



# TME PHARMA ANNOUNCES PUBLICATION OF ABSTRACT DISCLOSING POSITIVE INTERIM RESULTS FROM BEVACIZUMAB EXPANSION ARM OF NOX-A12 GLORIA PHASE 1/2 BRAIN CANCER CLINICAL TRIAL

# ADDITIONAL AND UPDATED DATA TO BE PRESENTED DURING SNO 2022 ANNUAL MEETING ON NOV 18, 2022

- Data show 83% of chemotherapy refractory patients achieved radiographic partial response
- All radiographic partial responses remained durable at a median follow up of 5.6 months
- Mean tumor reduction at best response was -65.9% for target lesions, -92.1% for nontarget lesions
- 12-month survival data expected in Q2 2023

Berlin, Germany, November 11, 2022, 01:00 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), announced today publication of the submitted abstract by conference organizers of positive interim data from the GLORIA Phase 1/2 clinical trial expansion arm with NOX-A12 combined with radiotherapy and bevacizumab (biosimilar of Avastin®) in first-line MGMT unmethylated brain cancer (glioblastoma) patients. A poster presentation containing additional and updated data will be presented by Dr. Frank A. Giordano, the principal investigator of the GLORIA study at the Society for Neuro-Oncology (SNO) Annual Meeting on Friday November 18, 2022 starting at 07:30 p.m. EST (01:30 a.m. CET on November 19, 2022) in Tampa, Florida, US.

The interim data from the published abstract show that five out of six patients (83.3%) achieved radiographic partial responses, which remained durable at a median follow-up of 5.6 months (range 3.6 to 9.3 months). Patients with MGMT-unmethylated brain tumors (refractory to chemotherapy) are particularly challenging and respond only rarely to standard of care. The GLORIA data compare favorably to a matched historical reference cohort of 20 glioblastoma patients treated with standard of care, where only 10% of patients achieved partial responses.

In the GLORIA Phase 1/2 brain cancer trial in combination with bevacizumab, the mean best response in tumor size reduction was -65.9% (-13.3% to -99.9%) for sum of target lesion and -92.1% (-76.2% to -100%) for sum of non-target lesions (NTL). In all three patients with NTL, at least one lesion disappeared. Advanced MRI parameters showed reduced blood flow to targeted tumor lesions vs. baseline in all patients, consistent with the anticipated mechanism of action of preventing tumor blood vessel regrowth. Importantly, the neurological function of patients receiving NOX-A12 + RT +

bevacizumab remained stable during follow-up as assessed by a scale adapted to patients with brain tumors, the Neurologic Assessment in Neuro-Oncology (NANO) scale.

"This abstract presents a brief overview of the status of the ongoing bevacizumab expansion arm of the GLORIA trial from several months ago which strengthens the previously published safety and efficacy profile of NOX-A12," said Aram Mangasarian, CEO of TME Pharma. "The data that will be presented at the conference by Dr. Giordano next week on November 18 are more recent and will go into significantly more detail on the follow-up of the patients enrolled in the bevacizumab expansion arm of the NOX-A12 GLORIA trial. I encourage investors interested in better understanding this data to attend the planned webinar on November 22 to hear Dr. Giordano explain the results."

Details of the poster presentation at the SNO are as follows:

**Presentation Title**: Dual inhibition of post-radiogenic angio-vasculogenesis by olaptesed pegol (NOX-A12) and bevacizumab in glioblastoma – interim data from the first expansion arm of the German phase 1/2 GLORIA trial.

Abstract: download

Session Title: Poster Session

Session Date: Friday, November 18, 2022

Presentation Time: 07:30 – 09:30 p.m. EST (01:30 – 03:30 a.m. CET, November 19, 2022)

Presenter: Dr. Frank Giordano, Professor and Chair of the Department of Radiation Oncology at the

University Medical Center Mannheim, Germany.

Dr. Giordano will discuss the data presented at the SNO in a dedicated webinar on November 22, 2022. Participants are required to <u>register for the webinar</u> in advance.

Preliminary data of the GLORIA Phase 1/2 study expansion arm evaluating NOX-A12 in combination with radiotherapy and bevacizumab in glioblastoma patients were previously announced on <u>June 23</u>, 2022.

# For more information, please contact:

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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. 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.

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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**

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