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TC BioPharm Announces Submission of Investigational New Drug (IND) Application to U.S. FDA for Treatment of Relapse/Refractory AML

- *Filing is supported by strong clinical data and IND enabling pre-clinical data associated withTCB-008 in treatment of Acute Myeloid Leukemia*

EDINBURGH, Scotland , Oct. 23, 2023 /PRNewswire/ -- TC BioPharm (Holdings) PLC ("TC BioPharm" or the "Company") (NASDAQ: TCBP) a clinical stage biotechnology company developing platform allogeneic gamma-delta T cell therapies for cancer, today announced submission of an Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA) for the use of TCB-008 in the treatment of relapse/refractory Acute Myeloid Leukemia. TCB-008, an allogeneic unmodified gamma delta t-cell, is the Company's lead product and is currently in Phase 2b trials in the U.K. for the treatment of AML.).

The IND application leverages pioneering research on the use of Gamma Deltas in the treatment of relapse/refractory Acute Myeloid Leukemia. TCB-008 has been designated Orphan Drug Status in the treatment arena of AML previously.

"Filing of the IND for TCB-008 is the next step in the clinical development of TCB-008 and aligns with our strategic refocus announced in Q2 of this year to target our clinical strategy to US trials in the future." said Bryan Kobel, Chief Executive Officer of TC BioPharm. "The IND application leverages supporting clinical study data from ongoing studies in patients with Acute Myeloid Leukemia and is also a reflection of substantial pre-clinical IND enabling work done over the course of the last 6 months by the TCB team. I would like to thank our entire team, who worked tirelessly to complete the Company's first ever US FDA trial filing. We look forward to working closely with the FDA to garner acceptance of our IND over the coming 30 days and advancing our lead candidate through clinical phases of development."

The FDA will review the application and determine the acceptability of the data before TC BioPharm begins its first clinical trial for TCB-008 It is possible that the FDA will require additional information.

About OmnImmune®

OmnImmune® an allogeneic unmodified cell therapy consisting of activated and expanded gamma delta T cells. The trial, for treatment of patients suffering from relapse/refractory Acute Myeloid Leukemia (AML). The therapeutic comprises GDT cells sourced from healthy donors, expanded and activated in large numbers before being purified and formulated for infusion into patients. OmnImmune® is a frozen and thawed product, now "banked" from donor derived cells.

About TC BioPharm (Holdings) PLC

TC BioPharm is a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of gamma-delta T cell therapies for the treatment of cancer with human efficacy data in acute myeloid leukemia. Gamma-delta T cells are naturally occurring immune cells that embody properties of both the innate and adaptive immune systems and can intrinsically differentiate between healthy and diseased tissue. TC BioPharm uses an allogeneic approach in both unmodified and CAR modified gamma-delta T cells to effectively identify, target and eradicate both liquid and solid tumors in cancer.

TC BioPharm is the leader in developing gamma-delta T cell therapies, and the first company to conduct phase II/pivotal clinical studies in oncology. The Company is conducting two investigator-initiated clinical trials for its unmodified gamma-delta T cell product line - Phase 2b/3 pivotal trial for OmnImmune® in treatment of acute myeloid leukemia using the Company's proprietary allogeneic CryoTC technology to provide frozen product to clinics worldwide. TC BioPharm also maintains a robust pipeline for future indications in solid tumors as well as a significant IP/patent portfolio in the use of CARs with gamma-delta T cells and owns our manufacturing facility to maintain cost and product quality controls.

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