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TC BioPharm Announces FDA Clearance of Phase 1B IND for TCB-008 in Acute Myeloid Leukemia

EDINBURGH, Scotland, Nov. 27, 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, announced today that the FDA provides clearance on the Company's investigational new drug (IND) application for a Phase 1B study in relapse/refractory Acute Myeloid Leukemia (AML).

The Phase 1B study, dubbed ACHIEVE2, will be a 9 patient, dose escalating study measuring for safety and dose optimization. The Open-label, multi-center study conducted in 2 parts (dose escalation followed by dose expansion) will evaluate safety, persistence/expansion, and preliminary efficacy of single and multiple IV doses of TCB008 in patients with AML or MDS/AML. Patients may be reinfused with TCB008 up to 3 times following initial infusion as deemed appropriate by the investigator or designee should protocol specified criteria be met.

"The acceptance of the TCB-008 IND is a significant milestone for TC BioPharm and reflects execution of our strategic plan which we announced to shareholders in April. TC BioPharm will continue to work towards its primary goal of establishing a better method of treatment for the millions of people around the world suffering blood and bone marrow cancer as we establish TCB008 the standard of care for these patients, with higher quality of life and extended remission of these devastating diseases," said Bryan Kobel, Chief Executive Officer of TC BioPharm.

Additionally, the Company will be continuing the UK ACHIEVE trial in AML, expecting to submit amendments to the protocol before year-end to align the dosing and other criteria with the ACHIEVE2 trial of TCBP's lead product.

Mr. Kobel continued, "TCB-008 has shown promising results previously as a therapeutic in late stage AML patients and we believe the safety profile and mechanism of action combine to make the asset a therapeutic for a number of blood related cancers, as well as an ideal combination treatment in oncology indications. As we look to 2024, we see copious milestones and inflection points, both in our US trial as well as our ongoing ACHIEVE trial and our platform expansion. Since announcing our refocused strategy this year, TC BioPharm has continued to execute and deliver key milestones. We expect to continue to

execute in 2024 and appreciate shareholders believing in our vision. Our team will maintain its focus on expanding our platform and generating strong clinical data as the leader in the gamma delta space, and we expect shareholder value will improve accordingly."

About TCB008 (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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