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NIPRO CORPORATION

News Release

STEMIRAC®, NIPRO's Regenerative Medical Product for Spinal Cord Injury, Receives Full Approval in Japan

First regenerative medical product in Japan to progress from conditional and time-limited approval to full approval*

Osaka, Japan – November 16, 2026 – NIPRO CORPORATION today announced that it has received full marketing approval from Japan's Ministry of Health, Labour and Welfare (MHLW) for STEMIRAC® for Injection ("STEMIRAC"), a regenerative medical product co-developed with Sapporo Medical University. The approval was granted on November 16, 2026. "Full approval" here means the marketing approval granted, following a new application, to a regenerative medical product that had previously received conditional and time-limited approval.
STEMIRAC is indicated for the improvement of neurological symptoms and functional impairment associated with spinal cord injury. It is the first regenerative medical product in Japan* to receive full approval after conditional and time-limited approval.

From conditional approval to full approval
STEMIRAC was designated under the MHLW's SAKIGAKE Designation System in February 2016 and received conditional and time-limited approval in December 2018 under Japan's regulatory framework for regenerative medical products. Over the approximately seven years that followed, NIPRO conducted a post-marketing use-results comparative survey in clinical practice, comparing patients who received STEMIRAC with those who did not, to further evaluate its efficacy and safety. Based on the results, NIPRO applied for full approval in November 2025.

Ensuring a stable, sustainable supply
STEMIRAC is manufactured individually for each patient from the patient's own cells at NIPRO's dedicated cell processing facilities in Sapporo and Tokyo. NIPRO will continue to work closely with medical institutions and other relevant parties to ensure a stable supply of STEMIRAC and to advance its initiatives in the field of regenerative medicine.
"STEMIRAC is a regenerative medical product developed in collaboration with Sapporo Medical University," said Tsuyoshi Yamazaki, Representative Board Director, President and CEO of NIPRO CORPORATION. "Within the regulatory and review framework that supports the practical application of regenerative medicine in Japan, we have advanced this work with the cooperation of many stakeholders, through repeated examination and discussion from a wide range of perspectives. I would like to once again express my sincere gratitude to everyone who has contributed along the way."
"We see this approval not as a finish line, but as a new starting point," Yamazaki continued. "To help expand treatment possibilities for patients, we will continue to build knowledge in collaboration with medical institutions, ensure a stable supply, and contribute to the further advancement of regenerative medicine."
This milestone reflects NIPRO's commitment to translating science into practical care for patients, and to its promise of helping people live longer and better lives.

About STEMIRAC® for Injection
STEMIRAC® for Injection is a regenerative medical product consisting of autologous bone marrow-derived mesenchymal stem cells, developed jointly by Sapporo Medical University and NIPRO CORPORATION. It is approved in Japan for the improvement of neurological symptoms and functional impairment associated with spinal cord injury. It is not approved outside Japan.

About NIPRO CORPORATION
NIPRO is a global healthcare company committed to improving patient outcomes through medical technologies, pharmaceutical solutions, PharmaPackaging, and regenerative medicine. Guided by its promise of helping people live longer and better lives, NIPRO partners with healthcare professionals around the world to deliver safe, reliable, and practical solutions that advance patient care.

* Based on NIPRO research as of November 16, 2026.

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