TME PHARMA REPORTS H1 2023 FINANCIAL RESULTS AND PROVIDES BUSINESS UPDATE

- **Survival data from NOX-A12 GLORIA Phase 1/2 trial in brain cancer continue to improve and have already surpassed all relevant competitors**

- **67% overall survival at 18 months for NOX-A12 combination regimen with VEGF inhibitor and radiotherapy vs. 5% for standard of care**

Berlin, Germany, October 27, 2023, 06:00 p.m. CEST – TME Pharma N.V. (Euronext Growth Paris: ALTME), a biotechnology company focused on developing novel therapies for treatment of cancer by targeting the tumor microenvironment (TME), announces its financial results and business highlights for the six months ending June 30, 2023, and provides an outlook for the rest of the year.

Aram Mangasarian, CEO of TME Pharma commented: *"This year has been a highly productive period for* TME Pharma *in which we have reported unprecedented survival rates for newly diagnosed brain cancer patients with chemotherapy resistant tumors not amenable to complete surgical removal receiving our lead asset NOX-A12 in combination with radiotherapy and VEGF inhibition. These maturing survival data not only position NOX-A12 as potentially the best available treatment for glioblastoma, but they also mean we have advanced to the point where we can now engage with the FDA on the next clinical and regulatory development steps for NOX-A12. These include an Investigational New Drug filing and potential access to expedited regulatory pathways, which we expect to achieve in early 2024. We are convinced that this will generate significant interest among investors and potential partners. This year has also seen* TME Pharma *take a major step forward in our commitment to our shareholders to end the use of convertible bond financing with the successful completion of a €2 million financing that included a lock-up of new shares and bond conversions for a period of six months. This innovative transaction secured new cash and investors while allowing us to remain focused on our goal of developing novel therapies for cancer and bringing them to market. We are solidly financed into 2024 and looking forward to achieving further clinical and regulatory progress in the months ahead."*

Business and Clinical Highlights

GLORIA trial in first-line brain cancer (glioblastoma)

- Maturing data from the ongoing GLORIA trial suggest a greater clinical benefit of NOX-A12 combination regimen with radiotherapy + VEGF inhibition over the standard of care:
    - 67% of patients were alive 18 months after the start of their therapy vs. 5% in the standard of care reference cohort – a 13-fold improvement.
    - Median overall survival (mOS) exceeds 18 months and continues to improve further with three of six patients (50%) receiving treatment or follow-up care.

    - Maturing mOS >18 months has surpassed all relevant competitor trials conducted in the US and EU involving chemotherapy resistant (MGMT promoter unmethylated) population despite the fact that the NOX-A12 trial excluded patients with complete tumor resection (and thus a better prognosis) that were allowed into competitor trials.
    - 50% of patients in the GLORIA trial expansion arm achieved a complete or near-complete response when treated with NOX-A12 + radiotherapy + VEGF inhibition.
- Data identifying a potential predictive biomarker for glioblastoma patients treated with NOX-A12 and radiotherapy, the "EG12 score", were presented at the June 2023 American Society of Clinical Oncology (ASCO) Annual Meeting.
    - The EG12 score is based on histopathological assessment of tumor tissue collected during standard of care surgery before drug therapy and predicts which patients will benefit most from treatment with NOX-A12 and radiotherapy.
    - Patients with a high EG12 score had a significantly longer median progression-free survival than patients with a low EG12 score (6.0 months vs. 3.0 months, p=0.031) and a strong trend for longer median overall survival (15.8 months vs. 11.1 months, p=0.075).
    - Further in-depth analysis of how the combination of radiotherapy and NOX-A12 remodels the immune tumor microenvironment was showcased in October 2023 in an oral presentation at the European Society for Medical Oncology (ESMO) Congress.
    - The biomarker could help identify target populations for future clinical trials, thereby enhancing the statistical power of trials and reducing the risk of failure in further development.

First authorization for clinical trial of NOX-A12 in the US granted by US FDA

TME Pharma's first Investigational New Drug (IND) application was approved by the US Food and Drug Administration (FDA) in May 2023 to evaluate the company's lead asset NOX-A12 in the OPTIMUS Phase 2 clinical trial in pancreatic cancer. This represents the first comprehensive review and approval of NOX-A12 – and more broadly the first review of the Group's class of compounds – by the FDA and will facilitate any future clinical development of NOX-A12 in the US. In addition to the US, the clinical trial protocol has been approved by regulatory authorities in France and Spain. To conduct the clinical trial, *TME Pharma* and MSD (Merck & Co., Inc., Kenilworth, N.J. USA) entered a clinical collaboration (it is the second clinical trial collaboration between the companies in this indication) by which MSD will provide pembrolizumab (Keytruda®) and expert advice for the study protocol. *TME Pharma* is planning to initiate the trial when appropriate financing and drug supply are available beyond that needed for development of NOX-A12 in brain cancer.

H1 2023 Financial Highlights

For the reporting period, the Group – *TME Pharma N.V.*, *TME Pharma AG* and *TME Pharma Inc.* – has not generated any revenues. The Group, like most pre-commercial biotech companies, does not expect any revenues to be generated from any product candidates that it develops until the Group either signs a licensing or collaboration agreement or obtains regulatory approval and commercializes its compounds.

Research and development (R&D) expenses decreased by 77% in H1 2023 over the same period last year. This significant reduction is primarily due to the GLORIA trial of NOX-A12 in brain cancer nearing completion, which required lower costs while at the same time generating more mature data. The process to bring the OPTIMUS pancreatic cancer trial Phase 2 protocol to FDA approval in the US was also successfully completed in Q2 2023, reducing ongoing costs related to this trial. As a result, *TME Pharma* was able to decrease drug manufacturing costs, service fees and other costs related to the clinical trials and preclinical testing, in addition to lower personnel expenses, patent costs and consulting services.

General and administrative (G&A) expenses decreased by 27% in H1 2023, mainly driven by lower personnel expenses and lower legal, consulting and audit fees. The net loss from operations for H1 2023 was €2.8 million, a 64% decrease on the prior year period. *TME Pharma* has focused its financial resources on achieving its primary near-term goal of generating mature overall survival data in the GLORIA trial of NOX-A12 in brain cancer. With the trial now nearing completion, *TME Pharma* will assess how and where to deploy the Group's available financial resources to maximize the chances of NOX-A12 reaching the market.

In April 2023, the company raised €2 million as part of an innovatively structured transaction that involved €1.00 million in equity financing (gross) from a group of new investors and a €1.08 million convertible bond financing (nominal) under the agreement with Atlas Special Opportunities, LLC (ASO). ASO also converted €2 million convertible bonds into shares as part of the transaction at the same price per share as the new investors, thus aligning the financial interests of all investors participating in the transaction. In addition, *TME Pharma* has committed not to draw any further tranches from the ASO convertible bond vehicle and the agreement with ASO was terminated other than with regards to the convertible bonds held by ASO following the transaction.

This transaction thus marked the company's commitment to end reliance on convertible bond financing. By removing the pressure of convertible bonds and introducing the six-month soft lock-up of shares, the company's objective was to strengthen its position and valuation in the financial market. Considering cash and cash equivalents of €3 million as of June 30, 2023, *TME Pharma* has financial visibility into February 2024. Management is engaged in active discussions and anticipates the ability in the coming weeks to extend financial visibility beyond the planned regulatory value inflection points in 2024.

Outlook for the Remainder of 2023 and 2024

Progress of NOX-A12 program in glioblastoma

TME Pharma continues to make progress in its ongoing Phase 1/2 trial of NOX-A12 combination therapies in first-line brain cancer (glioblastoma) patients who are resistant to the current standard of care chemotherapy. The company has made the strategic decision to concentrate its available resources on advancing the development of NOX-A12 in glioblastoma since management believes that this indication offers the fastest path to regulatory approval for NOX-A12 in the solid tumor space. For the remainder of the year, the company expects to report additional clinical data as our clinical trial matures. At the Society for Neuro-Oncology (SNO) conference in November 2023, *TME Pharma* will provide updates on the progress of the bevacizumab expansion arm.

FDA advice and IND for NOX-A12 in glioblastoma

Based on the latest positive survival data reported on October 20, 2023, showing a landmark overall survival at 18 months (OS-18) of 67%, the Group plans to request formal advice from the FDA by the end of October 2023, with feedback expected in late December, regarding its planned clinical development approach for NOX-A12 in glioblastoma and its potential eligibility for expedited regulatory pathways, such as Fast Track Designation. *TME Pharma* then plans to file an Investigational New Drug (IND) application for glioblastoma with the FDA along with expedited regulatory pathway access request. Successful IND filing and feedback are targeted by end of Q1 2024.

Financial security for further development of NOX-A12 in glioblastoma

The financial environment of the last 30 months has proven to be the most demanding funding environment for public biotech companies over the last 20 years. The market has seen valuations fall across the board with the S&P Biotech Index[1] down almost 60% since its peak in January 2021, with many institutional investors, including generalists and specialists, exiting the space and funding

[1] The XBI is an equal-weighted index tracking the value of 140 North American Biotech stocks.

becoming increasingly challenging to source and secure. The company believes that with its lean structure and value created through its clinical performance, it is now better positioned in terms of its attractiveness to investors despite the current adverse financing conditions.

The Group will carefully monitor its available cash and calibrate additional financings through available sources in order to ensure its ability to continue to advance its clinical development plans in brain cancer and, to the extent deemed appropriate, maintain a sufficient cash runway, yet minimize shareholder dilution whenever possible.

The Half-Year Financial Report 2023 can be downloaded from the *TME Pharma* website.

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About TME Pharma

TME Pharma is a clinical-stage company focused on developing novel therapies for treatment of the most aggressive cancers. The company's oncology-focused pipeline is designed to act on the tumor microenvironment (TME) and the cancer immunity cycle by breaking tumor protection barriers against the immune system and blocking tumor repair. By neutralizing chemokines in the TME, *TME Pharma's* approach works in combination with other forms of treatment to weaken tumor defenses and enable greater therapeutic impact. In the GLORIA clinical trial, *TME Pharma* is studying its lead drug candidate NOX-A12 in newly diagnosed brain cancer patients who will not benefit clinically from standard chemotherapy. *TME Pharma* has delivered top-line data from the NOX-A12 three dose-escalation cohorts combined with radiotherapy of the GLORIA clinical trial, observing consistent tumor reductions and objective tumor responses. Additionally, GLORIA expansion arms evaluate safety and efficacy of NOX-A12 in other combinations where the interim results from the triple combination of NOX-A12, radiotherapy and bevacizumab suggest even deeper and more durable responses, and improved survival. NOX-A12 in combination with radiotherapy has received orphan drug designation for glioblastoma in the United States and glioma in Europe. *TME Pharma* has delivered final top-line data

with encouraging overall survival and safety profile from its NOX-A12 combination trial with Keytruda® in metastatic colorectal and pancreatic cancer patients, which was published in the Journal for ImmunoTherapy of Cancer in October 2021. The company has entered in its second collaboration with MSD/Merck for its Phase 2 study, OPTIMUS, to further evaluate safety and efficacy of NOX-A12 in combination with Merck's Keytruda® and two different chemotherapy regimens as second-line therapy in patients with metastatic pancreatic cancer. The design of the trial has been approved in France, Spain and the United States. The company's second clinical-stage drug candidate, NOX-E36, is designed to target the innate immune system. *TME Pharma* is considering several solid tumors for further clinical development. Further information can be found at: www.tmepharma.com.

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About the GLORIA Study

GLORIA (NCT04121455) is *TME Pharma's* dose-escalation, Phase 1/2 study of NOX-A12 in combination with radiotherapy in first-line partially resected or unresected glioblastoma (brain cancer) patients with unmethylated MGMT promoter (resistant to standard chemotherapy). GLORIA further evaluates safety and efficacy of NOX-A12 three additional arms combining NOX-A12 with: A. radiotherapy in patients with complete tumor resection; B. radiotherapy and bevacizumab; and C. radiotherapy and pembrolizumab.

About the OPTIMUS Study

OPTIMUS (NCT04901741) is *TME Pharma's* planned open-label two-arm Phase 2 study of NOX-A12 combined with pembrolizumab and nanoliposomal irinotecan/5-FU/leucovorin or gemcitabine/nab-paclitaxel in microsatellite-stable metastatic pancreatic cancer patients.

Disclaimer

Translations of any press release into languages other than English are intended solely as a convenience to the non-English-reading audience. The company has attempted to provide an accurate translation of the original text in English, but due to the nuances in translating into another language, slight differences may exist. This press release includes certain disclosures that contain "forward-looking statements." Forward-looking statements are based on *TME Pharma's* current expectations and are subject to inherent uncertainties, risks and assumptions that are difficult to predict. Factors that could cause actual results to differ include, but are not limited to, the risks inherent in oncology drug development, including clinical trials and the timing of and *TME Pharma's* ability to obtain regulatory approvals for NOX-A12 as well as any other drug candidates. Forward-looking statements contained in this announcement are made as of this date, and *TME Pharma* undertakes no duty to update such information except as required under applicable law.