

StaGen Co., Ltd.

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Pioneering Energy-Based Drug Discovery for Neuro-Muscular Diseases

StaGen Co., Ltd. is a biotech venture company pioneering “Energy-Based Drug Discovery” (Chairman: Naoyuki Kamatani, MD, PhD, President: Junichi Kaku)

Naoyuki Kamatani: **Achieved the world’s first success in gene-based drug discovery (personalized therapy for MTAP-deficient cancers)**. Former Professor at Tokyo Women’s Medical University, former Director at RIKEN Genome Center, former Visiting Professor at the University of Michigan, currently Visiting Professor at Fujita Health University.

SGD-01 is a fixed-dose combination of two existing drugs, febuxostat and inosine, designed to enhance cellular ATP and fundamentally improve neuro-muscular diseases.

Based on the hypothesis that ATP (the cell’s energy currency) deficiency is a root cause of several major diseases.

Target indications: Parkinson’s disease (PD), Alzheimer’s disease (AD), muscular dystrophy, mitochondrial diseases (MD), sarcopenia.

Just as steroids work across multiple diseases by targeting inflammation and immunity, SGD-01 is expected to act across a broad range of conditions via the more fundamental mechanism of “energy”

Clinical evidence: Confirmed safety and efficacy in a total of 65 individuals (**18 healthy volunteers, 47 patients**: PD, MD, AD, ALS, and impaired glucose tolerance).

In a clinical study of **26 PD patients, 2-month treatment led to statistically significant improvement in motor function scores (MDS-UPDRS Part III, P=0.0146)**; results published.

In **2 MD patients, biomarkers improved markedly: BNP decreased by 31% in cardiomyopathy, insulin index increased 3.1-fold in MD-related diabetes**; results published.

A physician-led clinical trial in **24 PD patients is ongoing at Fujita Health University with funding by the Japanese Government**, aiming for proof-of-concept (POC) in 2026.

Patents of SGD-01: **Granted in 13 countries including Japan, the US, China, and the EU (Japanese Patent No. 6153281)**.

Patents for therapeutic use (granted or applied): PD, neurodegenerative diseases (including AD), sarcopenia, MD-related muscle disorders, disuse muscle atrophy, cachexia-related muscle loss, obesity, exercise mimetics, and muscular dystrophy.

Notable points:

US AI-based research identified febuxostat as the most effective FDA-approved drug for AD. Real-world big data analyses in Taiwan, Germany, the US, and Korea have supported its efficacy.

SGD-01 demonstrates overwhelming competitiveness in mechanism, and safety compared to current investigational drugs.

Future plans: NDA submission to the US FDA for PD in 2028, with expansion into such diseases as muscular disorders.

Currently raising funds for a Phase II clinical trial of SGD-01 in muscular diseases.

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