years, Philogen has primarily 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 objective 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 certain diseases, (ii) expertise in the development of products targeted at 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 certain chronic inflammatory diseases.

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### **FOR MORE INFORMATION:**

#### **Philogen - Investor Relations**

[IR@philogen.com](mailto:IR@philogen.com) - Emanuele Puca | *Investor Relations*