



## **BlueRock Therapeutics Receives FDA Fast Track Designation for DA01 in the Treatment of Advanced Parkinson's Disease**

CAMBRIDGE, Mass., July 19, 2021 -- BlueRock Therapeutics LP, a clinical stage biopharmaceutical company and wholly owned subsidiary of Bayer AG, announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for DA01 for advanced Parkinson's disease (PD). DA01, BlueRock's pluripotent stem cell-derived dopaminergic neuron therapy, is under evaluation in a Phase 1 study.

The FDA's Fast Track designation is intended to facilitate the development and review of drug candidates that treat serious conditions and address an unmet medical need. A drug candidate that receives Fast Track designation may be eligible for more frequent interaction with the FDA to discuss the drug candidate's development plan as well as eligibility for accelerated approval and priority review.

"Receiving Fast Track Designation from the FDA is an important step, which will help us further accelerate clinical development of our DA01 cell therapy approach for Parkinson's disease," says Joachim Fruebis, Ph.D., BlueRock's Chief Development Officer. "This is another critical step in the BlueRock mission to create authentic cellular medicines to reverse devastating diseases, with the vision of improving the human condition."

### **About the Trial**

The trial will enroll ten patients in the United States and Canada. The primary objective of the Ph1 study is to assess the safety and tolerability of DA01 cell transplantation at one-year post-transplant. The secondary objectives of the study are to assess the evidence of transplanted cell survival and motor effects at one- and two-years post-transplant, to evaluate continued safety and tolerability at two years, and to assess feasibility of transplantation.

More information about this trial is available at [clinicaltrials.gov](https://clinicaltrials.gov) (NCT#04802733).

### **About Parkinson's Disease**

Parkinson's disease is a progressive neurodegenerative disorder caused by nerve cell damage in the brain, leading to decreased dopamine levels. The worsening of motor and non-motor symptoms is caused by the loss of dopamine-producing neurons. At diagnosis, it is estimated that patients have already lost 60-80% of their dopaminergic neurons. Parkinson's disease often starts with a tremor in one hand. Other symptoms are rigidity, cramping and dyskinesias. Parkinson's disease is the second most common neurodegenerative disorder, impacting more than 7.5 million people, including 1.3 million people in North America.

### **About BlueRock Therapeutics**

BlueRock Therapeutics is an engineered cell therapy company with a mission to develop regenerative medicines for intractable diseases. The company's cell+gene platform enables the creation, manufacture, and delivery of authentic cell therapies with engineered functionality by simultaneously harnessing pluripotent cell biology and genome editing. This enables an approach where, in theory, any

cell in the body can be manufactured and any gene in the genome can be engineered for therapeutic purposes. The platform is broadly applicable, but the company is focused today in neurology, cardiology, immunology, and ophthalmology. In August 2019, the company was acquired by Bayer Pharmaceuticals, for an enterprise value of \$1B in upfront and milestone payments. For BlueRock this marks the next step in the journey to prove degenerative disease is reversible, and to bring our revolutionary new medicines to the patients who desperately need them. For more information, visit [www.bluerocktx.com](http://www.bluerocktx.com).

### **About Bayer**

Bayer is a global enterprise with core competencies in the life science fields of health care and nutrition. Its products and services are designed to help people and planet thrive by supporting efforts to master the major challenges presented by a growing and aging global population. Bayer is committed to drive sustainable development and generate a positive impact with its businesses. At the same time, the Group aims to increase its earning power and create value through innovation and growth. The Bayer brand stands for trust, reliability, and quality throughout the world. In fiscal 2020, the Group employed around 100,000 people and had sales of 41.4 billion euros. R&D expenses before special items amounted to 4.9 billion euros. For more information, go to [www.bayer.com](http://www.bayer.com).

### **Forward-Looking Statements**

*Certain statements in this press release are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995. These statements may be identified by the use of forward-looking words such as “anticipate,” “believe,” “forecast,” “estimate” and “intend,” among others. These forward-looking statements are based on BlueRock’s current expectations and actual results could differ materially. There are a number of factors that could cause actual events to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, the timing of our clinical trial for DA01; our results regarding the safety, tolerance and efficacy of DA01 cell transplantation for patients with Parkinson’s disease; and ongoing FDA and other regulatory requirements regarding the development of DA01. As with any pharmaceutical under development, there are significant risks in the development, regulatory approval and commercialization of new products. Except as expressly required by law, BlueRock does not undertake an obligation to update or revise any forward-looking statement. All of the Company’s forward-looking statements are expressly qualified by all such risk factors and other cautionary statements. The information set forth herein speaks only as of the date hereof.*

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