TME PHARMA RECEIVES US FDA FAST TRACK DESIGNATION FOR LEAD ASSET NOX-A12 IN BRAIN CANCER

- **Fast Track designation awarded by the FDA serves as an external validation of the potential of NOX-A12 for unmet need in glioblastoma and could support an accelerated pathway to US regulatory approval**
- **Fast Track designation for NOX-A12 follows recently announced FDA clearance of Investigational New Drug application for Phase 2 study in glioblastoma**
- **Capitalizing on unprecedented NOX-A12 median Overall Survival of 19.9 months in chemotherapy resistant patients with residual tumor after surgery, TME Pharma actively pursues multiple sources of financing for NOX-A12 further clinical development, with a focus on non-dilutive financing**
- **Fast Track designation is an important step in materializing discussions with potential industrial and financial partners**

Berlin, Germany, April 02, 2024, 08.00 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 that the US Food and Drug Administration (FDA) has granted Fast Track designation for NOX-A12 (olaptesed pegol), *TME Pharma's* CXCL12 inhibitor, in combination with radiotherapy and bevacizumab for use in the treatment of the aggressive adult brain cancer, glioblastoma, in the newly diagnosed setting where the tumor is resistant to chemotherapy and measurable tumor remains after surgery.

The FDA's Fast Track designation aims to bring important new drugs to patients more quickly, facilitating the development and expediting the review of therapies intended to treat serious conditions and address unmet medical needs. Companies whose programs are granted Fast Track designation can benefit from more frequent interactions with the FDA during the clinical development process and potentially "accelerated approval" and "priority review" if the relevant criteria are met.

TME Pharma continuously evaluates ways to advance the clinical development of NOX-A12 while remaining focused on identifying and securing financial resources from multiple sources, including those having no or minimal dilutive effect on its shareholders, such as governmental grants or free supply of combination drugs. In addition to engaging with industry partners and specialized healthcare investors, *TME Pharma* will also explore the eligibility of NOX-A12-based therapy for compassionate use programs once sufficient Phase 2 data have been generated. The company would prioritize such programs that support financial compensation for therapies leading to revenue generation, thus potentially reducing the financial needs of late-stage clinical development and also helping to generate real-world clinical evidence.

Recently announced clearance by the FDA of *TME Pharma's* Investigational New Drug (IND) application for a Phase 2 study with NOX-A12 in glioblastoma, that the company plans to initiate later this year, was a prerequisite to having Fast Track designation granted by the FDA. Having Fast Track designation in addition to an open IND with an FDA-approved study design that addresses questions of dosing and contribution of components optimizes late phase development and offers an economically efficient model which further de-risks *TME Pharma's* glioblastoma program. Following IND approval, this Fast Track designation is an external validation of NOX-A12's potential to address the unmet need for glioblastoma patients.

The necessary preparatory steps for the NOX-A12 Phase 2 in glioblastoma are ongoing, and *TME Pharma* is aiming to initiate the new Phase 2 study as soon as the necessary resources from financial and industrial partners have been secured. *TME Pharma* is prioritizing discussions with partners willing to support the company over the long term and having their financial interests aligned with current stakeholders. While discussions are ongoing, and until longer-term agreements with partners are reached, *TME Pharma* is determined to keep operational costs low to extend the financial visibility as far as possible and increase the chance of success.

TME Pharma's latest regulatory milestones were supported by recent survival data from the GLORIA Phase 1/2 study in which NOX-A12 demonstrated an unprecedented median Overall Survival of 19.9 months in chemotherapy resistant patients with residual tumor after surgery, which compared very favorably to a matched standard of care reference cohort and exceeds what *TME Pharma* believes to be all relevant competitor therapy trials in newly diagnosed glioblastoma patients resistant to standard chemotherapy.

"At the start of this year, we announced the next phase of our development of NOX-A12 by targeting IND approval and an expedited regulatory pathway in the US and we are very proud to have successfully achieved these milestones within the timeframe we set out," said **Aram Mangasarian, CEO of TME Pharma**. *"While advancing discussions with potential industrial and financial partners may require some time to materialize, the open IND and Fast Track designation awarded by the FDA are well-received signals by these partners. We now have a clear clinical development roadmap with which to take NOX-A12 forward in the treatment of glioblastoma and to support engagement with potential partners. We expect our new Phase 2 study will build on the unprecedented results of our GLORIA trial, which strengthens the potential of NOX-A12 to become the treatment option of choice for newly diagnosed chemotherapy-resistant glioblastoma. We look forward to working closely with the FDA as we advance NOX-A12 to market as quickly as possible for the benefit of patients suffering from this devastating and aggressive cancer for which there is extremely poor prognosis."*

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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.

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.

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