TME PHARMA ANNOUNCES SUCCESSFUL ADVICE MEETING WITH US FOOD AND DRUG ADMINISTRATION ON NOX-A12 DEVELOPMENT IN BRAIN CANCER

- **Constructive meeting held with FDA provided feedback and clear guidance on key aspects of further development of NOX-A12 combinations for the treatment of glioblastoma**
- **Preparatory work on-track to open IND and to have feedback on access to expedited regulatory pathway by end of Q1 2024**

Berlin, Germany, January 09, 2024, 06.00 p.m. CET – 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 it successfully completed its pre-IND advice meeting with the US regulator, the Food and Drug Administration (FDA), discussing plans for the further clinical development of NOX-A12 as a treatment of aggressive adult brain cancer, glioblastoma. Based on the feedback received, *TME Pharma* confirms that it is on track with preparations to file its Investigational New Drug (IND)[1] application and the expedited regulatory pathway request on a timeline that will allow successful completion of both by the end of Q1 2024.

"The informative discussion with the FDA allows our team to prepare an IND application that fits with the requirements of the US regulator in areas where there has been recent evolution in recommendations by the FDA's Oncology Center of Excellence, such as the selection of the appropriate therapeutic dose of new oncology drugs[2]," said **Aram Mangasarian, CEO of TME Pharma**. *"As a result, we are confident to be able to meet our target of having an FDA approved clinical trial protocol in glioblastoma with an expedited regulatory path in the US by the end of Q1 2024 in order to secure the funding for the necessary clinical trial via partnership, investment or other strategic transaction types. While the company plans to provide further updates on the status of applications during the ongoing discussions, the final trial design will be shared once the FDA has completed its assessment. We believe that the combination of a defined regulatory path and the mature data from the GLORIA brain cancer trial will, together, form an attractive package for potential partners."*

[1] Investigational New Drug (IND), the authorization from the FDA to administer an investigational drug or biological product to patients in the US as part of a clinical trial.
[2] See *Project Optimus – Reforming the dose optimization and dose selection paradigm in oncology* at Project Optimus | FDA.

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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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