

S.BIOMEDICS

S.Biomedics Selects Parexel as Contract Research Organization (CRO) to Accelerate U.S. Development of TED-A9 for Parkinson's Disease and Japanese Market Entry

[Seoul, Republic of Korea, April 27, 2026] S.Biomedics today announced the company has selected Parexel, a leading global clinical development partner, as its clinical trial partner for the clinical development of TED-A9, a cell therapy for Parkinson's disease, in the U.S. and Japan.

Under this partnership, Parexel will oversee U.S. clinical trial operations and lead pre-consultation with the relevant regulatory authorities, while also participating in subsequent activities to support the company's clinical development in Japan. This strategic collaboration, through which Parexel will support clinical development in both the U.S. and Japan, supports S.Biomedics' multi-track commercialization strategies, encompassing the U.S. confirmatory clinical trial, the accelerated commercialization pathway in South Korea under the proposed amendment to the Act on the Safety of and Support for Advanced Regenerative Medicine and Advanced Biological Products, commonly known as the Advanced Regenerative Bio Act, and conditional approval-based commercialization in Japan.

As one of the world's leading clinical research organizations, Parexel operates over 80 offices globally and has extensive experience conducting clinical trials for multinational pharmaceutical and biotech companies.

In S.Biomedics' domestic Phase 1/2a clinical trial, TED-A9—a cell therapy derived from embryonic stem cells for Parkinson's disease—demonstrated favorable safety and improvements in both motor and non-motor symptoms in 12 patients. The company aims to submit an FDA IND application this year. The company's strategy to enter a U.S. confirmatory clinical trial following a local clinical trial has garnered attention, as it could be the first such case by a Korean company.

Myung-Soo Cho, Head of Research at S.Biomedics, said, "Parexel is an optimal partner with global late-stage clinical trial operating experience and a broad regulatory network. We will move quickly to prepare for the U.S. clinical trial while also advancing clinical development and regulatory engagement for market entry in Japan."

Dr. Charlotte Moser, Chief Medical Officer at Parexel, commented: "We are excited to partner with S.Biomedics to accelerate U.S. clinical development and support their market entry efforts in Japan. Cell therapies represent a profound opportunity for patients with Parkinson's disease. Bringing them safely and efficiently to market requires a clinical development partner with deep operational expertise and first-time quality, with a robust bench of regulatory specialists who understand global regulatory requirements."

The company is advancing U.S. manufacturing capabilities in collaboration with Catalent, a leading global CDMO partner, and has recently secured approximately 40 billion Korean won in funding to support clinical development efforts. Additionally, following the recent referral of the proposed amendment to the Advanced Regenerative Bio Act to the National Assembly's Health and Welfare Committee, there is growing interest in establishing a commercialization pathway for embryonic stem cell-based cell therapies in South Korea.