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Phase 1 Clinical Development to Evaluate the Safety and Efficacy of IPS101A Gene Therapy Product for Severe Parkinson's Disease

PAEAN Biotechnology

PAEAN BIOTECHNOLOGY

NEUROLOGY | **Preclinical**

Product Type	Other-Bio.
Indication	Parkinson’s Disease
Target	Mitochondrial defects
MoA(Mechanism of Action)	Restoration of mitochondrial dysfunction via transplantation of exogenous healthy mitochondria
Competitiveness	**Clinical Perspective:** PAEAN has successfully completed Phase 1/2a clinical trials for Polymyositis and Dermatomyositis (PM/DM), validating its therapeutic platform. Key findings include. • **Efficacy:** A single dose delivered therapeutic effects lasting over 12 weeks. Inflammation (Cytokines): **Reduced by 60%.** Muscle Enzyme (CK Levels): **Reduced by 45%.** Muscle Strength (MMT-8): **Improved by 30%.** • **Safety:** **Zero Serious Adverse Events (SAEs)** reported. Clinically validated the **"Hit-and-Run"** mechanism: the drug is cleared quickly (short PK), but the restorative effect persists long-term (long PD). **Competitor Perspective:** From competitive perspective, PAEAN distinguishes itself from competitors through "Superior Source Cells" and "Clinically Proven Safety." **1. Age 0(Zero) Mitochondria (Source Advantage):** Unlike competitors using adult-derived cells or cell lines, PAEAN utilizes **Umbilical Cord MSCs** to harvest "Age 0" mitochondria, which are the youngest and most active. **2. High Purity & Proprietary Process:** A patented isolation process minimizes impurities (DAMPs) to ensure low immunogenicity (Hypoimmunogenic) and yields high-purity, intact mitochondria. **3. Scalable Manufacturing:** Utilizes an Allogeneic (off-the-shelf) approach with a Master Cell Bank (MCB), enabling consistent mass production and frozen storage, unlike autologous methods.
Development Stage	Preclinical
Route of Administration	IV injection