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IN-SPACE EXPANSION OF HEMATOPOIETIC STEM CELLS: TECHNICAL PROGRESS, ECONOMIC POTENTIAL, AND COMMERCIALIZATION CHALLENGES

Abstract

Hematopoietic stem cell (HSC) transplantation has revolutionized the treatment of a myriad of critical conditions, including various blood cancers, fatal blood disorders, and severe immune diseases. These stem cells, traditionally sourced from bone marrow, peripheral blood, or umbilical cord blood (UCB), have become a pivotal element in regenerative medicine. UCB-derived stem cells offer significant advantages due to their lower risk of inducing graft versus host disease. However, the primary limitation of UCB is the insufficient quantity of stem cells available, which either confines its use to pediatric patients or results in delayed engraftment and recovery in adults. A potential solution lies in culturing these stem cells in specialized media to expand their numbers, thus enhancing transplant efficacy by reducing engraftment times and improving patient outcomes.

Despite the potential of HSC expansion in a clinical setting, significant challenges remain, notably the loss of the stem cells' multipotent and self-renewal capabilities as they proliferate. This differentiation into specific blood cell progenitors limits their utility over the long term. For the treatment of hematologic malignancies, HSCs need to function for about a decade; however, for applications like gene therapy, particularly in pediatric cases, the requirement extends to several decades.

Addressing these challenges, we propose utilizing microgravity conditions to facilitate HSC expansion while maintaining their essential characteristics for successful transplantation. Our project involves developing specialized bioreactor technology for deployment on the International Space Station (ISS) and future commercial space platforms. This technology aims to support the expansion of HSCs collected on Earth, which are then cryopreserved and transported to space for cultivation. The objective is to produce large quantities of stem cells that can be returned to Earth for clinical use worldwide, potentially

revolutionizing the treatment of an array of medical conditions.

Supported by the In-Space Production Application (InSPA) Phase 1, our project is in the process of developing and testing a novel spaceflight culture system named the BioServe In-space Cell Expansion Platform (BICEP). This initial phase will validate the technology for HSC expansion, with subsequent flight studies aiming to demonstrate that HSCs expanded in space surpass the quantity and quality achievable on Earth, while ensuring genetic stability and clinical safety.

This presentation will discuss the progress to date, including the technological and economic aspects of in-space HSC expansion. It will also address the challenges and future capabilities required to make this innovative approach a viable option for regenerative and transplant medicine.