TME PHARMA REPORTS H1 2022 FINANCIAL RESULTS AND PROVIDES BUSINESS UPDATE

- **Promising top-line results warrant focus of the clinical development on NOX-A12 combination therapies in brain cancer**
- **NOX-A12 + bevacizumab 12-month survival data in glioblastoma expected in April 2023**
- **Cash runway into June 2023**

Berlin, Germany, October 26, 2022, 07:00 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, 2022, and provides an outlook for the rest of the year.

Aram Mangasarian, CEO of TME Pharma commented: *"In the last several months, years of focused efforts and commitment to our mission to develop novel therapies for cancer patients have begun to deliver impressive results and it is our bold ambition to change the landscape of treatments for glioblastoma patients, and more broadly patients affected with solid tumors. It has been a transformative period for us in which the announcement of the company's new name,* TME Pharma*, officially marked our evolution into an oncology biotech focused on the Tumor Microenvironment – TME. At the same time, we have reported promising and exciting clinical data with our lead asset NOX-A12 in glioblastoma in multiple combination approaches. We are especially encouraged by the results from the combination therapy of NOX-A12 and the anti-VEGF antibody, bevacizumab, that showed reduced tumor size and radiographic partial response in 100% of evaluable patients in June 2022, suggesting an even deeper and more sustained response compared to NOX-A12 alone. This is of particular importance considering the extremely poor response to treatment of patients with MGMT-unmethylated tumors (refractory to chemotherapy) that are incompletely removed by surgery. Updated data will be presented at a scientific conference in November 2022. The development of drugs to treat a difficult and aggressive cancer like glioblastoma is a challenging and lengthy process, and past studies in glioblastoma have shown the difficulty of proving the translation from overall response rate (ORR) to survival. Accordingly, the next phase of NOX-A12's development will need to focus on overall survival (OS) as well as the durability of responses. Once more mature data on survival, quality of life and neurological function is available,* TME Pharma *is planning to meet with regulators, which should provide improved visibility on the clinical trial design required to achieve our goal of an approved therapy, and hence the financial needs to move NOX-A12 closer to regulatory approval.*

Bryan Jennings, CFO of TME Pharma added: *"The financial environment of the last 18 months has been unprecedented in its impact on biotech stocks. Public and private market valuations have fallen across the board and financing volumes in the biotech industry have fallen accordingly.* TME Pharma *has recently introduced new capital structures including an August 2022 share consolidation as well as the introduction of a preferred share class, both of which will assist us in attracting long-term biotech-*

focused institutional investors. Given the significant clinical successes in the company, we are well-positioned to attract new investors despite the challenging equity market conditions globally."

2022 Year-to-Date Business and Clinical Highlights

NOX-A12 Combinations Therapies in Brain Cancer

- In June 2022, the top-line results from the Phase 1/2 GLORIA trial in first-line brain cancer (glioblastoma) patients treated with NOX-A12 and radiotherapy (RT) were presented by the lead investigator, Dr. Frank A. Giordano, at the American Society of Clinical Oncology (ASCO) Annual Meeting. Key points of the poster presentation included:
    - 90% of patients who received NOX-A12 and RT achieved tumor size reductions vs. 25% of patients in a matched reference cohort receiving standard of care.
    - 40% of patients who received NOX-A12 and RT achieved partial response (defined as tumor size reduction of more than 50%) vs. 10% in a matched reference cohort receiving standard of care.
    - In 30% of patients who received NOX-A12 and RT, one or more non-target lesions (smaller secondary lesions) completely disappeared.
    - Infiltration of the tumor with activated, cytotoxic T-cells and M1-like macrophages was seen in both patients who had repeat surgery during NOX-A12 therapy, consistent with NOX-A12 and RT overcoming immune cell exclusion and making the tumors immunologically hotter (i.e. more infiltrated by the immune system and therefore more likely to lead to a destruction of the tumor by the immune system).
    - The combination of NOX-A12 and RT was safe and well tolerated, with no dose limiting toxicities and no treatment-related deaths. Only 4% of the adverse events of Grade 2 or more were deemed solely NOX-A12-related.

- Preliminary data from the extension arm of the triple combination therapy of NOX-A12, RT and bevacizumab were published in June 2022. The combination appeared to be safe and well tolerated and resulted in radiographic partial response in 100% of patients evaluable at the time (five of the planned total of six). Reductions in tumor size at latest time-points as assessed in June 2022 by an independent central reader ranged from -54.7% to -94.7%, suggesting deeper and more sustained responses than seen with NOX-A12 plus radiotherapy.

- In August 2022, *TME Pharma* announced the Data Safety Monitoring Board (DSMB) confirmed safety data from the initial four weeks of treatment of the first patient enrolled in the extension arm of the triple combination therapy of NOX-A12, RT and pembrolizumab (commercialized under the name Keytruda®) and validated recruitment of the remaining 5 patients in that arm.

Collaboration with the U.S. National Cancer Institute

In June 2022, *TME Pharma* entered into a material transfer agreement with the U.S. National Cancer Institute (NCI) of the National Institutes of Health (NIH), to further explore the effects of *TME Pharma*'s lead compounds, the CXCL12 inhibitor NOX-A12 and the CCL2 inhibitor NOX-E36, on brain tumors as part of a research program that is led by Mark R. Gilbert, M.D., Chief of the Neuro-Oncology Branch at the National Cancer Institute's Center for Cancer Research (NCI/CCR), part of the NIH.

New Corporate Identity

In July 2022, NOXXON officially changed its name from *"NOXXON"* to *"TME Pharma"* to reflect its evolution into an oncology biotech with a clear focus on advancing approaches altering the tumor microenvironment (TME). The ticker symbol for the company's common stock on the Euronext Growth Paris was changed from "ALNOX" to "ALTME" In the same month, the company completed and effected its share consolidation (finalized in August 2022).

H1 2022 Financial Highlights

For the reporting period, the Group – *TME Pharma N.V.* and *TME Pharma AG* – has not generated any revenues. The Group does not expect to generate any revenues from any product candidates that it develops until the Group either signs a licensing agreement or obtains regulatory approval and commercializes its products or enters into collaborative agreements with third parties.

Operating costs increased by 28% in H1 2022 over the same period last year, almost 50% of this increase being driven by research and development (R&D) expenses, accounting for 74% of operating costs. The R&D expenses increased by 16% in H1 2022 over the same period last year due to higher costs for drug manufacturing, service fees and other costs related to clinical trials and preclinical testing. General and administrative (G&A) expenses increased by 79% to support operational activities. The G&A expenses were predominantly driven by higher personnel expenses as well as higher legal, consulting and audit fees, higher public and investor relations and related expenses. These operating costs led to €7.7 million loss from operations.

The Group was successful in strengthening its balance sheet by raising €4.3 million net cash under the agreement with Atlas Special Opportunities (ASO) in the first half-year 2022, complemented by an additional financing of €3 million net cash from the same facility secured since June 30, 2022, increasing the total of raised funding in 2022 to-date to €7.3 million net.

Considering cash and cash equivalents as of June 30, 2022, of €8 million and additional cash resources from convertible bonds drawn after balance sheet date as outlined above, *TME Pharma* has sufficient financial visibility into June 2023. In addition, the company has access to a committed convertible bond financing of €15.7 million net cash drawable at the company's discretion and subject to customary conditions being met.

Outlook for the Remainder of 2022 and 2023

TME Pharma continues to make progress in its ongoing Phase 1/2 trial of NOX-A12 combination therapies in first-line, brain cancer patients who are shown by biomarker analysis of their tumor tissue to be resistant to the current standard of care chemotherapy. The company has made the strategic decision to concentrate current capabilities on advancing development of NOX-A12 in glioblastoma since management believes that this indication 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 2022, *TME Pharma*

will provide an update on the progress of both the dose escalation cohort and the bevacizumab extension arm.

TME Pharma continues to operate efficiently, with almost three-quarters of operating costs dedicated to R &D and a small team of highly qualified professionals. As the company is concentrating its current capabilities towards the strategic goal of bringing NOX-A12 to patients, it will require additional funding to continue development on the most efficient path, and also to initiate its other clinical trial in pancreatic cancer. The planned Phase 2 OPTIMUS trial of NOX-A12 in pancreatic cancer has been fully approved in France and Spain and the study design is being discussed with the U.S. Food and Drug Administration (FDA) with the goal of reaching agreement such that the trial could be rapidly initiated when appropriate financing is available.

Once the data from the brain cancer trial matures sufficiently, the Group plans to confirm that its planned approach is acceptable to complete development and to achieve market approval in this indication. Since the Group will need to target a survival benefit in registrational trials, regulatory interactions on the NOX-A12 + RT + bevacizumab combination are planned as soon as *TME Pharma* has sufficient data on this parameter for substantive discussions with the European and U.S. regulators. Based on current trends the Group expects sufficient data, including 12-month survival rates, will be available in April 2023. It should be noted that the longer the patients remain in good clinical condition (neurological function and quality of life), the longer it takes to reach key survival data points such as overall survival and progression free survival and the better it is for the Group's regulatory discussions and partnering efforts even if later in time.

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, maintenance of a sufficient cash runway, yet minimize shareholder dilution whenever possible.

The Half-Year Financial Report 2022 can be downloaded from the *TME Pharma* website.

For more information, please contact:

TME Pharma N.V.
Aram Mangasarian, Ph.D., CEO
Bryan Jennings, CFO
Tel. +49 (0) 30 726247 0
investors@tmepharma.com

Investor and Media Relations:

LifeSci Advisors
Guillaume van Renterghem
Tel. +41 (0) 76 735 01 31
gvanrenterghem@lifesciadvisors.com

NewCap
Arthur Rouillé
Tel. +33 (0) 1 44 71 00 15
arouille@newcap.fr

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. 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 is in discussion with regulatory authorities in the United States and Europe. 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.

Keytruda® is a registered trademark of Merck Sharp & Dohme Corp.

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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.