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Press Release

Celaid Therapeutics Inc.

## **Celaid Therapeutics Advances to NEDO DTSU PCA Phase, Scaling HSC platform for Global Cell and Gene Therapy Manufacturing**

Tokyo, Japan – Celaid Therapeutics Inc. (Headquarters: Bunkyo-ku, Tokyo; CEO: Nobuyuki Arakawa, “Celaid”) today announced that it has successfully completed the STS phase (R&D – Early Stage) of the New Energy and Industrial Technology Development Organization (NEDO) “Deep Tech Startup Support Fund / Program (DTSU)”, and has been newly selected for the PCA phase (R&D – Late Stage) following a favorable third-party evaluation of its R&D and commercialization progress.

This milestone reflects external validation of Celaid’s human hematopoietic stem cell (HSC) expansion platform, which addresses one of the most critical manufacturing bottlenecks in cell and gene therapy.

### **Project Title: HSC Expansion Platform Technology for Cell and Gene Therapy Products**

Celaid is developing a scalable, clinically compatible HSC expansion platform designed to unlock broader commercial deployment of advanced therapies, including:

- Gene-modified HSC therapies
- iPS cell-derived immune and blood cell therapies
- Next-generation regenerative medicine

By enabling reliable and efficient expansion of high-quality HSCs, Celaid aims to position its technology as a foundational manufacturing platform that can be licensed to biotech companies, CDMOs, and global pharmaceutical partners.

### **Market Need: Why HSC Expansion Matters**

Hematopoietic stem cells (HSCs) are the source cells that generate all blood cell types and form the foundation for hematopoietic stem cell transplantation, HSC gene therapies, and next-generation regenerative medicine. Despite their central importance, the extremely limited availability of HSCs and the difficulty of expanding them ex vivo remain major bottlenecks to scalable manufacturing, cost efficiency, and broad clinical adoption across diverse cell and gene therapies.

### **Key Achievements in the STS Phase**

During the DTSU STS phase, Celaid achieved several commercially relevant milestones:

- Broad source compatibility: Demonstrated consistent HSC expansion across multiple sources, including
  - Cord blood-derived HSCs
  - Mobilized peripheral blood-derived HSCs
  - Bone marrow-derived HSCs

- iPS cell-derived HSCs
- Clinical-grade readiness: Completed prototyping of a clinical-grade culture medium, including
  - Optimization of compound combinations
  - Manufacturing and procurement readiness
  - Stability and safety evaluations aligned with regulatory expectations
- Early commercial validation: Through MTAs and collaborative research with partners in the United States, Europe, and Japan, validated the platform's ability to solve customer-specific manufacturing challenges.

These achievements significantly reduce technical and regulatory risk for downstream partners.

### **PCA Phase Focus: Scaling Toward Commercial Adoption**

In the newly adopted PCA phase, Celaid will accelerate R&D aligned with customer and partner needs, including:

1. Three-dimensional (3D) culture systems for scalable HSC expansion
2. Generation and expansion of high-quality iPS cell-derived HSCs
3. Customer-specific data packages to support integration into partner manufacturing workflows

Through these initiatives, we aim to establish our HSC expansion technology as a globally deployable platform that can be provided to gene and cell therapy developers worldwide. Ultimately, we seek to contribute to delivering new therapeutic options for patients suffering from hematologic and genetic diseases.

### **About Celaid Therapeutics Inc.**

Celaid Therapeutics Inc. is a biotechnology startup originating from the University of Tokyo and the University of Tsukuba, developing proprietary technologies for the robust and large-scale expansion of human hematopoietic stem cells. By safely and efficiently expanding human HSCs, Celaid aims to provide the next generation of cell and gene therapy products for cell therapies targeting hematologic and genetic diseases, ex vivo HSC gene therapies for genetic disorders, and angiogenesis for ischemic diseases.

### **Contact Information**

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