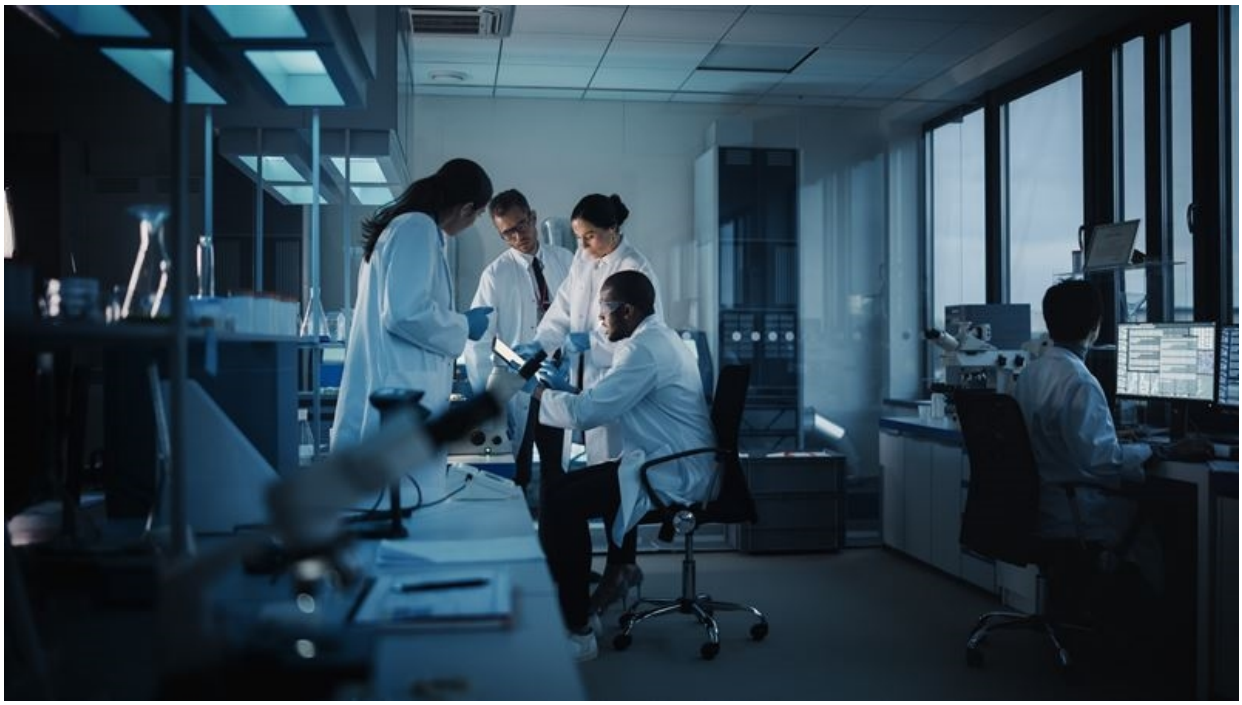
CuraCell Receives CTA Approval for Phase I/IIa Clinical Trial with Innovative TIL Therapy CC-38

Stockholm, Sweden **– CuraCell Holding AB (CuraCell) today announced that the Paul-Ehrlich-Institut (PEI), the German federal authority for vaccines and biomedicines, has approved the company's Clinical Trial Application (CTA) to initiate a Phase I/IIa clinical trial evaluating its novel autologous TIL (Tumor-Infiltrating Lymphocyte) therapy, CC-38, in patients with metastatic colorectal cancer and metastatic prostate cancer. The clinical trial is planned to commence in the second half of 2025.**



TIL therapy harnesses the body's own immune system by expanding tumor-reactive lymphocytes directly extracted from the patient's tumor. CC-38 is built on CuraCell's advanced T-cell activation and enrichment platform, CytoPLY™, which amplifies cytotoxicity through enhanced tumor-specific T-cell functionality and diversity.

The open-label Phase I/IIa trial will enroll up to 16 patients with advanced solid tumors, including colorectal and prostate cancer (EU-CT-Number: 2025-521227-70-00). The study will be conducted at Krankenhaus Nordwest in Frankfurt. The trial will assess the feasibility of repeated administration, with safety and tolerability as the primary objective. Secondary objectives include evaluating preliminary anti-tumor activity and immune responses.

“This CTA approval marks a major milestone for CuraCell and affirms the strength of our science and clinical strategy,” said Jonas Båtelson, CEO of CuraCell. “Our dedicated team, together with our expert collaborators, has worked tirelessly to advance our first TIL therapy from bench to bedside. This is a big step forward in our mission to provide curative treatments for the toughest and most deadly solid tumors.”

About CytoPLY™
CytoPLY™ is an advanced T-cell activation and enrichment platform that boosts anti-tumor cytotoxicity by enhancing tumor-specific T-cell functionality and diversity.

CuraCell’s CytoPLY™ platform represents a significant advancement in T-cell immunotherapy by enabling faster and more potent expansion of tumor-killing T cells than traditional IL-2 methods, broadening the TCR repertoire for greater neoantigen recognition, and enhancing cytokine production and T-cell persistence for stronger, longer-lasting anti-tumor responses.

For more information, please contact:
Jonas Båtelson, CEO
Phone: +46 (0)725 527232
Email: jonas.batelson@curacell.se

About CuraCell
CuraCell is a clinical-stage European immunotherapy company pioneering advancements in the treatment of cold solid tumors. Its unique T-cell activation and enrichment platform, CytoPLY™, enhances the cancer-fighting capabilities of immune cells. By progressing the development of its lead candidate CC-38, CuraCell is committed to make next-generation T-cell therapies more effective and accessible to patients.

CuraCell’s R&D facility and headquarters are located at Campus Karolinska in Solna, Sweden, with clinical operations in Frankfurt, Germany. To learn more, visit www.curacell.se and follow CuraCell on LinkedIn .