



REPROCELL Submits Application for Manufacturing and Marketing Approval in Japan for Stem Cell Therapy Stemchymal® for Spinocerebellar Ataxia (SCA3 and SCA6)

JAPAN, June 24, 2026 – REPROCELL Inc. today announced the submission of an application for manufacturing and marketing approval in Japan for the regenerative medicine product Stemchymal®, for which the company holds exclusive commercialization rights in Japan. The application seeks approval for the use of Stemchymal® to suppress the progression of ataxia in patients with spinocerebellar ataxia (SCA3 and SCA6).

Under the established framework, Stemchymal® will be manufactured by Taiwan-based Steminent Biotherapeutics Inc., with REPROCELL overseeing all sales and distribution activities within Japan. Notably, Stemchymal® was granted Orphan Regenerative Medicine Product designation (*1) by Japan's Ministry of Health, Labour and Welfare (MHLW) in December 2018. Consequently, the product is eligible for Priority Review, which targets a regulatory review period of nine months from the acceptance of the application (*2).

Chikafumi Yokoyama, CEO of REPROCELL, commented:

"We are highly pleased to announce the submission of the application for manufacturing and marketing approval for Stemchymal® in the treatment of spinocerebellar ataxia (SCA3 and SCA6). Spinocerebellar ataxia is a designated intractable disease characterized by the progressive loss of motor function. With currently limited effective treatments available, there has been a profound unmet medical need for new therapeutic options. We firmly believe that Stemchymal® has the potential to significantly contribute to slowing symptom progression and improving the quality of life (QOL) for these patients. Moving forward, our entire organization remains steadfast in our commitment to securing approval and delivering this groundbreaking therapy to patients as quickly as possible."

Financial Outlook

While the impact of this regulatory submission on the company's consolidated financial performance for the current fiscal year ending March 31, 2027, is expected to be minimal, REPROCELL views this milestone as a significant catalyst that will substantially contribute to the company's further growth and the sustainable enhancement of corporate value over the medium to long term. The company will promptly disclose any future material developments as they arise.

***1: Orphan Regenerative Medicine Product Designation**

A regenerative medicine product designated by the Minister of Health, Labor and Welfare that meets specific criteria regarding the "number of target patients," "medical need," and "feasibility of development." To qualify, the product must target a disease affecting fewer than 50,000 patients in Japan, with either no appropriate alternative treatments available or the expectation of significantly higher efficacy or safety compared to existing therapies. Products receiving this designation are eligible for comprehensive support measures, including priority clinical trial consultations and priority regulatory reviews.

***2: PMDA Review Schedule**

For further information regarding the review schedule for regenerative medicine products, please refer to the Pharmaceuticals and Medical Devices Agency (PMDA) website:

<https://www.pmda.go.jp/review-services/drug-reviews/about-reviews/ctp/0008.html>