TME PHARMA RECEIVES INVESTIGATIONAL NEW DRUG (IND) APPROVAL FOR NOX-A12 FROM THE US FDA

Positive decision grants permission for NOX-A12 to be evaluated in clinical trial in the US in addition to Europe

Berlin, Germany, June 15, 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), announced today that the US Food and Drug Administration (FDA), after reviewing the comprehensive submission, has approved the company's Investigational New Drug (IND) application to evaluate the company's lead asset NOX-A12 in a Phase 2 study in pancreatic cancer (OPTIMUS) in the United States.

OPTIMUS is an open-label Phase 2 study designed to evaluate the safety and efficacy of NOX-A12 combined with anti-PD-1 pembrolizumab (Keytruda® from Merck) and two different chemotherapy regimens (nanoliposomal irinotecan/5-FU/Leucovorin or gemcitabine/nab-paclitaxel) in second-line pancreatic cancer. The study is expected to enroll approximately 70 patients in clinical sites in the US, as well as France and Spain, where the study has been previously approved.

"*The US Food and Drug Administration's approval of our IND application is an important milestone for TME Pharma, as it represents the first review and approval of NOX-A12 – and more broadly the first review of our class of compounds – by the FDA. Now we will be able to test NOX-A12 in clinical trials in the US, and this is a very positive piece of news for the future development of NOX-A12. We have thus delivered on our promise to the market to bring the OPTIMUS IND application with the FDA to successful completion, allowing rapid resumption of the pancreatic cancer program once financing is available*," said Aram Mangasarian, CEO of *TME Pharma*.

As announced in June 2022, *TME Pharma* is currently focusing its capabilities on the development of NOX-A12 in glioblastoma. Therefore, the OPTIMUS Phase 2 trial in second-line pancreatic cancer will be initiated once appropriate funding becomes available.

NOX-A12 is currently being developed in GLORIA, a Phase 1/2 study evaluating NOX-A12 in combination with radiotherapy and with or without bevacizumab in first-line glioblastoma brain cancer (glioblastoma) patients with tumors resistant to standard chemotherapy (with unmethylated MGMT promoter). Interim data reported to date from GLORIA demonstrate that NOX-A12 has an excellent safety profile with extremely encouraging signs of efficacy showing an 83% rate of survival at 14 months in patients with detectable chemotherapy refractory tumor remaining after surgery.

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.