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REPROCELL seeks Japan approval for stem cell therapy in spinocerebellar ataxia

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The application covers Stemchymal, a regenerative medicine product intended to suppress disease progression in patients with SCA3 and SCA6.

REPROCELL has submitted an application for manufacturing and marketing approval in Japan for Stemchymal, a regenerative medicine product for spinocerebellar ataxia.

The application seeks approval for Stemchymal to suppress progression of ataxia in patients with spinocerebellar ataxia types 3 and 6. REPROCELL holds exclusive commercialisation rights for Stemchymal in Japan, while Taiwan-based Steminent Biotherapeutics will manufacture the product.

This is relevant because spinocerebellar ataxia is a progressive and intractable neurological disease that leads to worsening motor dysfunction. Patients have limited effective treatment options, creating a strong unmet need for therapies that can slow disease progression rather than only manage symptoms.

Stemchymal is a stem cell-based regenerative medicine product. It was granted Orphan Regenerative Medicine Product designation by Japan’s Ministry of Health, Labour and Welfare in December 2018. This designation provides access to support measures such as priority clinical trial consultation and priority regulatory review.

The regulatory pathway is important because Japan has one of the more developed frameworks for regenerative medicine products. Under the priority review system, the target review period by the Pharmaceuticals and Medical Devices Agency is nine months from acceptance of the application.

For REPROCELL, the submission is a significant commercial and regulatory milestone. The company said the near-term financial impact for the fiscal year ending March 31, 2027 is expected to be minimal, but views the milestone as important for medium- to long-term growth.