Gb Sciences Poised to Treat Parkinson's Disease with Plant-Inspired Drugs

WHITE PAPER





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Neurodegenerative diseases occur when neurons in the brain and spinal cord begin to deteriorate. The onset of this deterioration usually occurs in mid-to-late life. As the population ages and continues to live longer, especially in the US, incidence of these diseases are expected to soar.

As the second most common neurodegenerative disease, Parkinson's Disease (PD) is already extremely prevalent and the market for treatment and potential cures is tremendous. In 2016, the market for PD drugs was approximately \$3.1 billion. By 2026, this market is expected to grow to \$8.8 billion, with novel drugs poised to lead the way by addressing unmet needs in the current market.

Plant-Inspired Science

Gb Sciences is a dedicated plant-based research and biopharmaceutical drug development company working to meet these unmet needs with therapeutics for PD. Because of their Al-enabled drug discovery platform (PhAROS™) and high throughput cell and animal screening systems, progress in their early development pipeline is accelerated. Exploring the natural plant-based pharmacopeia with modern tools, Gb Sciences is developing better, safer therapeutics, including a potential first-in-class drug. With more than 50% of all drugs approved by the FDA at least initially isolated from plant species, biopharmaceutical research involving plants continues to be fertile ground.

With their patent-pending drug discovery platform, PhAROS™ (Phytomedical Analytics for Research Optimization at Scale), Gb Sciences is able to provide transformative data integration, analytic methods, and visualization tools for the meta-analysis of contemporary and traditional medical knowledge systems. Gb Sciences uses PhAROS' data analytics and machine-learning processes to pre-validate the efficacy of novel combinations of plant-inspired Active Pharmaceutical Ingredients (APIs).



Gb Sciences then validates these novel API formulas using high throughput screening in disease-specific cell and animal models. As in nature, it's often not a single ingredient that works best, but rather, a combination of parts resulting in synergy that is most effective. Next, the ratios of the novel combinations of APIs are refined to create Optimized Therapeutic Mixtures (OTMs). Using modern tools to build upon traditional medicine formulas and traditional plant-based medical preparations, Gb Sciences creates OTMs that are far more therapeutically effective than their individual components when used separately, or the original plant extracts.

To increase productivity and reduce variability, once novel combinations of APIs are discovered and optimized, Gb Sciences works with partners to create synthetic homologues — chemical copies of the natural API compounds. Instead of relying on the whims of mother nature, the most effective APIs can be created as needed in the lab and manufactured at a larger scale under current Good Manufacturing Practices (cGMP) to meet the quality standards required of pharmaceutical drugs. This limits possible variation in efficacy or yield and ensures a steady supply of these 'plantinspired' APIs for research and development.

Fighting Parkinson's Disease



Gb Sciences' novel drug discovery process has led to 5 US and 2 international issued patents, as well as 19 US and 40 international patentpending applications. Last year, Gb Sciences was issued its first patent for the treatment of PD. However, more than ensuring their IP is protected, Gb Sciences has shown that it works.

In an <u>animal study</u> conducted for Gb Sciences by the National Research Council Canada, multiple OTMs discovered by Gb Sciences were tested for safety and toxicology, as well as for proof of concept: acute PD symptom relief. In this study, zebrafish were exposed to OHDA for 72 hours to model PD. They were then exposed to Gb Sciences' OTMs and showed statistically significant PD-symptom reduction.



This included regaining pre-PD movement levels, maintaining a normal startle response, and the reduction of "resting tremors," one of the most common symptoms of Parkinson's. The animal data in this study is being used to support an Investigational New Drug application with both the US FDA and Health Canada.

Gb Sciences expects to file an Investigational New Drug Application (IND) to begin first-in-man clinical trials beginning in Q3 of 2022. Following new drug approval from the US FDA, the official market launch would likely occur between Q3 of 2028 and Q3 of 2029. At this time, the total number of PD patients in the US is estimated to be <u>3 million</u>. With their potential first-in-class drug, Gb Sciences would aim to supply between 2-5% of the US PD patients during the launch period. This represents a target market of up to 150,000 patients in the first cycle and if doses are taken twice a day, over 109 million doses in the first year.

Novel Delivery E

PD is a neurodegenerative disease that impairs body function, meaning more than 50% of PD patients have trouble swallowing. Therefore, typical delivery through pill form can be difficult and lead to non-compliance. After all, it doesn't matter how good a drug is if patients can't take it.

This is why Gb Sciences delivers its therapeutics via oral dissolving tablets (ODTs). By utilizing Catalent Pharma's Zydis(R) platform of ODTs dispersion is virtually instant, typically less than 3 seconds. Due to buccal or sublingual absorption the bioavailability is improved, leading to a faster, more effective treatment.

Competitive Advantage &

Gb Sciences sits in a unique place when it comes to drug development. With their experienced team and lean operations, including partnering to outsource research and development, they are more nimble than both academic researchers and pharmaceutical companies when it comes to the discovery and validation of new drug formulations. Combining high throughput screening with their PhAROS™ drug discovery platform, they're many steps ahead of traditional drug developers by the time they begin testing OTMs in animal models.

As the population ages and lives longer than ever before, the PD market will continue to grow. With new developments, patients are expected to seek out better alternatives to current therapies. By addressing unmet clinical needs with novel drugs and delivery, including a potentially first-inclass therapeutic, Gb Sciences is poised to be a major contributor to the expanding world of PD therapeutics for years to come.

Learn More about GbSciences by visiting gbsciences.com or contact us at info@gbsciences.com.

