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TC BioPharm Announces Successful Completion of Safety Cohort and Positive DSMB Results

- *No Significant Safety Concerns Observed in Safety Cohort*
- *Management expects to expand ACHIEVE trial in Q1*

EDINBURGH, Scotland, Nov. 14, 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, announces today that the Company has successfully completed its Safety Cohort and received positive review from the Data Safety Monitoring Board (DSMB).



The DSMB review was held after completion of enrollment of the initial cohort of the ACHIEVE trial and examined the safety data from all patients enrolled to ensure of no dose limiting toxicities or drug related serious adverse events. TC BioPharm's trial involves administering TCB008, dubbed OmniImmune® in the UK, to treat Acute Myeloid Leukemia in a large swathe of patient population. Management now intends to move the ACHIEVE Trial forward with enrollment and will continue dosing patients for the phase 2B clinical trial beginning in 2024, with an additional 14 patients to be dosed prior to an interim look at data. TC BioPharm expects to propose amendments to the existing protocol of ACHIEVE to better align ACHIEVE and ACHIEVE 2 protocols in dosing and other areas in an effort to generate a more heterogeneous data set across trials.

"This positive safety review marks an important milestone in the development of our allogeneic gamma delta platform, building on the strong safety profile that we previously established for our novel therapeutic," said Bryan Kobel, Chief Executive Officer of TC BioPharm. "We expect the trial to enroll well in 2024, as we believe there is a high degree of interest in our therapeutic and a growing recognition of the role gamma deltas play in the fight against cancer. We will begin redosing in ACHIEVE based on the compelling existing therapeutic profile. While the process has been relatively slow getting to this point in ACHIEVE, we believe those headwinds to have subsided and been addressed by our team and we look forward to a more rapid open enrollment throughout 2024 now that the safety portion of the trial is complete."

The [global market for acute myeloid leukemia](#) is anticipated to reach \$3.2 billion by 2029, growing at a CAGR of 9.1% over the forecast period, driven by introduction of high-priced

products, and a strong pipeline of upcoming candidates.

About OmniImmune®

OmiImmune® an allogeneic unmodified cell therapy consisting of donor derived, 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.

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 OmiImmune® 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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