

July 22, 2024



TCBP Announces Dosing of 6th Patient in ACHIEVE Study in Patients with Acute Myeloid Leukemia

- *5 patients treated in "safety cohort" showed no drug related Serious Adverse Events*
- *Restart of trial after amendment approved by MHRA to increase dose level*

EDINBURGH, Scotland, July 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 on July 16, the sixth patient in ACHIEVE (UK) was treated. This is the first patient treated with a higher dose of TCB-008 post the amendment approved by the MHRA on Feb 22, 2024.



The ACHIEVE UK clinical trial is an open-label, phase II study designed to evaluate the efficacy and effectiveness of TCB-008 in patients with AML or MDS/AML, with either refractory or relapsed disease. ACHIEVE is comprised of two cohorts representing separate disease states. The protocol allows for either cohort to be advanced as an independent Phase III Pivotal Trial upon completion of the cohort, presuming the primary efficacy endpoints is met.

Cohort A represents relapsed/refractory patients who have been unable to attain remission and are in palliative care as they are unable to tolerate further chemotherapy. Initially, 5 patients were treated at the lower dose. Up to 14 patients may be recruited into this cohort at the higher dose. Pending confirmation of the primary endpoints, a further 10 patients may be recruited into Cohort A for a total of 24 patients.

Cohort B represents patients who have attained remission following prior treatment, however, continue to have a detectable residual disease. Up to 14 patients may be recruited into this cohort at the higher dose. Pending confirmation of the primary endpoints, a further 10 patients may be recruited into Cohort B for a total of 24 patients.

Interim data review is not reliant on the completion of either Cohort, and consequently the Company is not required to complete investigation of both Cohorts prior to advancing to a Pivotal Phase 3 study in one or both Cohorts simultaneously.

Enrolled patients will be treated with an increased dose of TCB-008, containing up to

230,000,000 cells per dose compared to the previous dose of 35,000,000. The increased dose is commensurate with the proposed medium dose cohort in the Company's FDA trial in AML. Eligible patients will receive up to three additional infusions of TCB008, starting 14 days after the previous infusion and administered every subsequent 14 days, representing a total of 4 doses of TCB-008 or approximately 1,000,000,000 cells. Details of the ACHIEVE Study can be found at <https://www.clinicaltrials.gov/study/NCT05358808>

"The dosing and restart of ACHIEVE represents an important milestone in our progress towards Phase 2b efficacy data in AML with an interim data announcement in the next six to nine months, as well as proof in our ability to successfully navigate potentially arduous regulatory and clinical trial environments in both ACHIEVE and ACHIEVE2," said Bryan Kobel, CEO of TC BioPharm. "In addition to dosing our 6th patient and restarting ACHIEVE, we've screened and enrolled additional patients into the trial and expect to dose up to 10 more in 2024 and expect to open at least one additional clinical trial site in Q3. These efforts, combined with additional refinement of TCB-008 over the last 6 months, escalating the dose size in the ACHIEVE trial and existing data, have us poised for inflection points in 2024 and confidence in our ability to continue to execute on our clinical trial plans. Based on the substantial clinical safety and efficacy data to date and encouraging tolerability information generated in the five-patient safety cohort of ACHIEVE, we are excited to realize the potential of TCB-008 as a mono-therapy and continue to pursue partners for combination therapies."

Forward-Looking Statements

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.

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 OmniImmune® in treatment of acute myeloid leukemia using the Company's proprietary allogeneic CryoTC technology to provide frozen product to clinics worldwide.

View original content to download multimedia:<https://www.prnewswire.com/news-releases/tcbp-announces-dosing-of-6th-patient-in-achieve-study-in-patients-with-acute-myeloid-leukemia-302201109.html>

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