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TCBP Announces MHRA Acceptance of Amendment for ACHIEVE UK Trial

- *Increases dose level in line with Cohort 2 in IND*
- *Changes from "in patient" to "out patient" procedure*

EDINBURGH, Scotland, Feb. 22, 2024 /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 and other indications, today announced that the MHRA has officially accepted its proposed amendment to the Company's clinical trial authorisation (CTA). The amendment allows for an increase in dosing size of TCB008 (unmodified expanded gamma delta T cell Lymphocytes) to 12x10^7-23x10^7 gamma delta t-cells.

Additionally the amendment allows for patients to be treated as "out patients", easing the burden on patients and lessening the burden on clinical sites as patients will not need to be monitored overnight after the first five patients are dosed. The ACHIEVE trial is a Phase 2b trial in Acute Myeloid Leukemia testing efficacy for TCBPs lead product TCB-008 (Omnimmune).

Medical and Healthcare Products Regulatory Agency (MHRA) is the UK regulatory authority, a government agency, for medicines and medical devices. The MHRA is responsible for the regulation of medicines and medical devices and equipment used in healthcare and the investigation of harmful incidents.

Bryan Kobel, Chief Executive Officer of TC BioPharm stated, "Management is pleased to receive amendment clearance from the MHRA, this is yet another example of the team executing on plans we have laid out for the investment community. The changes to the protocol will substantially impact both the timing of data in the ACHIEVE trial as well as impacting the proposed FDA trial. Shifting to an out patient procedure means patients in the trial are not forced to spend a night in the hospital, increasing their quality of life in a difficult time, and also allows hospitals to not need to hold a bed for a patient in a time when beds are scarce in the NHS. We believe, after feedback from the clinical sites, that this was a material rate limiting concern in enrolment and are happy we can now provide them relief. Increasing the dose size, in accordance and discussion with our investigators, can increase the positive impact in patients with no safety concerns, furthering our stance that TCB-008 should be used in a myriad of settings at high doses. This step also aligns the dosing levels with the IND, where our second cohort would be receiving this dose, and gives us a window

to approach the FDA with data at this level to potentially go immediately to dose level two in our US Phase 1b in relapse/refractory AML."

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 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.

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