



TME PHARMA PROVIDES POSITIVE DATA UPDATE ON BEST RESPONSE TO THERAPY WITH FIRST COMPLETE RESPONSE IN GLORIA TRIAL IN GLIOBLASTOMA, BRINGING 50% OF PATIENTS IN EXPANSION ARM TO COMPLETE OR NEAR-COMPLETE RESPONSE

Berlin, Germany, July 13, 2023, 08.00 a.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 a positive clinical update on the best response to therapy, reporting one patient achieving complete response in the GLORIA expansion arm evaluating NOX-A12, *TME Pharma's* CXCL12 inhibitor, in combination with standard of care radiotherapy and anti-VEGF, bevacizumab, in first-line glioblastoma.

One patient (out of 6) in the expansion arm with a previous best response of 89.9% tumor shrinkage has achieved complete response, meaning **the tumor disappeared completely and was no longer detectable by MRI**. The complete response comes in addition to 2 patients with reported near-complete reductions (>99%) in tumor size, leading to 50% of patients in the GLORIA trial expansion arm achieving a complete or near-complete response.

"We are very pleased to report this highly positive update from the expansion arm of our GLORIA clinical trial evaluating our lead asset NOX-A12 in combination with radiotherapy and bevacizumab in glioblastoma," said Aram Mangasarian, CEO of TME Pharma. "It is very encouraging to see one patient achieve no detectable tumor and two patients coming extremely close to complete response, achieving a reduction in tumor size of more than 99 percent. This complete response took about 12 months of therapy to achieve, underlining the importance of mature data to fully evaluate the power of NOX-A12-based therapy. Taken together with the promising picture emerging from our survival data, it is becoming clearer that NOX-A12 used in this treatment combination can provide clinically meaningful benefit over standard of care for brain cancer patients, who currently have such limited therapeutic options."

The <u>latest survival data reported from the GLORIA expansion arm</u> demonstrated that after 15 months on study (median), 83% of 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 improve¹. As a reference, the expected median overall survival for patients under current standard of care with chemotherapy

¹ 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.

refractory tumors (MGMT unmethylated) and whose tumor remains detectable after surgical intervention is approximately 10 months².

In November 2022, <u>TME Pharma</u> announced interim results from the GLORIA expansion arm that demonstrated:

- 100% of target lesions treated with the triple combination of NOX-A12, radiotherapy and bevacizumab were reduced by more than 50% as measured by MRI.
- 5 of 6 patients (83%) achieved durable partial responses (PR) by mRANO criteria³, which take into account radiographic response as well as other factors such as the clinical condition of the patient. One patient experienced progressive disease (PD) due to distant failure while target lesion control was maintained.
- The triple combination was well tolerated and safe. No dose-limiting toxicities were observed.

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² 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).

³ 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. 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.

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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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