



# TME PHARMA PROVIDES POSITIVE CLINICAL UPDATE AND 14-MONTH SURVIVAL DATA FROM GLORIA EXPANSION ARM EVALUATING NOX-A12 IN COMBINATION WITH RADIOTHERAPY AND BEVACIZUMAB IN GLIOBLASTOMA

- 83% of glioblastoma patients remain alive after 14 months on study,
   a percentage well above what is expected for the enrolled population of chemotherapy refractory patients
- Survival data will improve further as time progresses and patients remain on study
- Continued strong performance improves NOX-A12 profile for partnering and eligibility for accelerated regulatory pathways

Berlin, Germany, May 25, 2023, 06.00 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 clinical update on survival of newly diagnosed glioblastoma patients in the GLORIA expansion arm evaluating NOX-A12, *TME Pharma's* CXCL12 inhibitor, in combination with standard of care radiotherapy and anti-VEGF, bevacizumab.

After 14 months on study (median), 83% of GLORIA expansion arm patients (5 of 6) are still alive. As long as treatment or follow-up for these patients is ongoing, median overall survival (mOS) will continue to improve. As a reference, the expected median overall survival for patients under current standard of care with chemotherapy refractory tumors (MGMT unmethylated) and whose tumor remains detectable after surgical intervention is approximately 10 months.

"The fact that the glioblastoma patients are 14 months on study and median overall survival will continue to improve is a very positive clinical development. It demonstrates a clinically meaningful improvement over the 10-month expected survival rate for this patient population as well as the median overall survival of 12.7 months achieved in the GLORIA cohort treated with NOX-A12 and radiotherapy alone," said Aram Mangasarian, CEO of TME Pharma. "The latest survival data from the treatment combination of NOX-A12 with radiotherapy and bevacizumab continues to validate our therapeutic approach, demonstrates a highly encouraging trend towards prolonged overall survival and underlines the potential for superior benefit of this treatment combination for glioblastoma

<sup>&</sup>lt;sup>1</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 decease.

<sup>&</sup>lt;sup>2</sup> Kreth 2013, Annals of Oncology 24:3117. Rounded up from mOS 9.7 months reported in patients with incomplete resection, without MGMT promoter methylation who received standard of care (radiotherapy +/-chemotherapy).

patients. We believe that this further improves the profile of NOX-A12 for partnering discussions and for access to accelerated regulatory pathways in glioblastoma, which we estimate to be \$2.5 billion per year addressable market. We are looking forward to providing more clinical updates as the data mature."

### For more information, please contact:

### TME Pharma N.V.

Aram Mangasarian, Ph.D., CEO 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 has been approved in France and Spain and is in discussion with regulatory authorities in 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.

TME Pharma® and the TME Pharma logo are registered trademarks.

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

Visit TME Pharma on LinkedIn and Twitter.

#### **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.