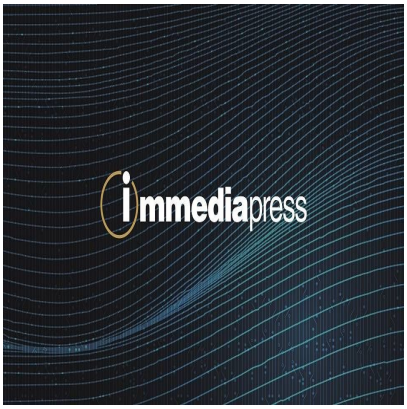

REPROCELL Launches GMP Master Cell Bank Manufacturing for Clinical iPSCs

Descrizione

COMUNICATO STAMPA â?? CONTENUTO PROMOZIONALE

Integrated Workflow Including Clinical Seed Production and StemEdit Gene Editing Services

BELTSVILLE, Md., March 3, 2026 /PRNewswire/ â?? REPROCELL (TYO: 4978) today announced the launch of its US FDA compliant Good Manufacturing Practice (GMP) Master Cell Bank (MCB) manufacturing service for human induced pluripotent stem cells (iPSCs). Operating from its Beltsville, Maryland facility, REPROCELL now offers a comprehensive, end-to-end workflow for clinical iPSC manufacturing. This integrated service spans from StemRNAâ?¢ clinical seed iPSC manufacturing and StemEdit gene editing to GMP Master Cell Bank (MCB) production in compliance with FDA standards. By unifying these critical steps, REPROCELL enables cell therapy developers to accelerate IND submissions while reducing regulatory and manufacturing uncertainty.

As part of this platform, the StemRNA Clinical iPSC Seed Clone â?? LLF-34-F3, derived from US sourced donor material, is supported by an active FDA Drug Master File (DMF). This clone has been expanded into a GMP MCB using FDA-compliant closed system processes. This off-the-shelf GMP iPSC MCB is now available for commercial use, providing ready-to-use clinically validated starting material. For sponsors requiring European alignment, REPROCELL also offers MCB/WCB manufacturing through its partner, Histocell. This service operates with a GMP certificate and authorization from the Spanish Agency for Medicines and Medical Devices (AEMPS) under European Medicines Agency (EMA) oversight.

Key Highlights: Clinical iPSC Capabilities

About StemRNAâ?¢ Clinical iPSC Seed Clone â?? LLF-34-F3StemRNAâ?¢ Clinical iPSC Seed Clone â?? LLF-34-F3 is derived from a healthy O+ female US donor, fully consented for commercial and therapeutic use, and is homozygous at HLA-A and HLA-DPA1 loci enhancing its potential for allogeneic applications. The seed clone meets FDA, EMA and PMDA standards and is supported by a DMF while GMP MCB expansion uses FDA-compliant processes providing a traceable clinically ready starting material.

REPROCELL also offers options of StemRNAâ?¢ Clinical iPSC Seed Clones from different donor profiles.

Dr. Chikafumi Yokoyama, CEO of REPROCELL Inc., commented:â?•By completing clinical iPSC workflow starting from donor screening, seed iPSC manufacturing, StemEdit gene editing, and GMP cell banking under one coordinated framework, we are delighted to provide cell therapy developers a streamlined path for clinical program development. This integrated platform is designed to accelerate IND/CTA submissions while preserving quality, traceability, and global regulatory alignment.â?•

About REPROCELLREPROCELL provides integrated stem cell, gene editing, and GMP manufacturing solutions supporting the entire path from discovery to clinical translation. With clinical grade iPSC generation (StemRNAâ?¢ Clinical iPSC), StemEdit gene editing, and GMP banking capability, REPROCELL serves academic, biotech, and pharmaceutical organizations seeking reliable, regulatory ready cell starting materials and services.

This work was supported by a Commercialization Grant (no. 2024-MSCRFCO-6418) from the Maryland Stem Cell Research Fund (MSCRF)

For more information, visit www.reprocell.com.

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Categoria

1. Comunicati

Tag

1. ImmediaPress

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