Vitalgen’s Gene Therapy Drug VGN-R09b for Primary Parkinson’s Disease Receives FDA Fast Track Designation

SHANGHAI, CHINA, June 30, 2025 /EINPresswire.com/ -- Shanghai Vitalgen BioPharma Co., Ltd. ("Vitalgen") announced that its gene therapy drug, VGN-R09b, for the treatment of Primary Parkinson’s Disease (PD), has received Fast Track Designation (FTD) from the U.S. Food and Drug Administration (FDA).

Vitalgen office in Shanghai

VGN-R09b received IND approvals in China and the US in 2024, as a first-in-class recombinant adeno-associated virus (rAAV) gene therapy that targets two key pathways for the treatment of Parkinson's Disease (PD). The Phase I/II clinical trials have been ongoing in China since September, 2024, with all six patients dosed in the Phase I dose-escalation study. Safety data shows that the product is well-tolerated with no findings of VGN-R09b-related adverse events. Preliminary efficacy readouts show that VGN-R09b has a rapid onset of action, with significant gait improvements within two weeks post-treatment. The MDS-UPDRS Part III OFF scores decreased significantly after one month, with an average of 25-point improvements (approximately 50% improvements from the baseline) at six months. Overall, the Hoehn-Yahr (H-Y) scores progressively decreased, along with a reduction in oral medication dosages.

The FTD indicates FDA’s recognition of the clinical potential of VGN-R09b, marking an important milestone for Vitalgen’s expansion into the chronic disease area, and it also represents a global breakthrough for a Chinese gene therapy company in the neurodegenerative field. Together with its FDA IND approval in July 2024, this FTD further validates VGN-R09b’s global development potential and will provide expedited support for its future US clinical trials and regulatory filings.

About Fast Track Designation (FTD)

FTD is an FDA program designed to accelerate the development and approval of drugs that treat serious or life-threatening conditions and have the potential to address unmet medical needs. According to the performance report from the FDA's Center for Biologics Evaluation and Research (CBER), over 800 products have applied for FTD, with a success rate of approximately 68%. After receiving FTD, applicants are given the opportunity for frequent discussions with the FDA regarding their drug development plans, thereby increasing development efficiency. If the product meets certain criteria, it can qualify for accelerated approval, priority review, and rolling reviews, which can further accelerate development and market approval processes.

About Parkinson's Disease (PD)

Parkinson's Disease (PD) is the second most common neurodegenerative disease, with fast-growing incidences. It is projected that the global PD patient numbers will increase to more than 25 million by 2050. Current PD treatments are primarily small-molecule drugs for symptom relief. As the disease progresses, patients gradually lose response to oral medication, and significant motor complications persist despite fine-tuning the treatment regimens. There is currently no available treatment to delay disease progression or improve long-term outcomes.

a: Projections for prevalence of Parkinson's disease and its driving factors in 195 countries and territories to 2050: modeling study of Global Burden of Disease Study 2021. BMJ. 2025;388:e080952. doi:10.1136/bmj-2024-080952.

About Vitalgen

Vitalgen was founded in March 2020 as a cell and gene therapy (CGT) company based in Shanghai, China, dedicated to translating cutting-edge CGT technologies into clinically accessible treatments for patients worldwide.

With proprietary intellectual property rights covering three core CGT platforms: ViVec® (AAV manufacturing platform), ViCas® (CRISPR gene-editing platform) and ViLNP® (Lipid nanoparticle delivery platform), Vitalgen has developed a diversified portfolio of innovative CGTs targeting CNS diseases, ophthalmic conditions, metabolic and hematologic disorders, and oncology, including multiple potential First-in-Class (FIC) products.

Up-to-date, Vitalgen has received multiple rounds of investment from renowned venture funds and has established CGT R&D labs and operational centers in the Zhangjiang High-tech Park and a GMP commercial production facility in the Waigaoqiao Free Trade Zone, Shanghai, China.

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