Notice Regarding Commencement of U.S. Phase II Clinical Trial for Stemchymal® Stem Cell Drug by Investee (Steminent Biotherapeutics Inc.) and Progress of Global Expansion

March 11, 2026

REPROCELL Inc. (“the Company”) hereby announces that on March 9, 2026, its investee, Steminent Biotherapeutics Inc. (Headquarters: Taiwan; hereinafter “Steminent”), issued an announcement regarding the commencement of a Phase II clinical trial in the United States for "Stemchymal®," a novel stem cell drug candidate for the treatment of Spinocerebellar Ataxia (SCA), as well as progress in its global expansion, including Japan and Taiwan.

While the impact of this matter on the Company's consolidated financial results for the current fiscal year is expected to be immaterial at this time, the Company believes that the enhancement of Steminent’s corporate value will contribute to the appreciation of the Company’s investment asset value over the medium to long term. The Company will promptly disclose any further matters that require public announcement as they arise.

The following is a translation of the release issued by Steminent.
(Reference URL: https://steminent.com/news/view2?news_category_id=3&news_id=21&page=1)

Steminent Biotherapeutics to Launch U.S. Phase II Clinical Trial; Global Deployment Advances on Three Fronts, Listing Plan to Be Promoted This Year

Steminent Biotherapeutics (7729) announced today (9) that its stem cell new drug Stemchymal, for the treatment of Spinocerebellar Ataxia (SCA; cerebellar atrophy), will initiate a Phase II clinical trial in the United States, with the first patient enrollment expected to be completed by September this year. In addition, regulatory approval and commercial mass-production deployment in Taiwan and Japan are being promoted simultaneously. Japan is expected to submit a drug approval application within this year, while Taiwan will proceed on two parallel tracks: project consultation guidance and application for Orphan Drug Designation (ODD).

In response to the launch of the U.S. Phase II clinical trial and the development of new indications, Steminent has planned to conduct a capital increase in the first half of this year, with the scale of fundraising still under discussion. In addition, the company will initiate a listing plan, and after the board of directors discusses the matter in March, related proposals are expected to be approved at the shareholders’ meeting in June.

Steminent stated that the company has conducted an in-depth analysis of the experience of Biohaven's product troriluzole, which encountered setbacks in clinical development and regulatory review. The company has carefully evaluated its trial design, publicly disclosed clinical data, and regulatory focus. Based on this, Steminent will use the latest Real-World Evidence (RWE) with stronger scientific validation as the basis for its clinical trial design, and will formulate a Statistical Analysis Plan (SAP) with the U.S. Food and Drug Administration (FDA) in order to initiate the U.S. Phase II clinical trial.

The U.S. Phase II clinical trial is expected to begin patient enrollment at the University of California, Los Angeles (UCLA) and the University of South Florida (USF). The study will mainly focus on SCA3 patients, with a planned total enrollment of 20 participants and an observation period of two years. The goal is to complete the enrollment of the first patient by September this year, and the preliminary estimate of clinical trial expenditure is within USD 4 million. The project has invited internationally renowned neuroscience authorities Dr. Susan Perlman and Dr. Theresa Zesiewicz to serve as co-principal investigators. Their extensive experience in the field of neurodegenerative diseases and rare disease clinical trials is expected to strengthen the trial design, regulatory coordination, and execution quality, and is anticipated to benefit subsequent regulatory review and product development progress.

Chairperson Wang Ling-Mei stated that Stemchymal has entered a critical stage of global deployment. In addition to the clinical plan in the United States, regarding regulatory approval in the Japanese market, the licensing partner REPROCELL has communicated with Japanese regulatory authorities multiple times over the past year and is expected to submit the application for approval within this year.

Regarding the Taiwan market, in addition to applying for project consultation guidance with the Center for Drug Evaluation (CDE) in accordance with the Regenerative Medicinal Products Act, which came into effect this year, the company has also formally submitted an application to the Ministry of Health and Welfare for Orphan Drug Designation (ODD), proceeding on two tracks in parallel and actively striving for Stemchymal to obtain drug approval in Taiwan as soon as possible.

Senior Vice President Ko Ching-Huai stated that as the U.S. Phase II clinical trial, regulatory approvals in Taiwan and Japan, and mass-production cooperation frameworks are gradually put in place, the company will actively negotiate global commercial licensing for Stemchymal. At the same time, Steminent will continue to evaluate development opportunities for new indications in other neurodegenerative diseases, and engage with potential partners in Southeast Asia, the Middle East, and South Korea, continuously expanding overseas licensing and localized mass-production cooperation opportunities in order to build a complete regenerative medicine ecosystem and establish a global commercialization supply chain.

Source: Investment Media Ltd.