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TC BioPharm Announces FDA Orphan Drug Status Granted for OmniImmune®

- *Allogeneic unmodified Gamma Delta product can be stored frozen and used as an 'off-the-shelf' cell therapy*

EDINBURGH, Scotland, March 17, 2022 /PRNewswire/ -- TC BioPharm (Holdings) PLC ("TC BioPharm" or the "Company") (NASDAQ: TCBP) (NASDAQ: TCBPW), a clinical stage biotechnology company developing platform allogeneic gamma-delta T cell therapies for cancer and viral indications, announces orphan drug status has been granted for lead product OmniImmune® for use in Acute Myeloid Leukemia ("AML"). After reviewing the Phase 1b/2a trial results in relapse/refractory AML patients the FDA approved the Company's application for Orphan Drug Status.



"This is another milestone achieved by TC BioPharm, further strengthening our leadership position in Gamma Delta therapies for oncology," stated CEO Bryan Kobel. "The granting of orphan drug status provides us a seven-year window post approval of exclusive marketing rights for allogeneic gamma delta use in AML, another added layer of protection around our lead product in a commercial setting beyond our existing strong IP. We look forward to the advancement of OmniImmune® in the Phase 2b/3 trial and to helping patients with AML in the near future."

Orphan drug status is a designation granted by the Federal Drug Administration for therapies targeting rare diseases. The status allows for a seven-year exclusive marketing window post approval of the drug, certain lowered application fees and tax incentives, broadly.

About OmniImmune®

OmniImmune® 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), OmniImmune® comprises GDT cells sourced from healthy donors, expanded and activated in large numbers before being purified and formulated for infusion into patients. OmniImmune® is a frozen and thawed product, now "banked" from donor derived cells. Phase 2/3 trials will begin enrollment in the first quarter of 2022 in the UK with expansion into the US in 2022.

About TC BioPharm, Ltd.


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 and viral infections 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 banked allogeneic gamma-delta T cell therapies, and the first company to conduct ICH compliant 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 and Phase I trial for ImmuniStim® in treatment of Covid patients using the Company's proprietary allogenic CryoTC technology to provide frozen product to clinics worldwide. TC BioPharm also maintains a robust pipeline for future indications in solid tumors and other aggressive viral infections 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.

Forward Looking Statements

This press release may contain statements of a forward-looking nature relating to future events. These forward-looking statements are subject to the inherent uncertainties in predicting future results and conditions. These statements reflect our current beliefs, and a number of important factors could cause actual results to differ materially from those expressed in this press release. We undertake no obligation to revise or update any forward-looking statements, whether as a result of new information, future events or otherwise. The reference to the website of TC BioPharm has been provided as a convenience, and the information contained on such website is not incorporated by reference into this press release.

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