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TCBP Announces Successful Completion of Cohort A in the ACHIEVE Clinical Trial

- No adverse events related to TCB008 have occurred
- Evidence of stable disease following TCB008 infusion

EDINBURGH, Scotland, Feb. 13, 2025 /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 it has concluded dosing of Cohort A patients in the ACHIEVE Phase 2B UK clinical trial.



The available data show a favorable safety and efficacy response in Cohort A patients, patients with relapse or refractory AML. No patients have experienced any drug-related adverse event, and preliminary efficacy data demonstrate a number of patients attaining stable disease following multiple infusions of TCB008.

"We're thrilled to be sharing these preliminary results," stated Alison Bracchi, EVP of Clinical Operations. "These early data points pave the way for future clinical studies, as we consider how the therapeutic effect of TCB008 can be prolonged or enhanced to reverse the disease state in these incredibly sick patient populations. We have additional data review to complete, which will further define our next steps with TCB008, including as a potential bridge to transplant or other combination efforts."

The ACHIEVE trial is an open-label Phase II study dedicated to evaluating the efficacy and safety of TCB008. This trial is focused on assessing the treatment's effectiveness and tolerability in patients suffering from acute myeloid leukemia (AML) and myelodysplastic syndromes (MDS/AML). Cohort A targeted patients who were ineligible for, or had exhausted all, available therapies, as they were unable to achieve remission or had subsequently relapsed following remission.

Cohort A recruitment was re-initiated in July 2024 [using higher doses of TCB008](#) that contained a cumulative dose of up to a billion Gamma Delta T-Cells. Investigator and patient interest in the ACHIEVE trial has allowed the Company to expedite recruitment; as such, enrolment into Cohort A has concluded. Recruitment into Cohort B continues.

"This early safety and efficacy data, obtained in patients with significant unmet clinical need, reiterates our confidence in our lead candidate, TCB008," said Bryan Kobel, CEO of TC

BioPharm. "We're seeing the expedited delivery of data, six months after study re-initiation, signalling a positive safety and efficacy profile for TCB008. This data will shape our approach to clinical development as we continue to investigate how stable disease can be sustained, both to prevent relapse and to progress patients to additional treatment options in conjunction with TCB008."

About TC BioPharm (Holdings) PLC

TC BioPharm is a clinical-stage biopharmaceutical company focused on discovering, developing, and commercializing gamma-delta T-cell therapies for cancer treatment 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 in the treatment of acute myeloid leukemia using the Company's proprietary allogeneic CryoTC technology to provide frozen product to clinics worldwide.

Forward-Looking Statements for TC BioPharm

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this Current Report on Form 8-K that do not relate to matters of historical fact should be considered forward-looking statements, including without limitation statements regarding the Company's intent or ability to affect any budget savings or execute on any M&A or capital raising strategy. These statements are based on management's current assumptions and are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause the Company's actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. For other important factors that could cause actual results to differ materially from the forward-looking statements in this Current Report on Form 8-K, please see the risks and uncertainties identified under the heading "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2023, and our other reports filed with the SEC, all of which is available on the Company's Investor Relations website at www.tcbiopharm.com and on the SEC website at www.sec.gov. All forward-looking statements reflect the Company's beliefs and assumptions only as of the date of this Current Report on Form 8-K. The Company undertakes no obligation to update forward-looking statements to reflect future events or circumstances.

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