MaaT Pharma Announces 2023 Annual Results and Provides a Business Overview

- The DSMB, based on Phase 3 trial ARES preliminary data, concluded that MaaT013 has a favorable benefit/risk ratio with *"high efficacy and low toxicity"* in 3rd line aGvHD[1]. This evaluation confirms previous ones in a similar patient population from the EAP[2]. Primary endpoint ORR now expected in mid Q4 2024.
- Good safety profile and positive efficacy results with 47% overall survival (OS) at 12 months for all patients with aGvHD (n=111) and 52% for patient subgroup within the EAP with a similar profile to those in the ARES trial presented at ASH 2023. Long term follow-up data at EBMT conference 2024.
- Ongoing recruitment for Phase 2b trial PHOEBUS investigating MaaT033's impact on OS in allo-HSCT patients.
- Completion of recruitment in March 2024 for Phase 2a trial PICASSO sponsored by AP-HP[3], evaluating MaaT013 in combination with ICI in metastatic melanoma. Results expected end of 2024 or Q1 2025.
- First positive preclinical data for MaaT034, an AI-generated co-cultured product aimed at improving responses to ICI, presented at SITC conference 2023. New preclinical data at AACR conference 2024.
- Completion of the largest European cGMP manufacturing facility for Microbiome Ecosystem Therapies with first batches produced.
- FDA lifted the clinical hold and cleared the IND application for MaaT013 in patients with aGvHD; EMA granted ODD to MaaT033 to improve OS in patients undergoing allo-HSCT.
- As of December 31, 2023, cash and cash equivalents were €24.3 million, anticipated cash runway now set for end of Q3 2024. Revenues of €2.2 million for 2023, the highest revenues generated from the EAP so far.

Lyon, France, March 28, 2024, 6:00 pm CET – MaaT Pharma (EURONEXT: MAAT – the "Company"), a clinical-stage biotechnology company and a leader in the development of Microbiome Ecosystem Therapies™ (MET) dedicated to enhancing survival of patients with cancer, today reported the full-year 2023 annual results and provided a business overview.

"As we reflect on the achievements of 2023, I am proud to announce that we have successfully delivered on milestones across our entire pipeline, while being cash conscious. This past year has been pivotal, laying the foundations for the next phase of development for our lead asset MaaT013 with completion of the Phase 3 and readiness for commercialization. We look forward to reaching new milestones in 2024 and anticipate a major inflection point with the publication of the primary

[1] *acute Graft versus Host Disease*
[2] Early Access Program
[3] *Assistance Publique - Hôpitaux de Paris is the leading university hospital center in Europe*

endpoint of our Phase 3. By relying on our team and our network of physicians, and continuing to work closely with regulators, we anticipate continuing to create value for our shareholders and make significant progress in bringing new therapeutic options for patients with cancer," **states Hervé Affagard, CEO and co-founder of MaaT Pharma.**

Pipeline highlights

MET-N

MaaT013

In hemato-oncology:

- In April 2023, the U.S. Food and Drug Administration (FDA) lifted the clinical hold and cleared the Investigational New Drug (IND) application for MaaT013 in patients with aGvHD[4]. The Company has engaged active discussions with prominent US clinicians in the field of stem cell transplantation to explore the most efficient path forward to introduce MaaT013 to patients in the United States.
- In July 2023, the Company announced that clinical data from its Phase 2 study assessing MaaT013 as a treatment for aGvHD was published in eClinicalMedicine, one of the Lancet Discovery Science suite of journals.
- In October 2023, the Company announced that the DSMB[5] unanimously recommended that the open-label, single arm pivotal Phase 3 ARES clinical trial (NCT04769895), evaluating MaaT013 in aGvHD, continue without modification. The Overall Response Rate (ORR) was superior to pre-defined protocol assumptions. Therefore, the DSMB concluded that the benefit/risk ratio with *"high efficacy and low toxicity"* was favorable in this patient population. Primary endpoint, gastrointestinal overall response rate (GI-ORR), is now expected mid Q4 2024.
- In December 2023, the Company presented positive results from the Early Access Program (EAP) in Europe involving 111 patients with aGvHD treated with MaaT013, at the 2023 American Society of Hematology (ASH) Annual Meeting. The GI-ORR was 54% at day 28, positively and significantly impacting overall survival (OS) with 47% OS at 12 months for all patients with aGvHD and 52% for a patient subgroup from the EAP with a similar profile to those in the ARES trial with GI-ORR of 61% and 58% of complete responses observed at day 28.
- As a post period event, in March 2024, the Company announced that it will present for the first time extended results that include OS data after 12 months in more aGvHD patients from its EAP that were treated with MaaT013. The data will be shared during an oral presentation at the 50th Annual Meeting of the European Society for Blood and Marrow Transplantation held in Glasgow, UK, from April 14-17, 2024.
- As a post period event, the Company announces the launch of a retrospective multicenter trial called CHRONOS in Europe. Its objective is to provide the Company efficacy data for 3rd-line therapies for patients not receiving MaaT013 or any Microbiome intervention. This retrospective study does not impact cash projections as funding is already secured.

[4] *acute Graft Versus Host disease*
[5] *DSMB = Data Safety Monitoring Board*

In immuno-oncology:

- As a post period event, in March 2024, the Company informed on the completion of patient recruitment for the Phase 2a clinical trial (NCT04988841) sponsored by AP-HP and in collaboration with INRAe[6] and Institut Gustave Roussy[7], evaluating MaaT013, the Company's lead product candidate, in combination with immune checkpoint inhibitors (ICI), ipilimumab (Yervoy®) and nivolumab (Opdivo®) in ICI naïve patients with metastatic melanoma. Having reached this key recruitment milestone, the first publication will be submitted at the end of 2024 or in the first quarter of 2025.

MaaT033

In hemato-oncology:

- In April 2023, data from the Phase 1b study (CIMON) with MaaT033, previously communicated during the 64th annual ASH meeting, were also presented at the EBMT 2023 conference.
- In September 2023, the Company announced that the European Medicines Agency (EMA) had granted orphan drug designation (ODD) to MaaT033, which is aimed at improving overall survival in patients undergoing allo-HSCT[8]. The EMA recognized the significant benefit that MaaT033 could therefore bring to this patient population. The status offers key benefits including market exclusivity, clinical protocol assistance, waivers or reductions in regulatory fees.
- In November 2023, the Company announced that the first patient was treated in the Phase 2b trial (PHOEBUS) investigating the efficacy of MaaT033 in improving OS at 12 months in patients with blood cancer that are receiving allo-HSCT. The international, multi-center, randomized, double-blind, placebo-control study (NCT05762211), will be conducted in up to 56 clinical investigation sites and is expected to enroll 387 patients. It is, to date, the largest randomized controlled trial assessing a microbiome therapy in oncology.
- In November 2023, the Company announced that its ongoing Phase 2b trial, PHOEBUS has been selected for funding of 7.4 million EUR as part of the France 2030 Health Innovation plan, in response to the 'Innovation in Biotherapy and Bioproduction' call for projects from the 'Biotherapies and Bioproduction of Innovative Therapies' acceleration strategy, operated by Bpifrance (project code: METALLO). Post period the first tranche of 1.8 million EUR was received.

In neurodegenerative diseases:

- In September 2023, the Company announced that the first patient was dosed in the IASO Phase 1b pilot study (NCT05889572) in Amyotrophic Lateral Sclerosis (ALS), also known as Lou Gehrig's disease in the U.S. and Charcot's disease in French-speaking countries. As a

6 National Research Institute for Agriculture, Food and the Environment
7 Leading Cancer Centre in Europe
8 Allo-HSCT : Allogeneic hematopoietic stem cell transplantation

post period event, in February 2024, the Company announced that the DSMB reviewed safety data in the IASO trial in the first 8 patients with ALS treated with MaaT033. The DSMB recommended that the trial continue without modifications.

MET-C

MaaT034

In immuno-oncology:

- In November 2023, the Company had two presentations at the 38th Society for Immunotherapy of Cancer (SITC) Annual Meeting highlighting *in vitro* results for its new Artificial Intelligence (AI)-generated lead product, MaaT034, designed to improve responses to immunotherapy for patients with solid tumors. MaaT034 is the first member of the MET-C platform. Data presented at SITC 2023 shows that MaaT034 replicates, at large industrial scale, the richness, and diversity of healthy native-based microbiome ecosystems. The first clinical batches are expected to be produced in 2024 and the first-in-human study is planned for 2025.
- As a post period event, in March 2024, the Company announced that it will present new *in vitro* data at the American Association for Cancer Research (AACR) Annual Meeting 2024, taking place on April 5-10 in San Diego, California.

Corporate update

- In February 2023, the Company completed a successful capital increase of approximately €12.7 million with the support of current shareholders.
- In July 2023, MaaT Pharma joined the Microbiome Therapeutics Innovation Group (MTIG). MTIG is a coalition of companies focused on developing FDA-approved microbiome therapeutics and products to improve medical care, outcomes, and cost-effectiveness.
- In September 2023, the Company and Skyepharma announced completion of the cGMP manufacturing facility and the transfer of MaaT Pharma's Production and Development teams to the new site.
- During 2023 and Q1 2024, MaaT Pharma reinforced its board of directors, executive team, and key functions:
    - Karim Dabbagh as Chairman and Nadia Kamal as Director, both independent.
    - Jonathan Chriqui, as Chief Business Officer and member of the executive management team.
    - Guilhaume Debroas, as Head of Investor Relations.

Financial highlights

The key financial results for the 2023 full year are as follows:

Income Statement

In thousands of euros	31 December 2023	31 December 2022
Revenue	2 228	1 430
Cost of Goods Sold	(573)	(339)
Gross Margin	**1 655**	**1 091**
Other Income	4 667	4 122
Sales and distribution costs	(449)	(347)
General and administrative costs	(4 965)	(4 111)
Research and development costs	(20 851)	(14 311)
Operating income (expense)	**(19 943)**	**(13 557)**
Financial Income	639	45
Financial Expense	(413)	(201)
Net financial income (expense)	**226**	**(156)**
Income (loss) before income tax	**(19 717)**	**(13 713)**
Income tax expense	-	-
Net Income (loss) for the period	**(19 717)**	**(13 713)**

Prepared in accordance with international standards, IFRS.

Revenues totaled €2.2 million for the year ended December 31, 2023, the highest revenues generated thus far by the Company, which includes compensation invoiced from the Early Access Program in France and for which data was presented at the American Society of Hematology Annual Meeting in December 2023. The gross margin generated by the compassionate access program amounts to €1.7 million.

Operating expense amounted to €19.9 million compared with €13.6 million for 2022, an increase of €6.3 million. This increase reflects the growth of research and development costs which have risen from €14.3 million in 2022 to €21.2 million in 2023, representing an overall increase of €6.9

million and consistent with the advancement of clinical and operational activities as detailed in the pipeline highlights' section above.

Other income of €4.7 million includes the R&D tax credit of €3.6 million, an increase of €0.4 million compared with prior year, which amounted to €3.2 million and in line with the growth of research and development activities and eligible expenses.

General and administrative expenses amounted to €5.0 million compared with €4.1 million in 2022 reflecting the increase in regulatory advisory costs and expenses to support the early access program.

The net loss amounts to €19.7 million for the year ended December 31, 2023, compared with €13.7 million for the year ended December 31, 2022.

Average annual employees evolved from 43 in 2022 to 53 in 2023 following the strengthening of the clinical and production and supply chain and to a lesser extent administrative teams.

Cash Position

As of December 31, 2023, total cash and cash equivalents were €24.3 million, as compared to €31.7 million as of September 30, 2023, and €35.2 million as of December 31, 2022.

The net decrease in cash position of €11.0 million between December 31, 2022, and December 31, 2023, is due to the financing of operations for a total of €18.7 million, offset by cash inflows from financing of €8.1 million. Cash inflows from financing reflects the share capital increase in February 2023 of approximately €12.7 million, offset by debt repayments over 2023 €4.2 million. Total financial debt totaled €14.1 million as of December 31, 2023, of which €0.4 million relates to state-backed loans ("PGE") and €6.1 million of lease liabilities, which includes future contractual payments due to Skyepharma for the use of the manufacturing facility completed in 2023.

Based on the development plans and corresponding cash needs, the Company believes it has sufficient cash to finance operations to the end of Q3.2024 extending the cash runway by three months compared to prior communications as a result of a voluntary slowdown in headcount growth, optimization of its manufacturing plan and prioritizing expenses to support on the roll out of the Phase 2b trial PHOEBUS in France and Germany (approved countries) and finalizing recruitment into the Phase 3 ARES trial in Europe. The Company has active discussions ongoing to finance operations beyond the end of Q3.2024 and remains confident in extending its cash runway.

Note: This press release contains financial data approved by the Board of Directors on March 27, 2024, based on the financial statements for the year ended December 31, 2023. The audit is in progress at the date of this communication.

Upcoming financial communication*

- May 14, 2024: Publication of revenues for Q1 2024
- May 28, 2024: Annual General Shareholders Meeting
- September 19, 2024: Publication of half year financial results H1

- November 5, 2024: Publication of revenues for Q3 2024

**Indicative calendar that may be subject to change.*

Upcoming investor conferences participation

- April 15-17, 2024 – Kempen Life Sciences Conference, Amsterdam
- June 11-12, 2024 – Portzamparc Mid & Small Caps 2024 Conference
- June 25-27, 2024 – Stifel European Healthcare Summit Lyon

Upcoming scientific conference participation

- April 5-10, 2024 - American Association for Cancer Research (AACR) Annual Meeting 2024, San Diego
- April 14-17, 2024 – 50th Annual meeting of the European Bone Marrow Transplant (EBMT), Glasgow

The Company's universal registration document, which includes the annual financial report, will be available on MaaT Pharma's website on 02/04/2024: www.maatpharma.com

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About MaaT Pharma

MaaT Pharma, a clinical stage biotechnology company, has established a complete approach to restoring patient-microbiome symbiosis in oncology. Committed to treating cancer and graft-versus-host disease (GvHD), a serious complication of allogeneic stem cell transplantation, MaaT Pharma has launched, in March 2022, an open-label, single arm Phase 3 clinical trial in patients with acute GvHD, following the achievement of its proof of concept in a Phase 2 trial. Its powerful discovery and analysis platform, gutPrint®, enables the identification of novel disease targets, evaluation of drug candidates, and identification of biomarkers for microbiome-related conditions. The company's Microbiome Ecosystem Therapies are produced through a standardized cGMP manufacturing and quality control process to safely deliver the full diversity of the microbiome, in liquid and oral formulations. MaaT Pharma benefits from the commitment of world-leading scientists and established relationships with regulators to support the integration of the use of microbiome therapies in clinical practice. MaaT Pharma is listed on Euronext Paris (ticker: MAAT).

Forward-looking Statements

All statements other than statements of historical fact included in this press release about future events are subject to (i) change without notice and (ii) factors beyond the Company's control. These statements may include, without limitation, any statements preceded by, followed by or including words such as "target," "believe," "expect," "aim," "intend," "may," "anticipate," "estimate," "plan," "project," "will," "can have," "likely," "should," "would," "could" and other words and terms of similar meaning or the negative thereof. Forward-looking statements are subject to inherent risks and uncertainties beyond the Company's control that could cause the Company's actual results or performance to be materially different from the expected results or performance expressed or implied by such forward-looking statements.

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