TME PHARMA ANNOUNCES ENROLLMENT OF FIRST PATIENT IN PEMBROLIZUMAB EXPANSION ARM OF NOX-A12 GLORIA PHASE 1/2 BRAIN CANCER CLINICAL TRIAL

Berlin, Germany, August 03, 2022, 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), announced today that the first patient was enrolled and has received their first week of treatment in the GLORIA Phase 1/2 clinical trial expansion arm with NOX-A12 combined with radiotherapy and the PD-1 immune checkpoint inhibitor pembrolizumab.

Once this first patient of this expansion arm has received a four-week treatment of NOX-A12, radiotherapy, and pembrolizumab, the Data Safety Monitoring Board will convene to determine whether it is safe to recruit the remaining five patients into the arm.

"We are very pleased to have dosed our first patient in this GLORIA expansion arm combining NOX-A12 with radiotherapy and pembrolizumab in brain cancer patients," said **Aram Mangasarian, CEO of TME Pharma.** *"We continue to make progress in our clinical evaluation of NOX-A12 in glioblastoma in multiple combination approaches, which have so far yielded exciting and very promising results. We aim to demonstrate the potential of NOX-A12 in this challenging and aggressive cancer to support our strategic focus on bringing NOX-A12 to market as soon as possible, for the benefit of patients, physicians, and our shareholders."*

The expansion arms of the GLORIA trial will each enroll 6 patients with recruitment ongoing at 6 clinical sites. The clinical sites are now focused on patient recruitment into the second expansion arm with pembrolizumab after having completed recruitment of patients in the expansion arm with bevacizumab.

Initial data from the bevacizumab expansion arm exploring the triple combination of NOX-A12, radiotherapy and bevacizumab reported by the company on June 23, 2022, showed reduced tumor size and radiographic partial response (defined as tumor size reduction of more than 50%) in 100% of evaluable patients, with tumor size reductions ranging from -54.7% to -94.7%.

Data from the NOX-A12 dose-escalation part of the clinical trial were reported at ASCO 2022 in June and showed that 90% of patients who received NOX-A12 and radiotherapy achieved tumor size reductions and 40% of patients achieved partial response. *TME Pharma* aims to disclose more detailed data, including longer follow-up at a scientific conference later this year.

The data generated from the GLORIA trial dose-escalation and expansion arms will form the basis of discussions with the US FDA and European regulators on the optimal regulatory path, which are expected to take place in Q4 2022.

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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.

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