

## **TME PHARMA ANNOUNCES ADDITIONAL DATA FROM NOX-A12 COMBINATION REGIMEN IN BRAIN CANCER PRESENTED AT SNO 2023 ANNUAL MEETING**

- **Substantially improved survival and progression-free survival under NOX-A12 treatment combination compared to matched standard of care cohort**
- **Treatment and follow-up of patients in the expansion arm are ongoing with median overall survival continuing to improve**

**Berlin, Germany, November 18, 2023, 08.00 a.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), announced today investigators from the GLORIA trial have presented a poster featuring a clinical update from the ongoing GLORIA Phase 1/2 trial studying NOX-A12, *TME Pharma's* CXCL12 inhibitor, in combination with radiotherapy and anti-VEGF (bevacizumab), at the 2023 **Society for Neuro-Oncology (SNO) Annual meeting**, taking place in Vancouver, Canada, November 15-19, 2023.

*"The Society of Neuro-Oncology Annual Meeting is one of the year's foremost international scientific conferences in the field of brain cancer, so it is a great forum for the clinical investigators leading the GLORIA trial to share NOX-A12's latest impressive clinical achievements,"* said **Aram Mangasarian, CEO of TME Pharma**. *"These unprecedented survival data demonstrate NOX-A12's clinical potential and are providing the basis for our forthcoming discussions with regulators on the next steps for NOX-A12's development in glioblastoma. We are looking forward to updating the market on our progress over the coming months, which we expect will include filings for an Investigational New Drug and expedited regulatory pathways."*

The presentation, entitled *"Interim data on dual inhibition of post-radiogenic angio-vasculogenesis by olaptosed pegol (NOX-A12) and bevacizumab in glioblastoma from the first expansion arm of the Phase 1/2 GLORIA trial"*, highlights the response, survival and safety data as of October 24, 2023, for patients with the aggressive adult brain cancer, glioblastoma, in the GLORIA expansion arm receiving NOX-A12 with the VEGF inhibitor bevacizumab and radiotherapy. All patients recruited in this expansion arm have residual chemotherapy-refractory tumor detectable after maximal safe surgery.

The 67% survival at 18 months observed in patients treated with NOX-A12 + bevacizumab (anti-VEGF) + radiotherapy outperforms by 13-fold the 5% survival seen in the matched group of reference patients

receiving standard of care<sup>1</sup>. At 18.3 months median follow-up, 50% of patients remain alive and the median overall survival is expected to improve further as patients continue to receive treatment or follow-up care<sup>2</sup>. For comparison, the matched standard of care reference cohort achieved a median overall survival of 10.5 months. Median progression-free survival for patients receiving the NOX-A12 combination regimen reached 9 months, compared to 4 months for the matched group of reference patients.

The radiographic response to treatment, which measures the change in size of target tumor lesions as response to treatment, was also highly encouraging with an overall response rate (ORR) of 100%. mRANO<sup>3</sup> response, which also incorporates a clinical assessment, was 83.3%. One patient achieved complete response (CR) as per mRANO, meaning the tumor disappeared completely and was no longer detectable by MRI, and the patient was in good clinical condition. Two additional patients achieved a reduction in tumor size of more than 99%, leading to 50% of patients in the GLORIA trial expansion arm achieving a complete or near-complete response.

The poster with the most recent data is available on the [TME Pharma website](#).

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<sup>1</sup> Matched reference cohort of 20 patients from Giordano et al (2022 SNO Poster).

<sup>2</sup> In a clinical study, measuring the median Overall Survival (mOS) is one way to assess how well a new treatment works. The longer the patients remain alive, the longer it takes to reach mOS. mOS can only be calculated when more than half of patients in the study have deceased.

<sup>3</sup> modified Response Assessment in Neuro-Oncology.

## 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](http://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.