

## News Release

**Not intended for UK Media**

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### **BlueRock's neuronal stem cell therapy for Parkinson's disease is first to show positive results in Phase I clinical study**

- Investigational Bemdaneprocel (BRT-DA01) was well tolerated with no major safety issues in all 12 patients through one year
- Assessment of secondary endpoints demonstrates feasibility of transplantation and evidence of cell survival and engraftment
- Phase II clinical study expected to begin enrolling patients in H1 2024
- Detailed Phase I trial data from primary and secondary endpoints will be presented at the 2023 International Congress on Parkinson's Disease and Movement Disorders taking place in Copenhagen from August 27-31

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**Berlin, Germany and Cambridge, M.A., U.S.A., June 28, 2023** – Bayer AG and BlueRock Therapeutics LP, a clinical stage cell therapy company and wholly owned independently operated subsidiary of Bayer AG, today announced positive top-line results from a Phase I clinical trial of investigational drug, bemdaneprocel (BRT-DA01), a potential first-in-class cell therapy for Parkinson's disease. The trial showed that bemdaneprocel was well-tolerated in all 12 patients in the study to date, with no major safety events. In addition, an assessment of the study's secondary endpoints demonstrated feasibility of transplantation and evidence of cell survival and engraftment in the brain through one year. Based on these results, planning is underway for a Phase II study that is expected to begin enrolling patients in H1 (first half) 2024.

"We are on a mission to harness the power of cell therapy with the aim to help people with Parkinson's disease regain control of their lives by restoring the functions that they have lost to this disease," said Ahmed Enayetallah, Senior Vice President and Head of Development, BlueRock Therapeutics. "The safety profile of bemdaneprocel was encouraging along with early evidence of cell survival and engraftment, marking a very important step in the development of a potential new therapy for patients with this

disease. These topline data provide a strong rationale for initiating the next phase study, and we look forward to advancing this clinical program.”

Parkinson’s disease is a progressive neurodegenerative disorder caused by nerve cell damage in the brain, leading to decreased dopamine levels. At diagnosis, it is estimated that patients have already lost 50-80% of their dopaminergic neurons. The loss of these neurons leads to a progressive loss of motor function and symptoms such as tremors, muscle rigidity, and slowness of movement (bradykinesia). According to the Parkinson’s Foundation, more than 10 million people worldwide suffer from Parkinson’s disease, with approximately one million living in the United States. There is no cure, and the efficacy of current treatments decreases over time.

Bemdaneprocel (BRT-DA01), an investigational therapy comprised of dopamine producing neurons derived from pluripotent stem cells, is surgically implanted into the brain of a person with Parkinson’s disease. When transplanted, these cells have the potential to reform neural networks that have been destroyed by Parkinson’s disease in the hope of restoring motor and non-motor function to patients.

“At Bayer, we are committed to advancing cell and gene therapy innovations for patients with Parkinson’s disease, a neurodegenerative disorder with debilitating effects on people’s lives for which there is currently no cure and only limited treatment options,” said Christian Rommel, Member of the Executive Committee of Bayer’s Pharmaceuticals Division and Head of Research and Development. “The positive outcome of our first cell therapy clinical trial for Parkinson’s is encouraging not only for the bemdaneprocel development program but also our entire pluripotent stem cell-based platform and warrants further investigation in larger groups of patients.”

Detailed Phase I trial data from primary and secondary endpoints will be presented at the 2023 International Congress of Parkinson’s Disease and Movement Disorders in Copenhagen from August 27 – 31.

#### **About the bemdaneprocel (BRT-DA01) Phase I Trial**

The primary objective of the Phase I trial is to assess the safety and tolerability of bemdaneprocel (BRT-DA01) transplantation at one-year post-transplant. The secondary objectives of the trial 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.

The transplant surgeries were performed by Dr. Viviane Tabar, MD, Chair of the Department of Neurosurgery at Memorial Sloan Kettering (MSK) Cancer Center and Dr. Andres Lozano, M.D., Ph.D., F.R.C.S.C., F.R.S.C., F.C.A.H.S., Neurosurgeon and Senior Scientist, Krembil Brain Institute, Alan & Susan Hudson Cornerstone Chair in Neurosurgery, Toronto Western Hospital, University Health Network and Chairman of the Division of Neurosurgery at the University of Toronto (UoT). Participants were followed at clinical sites by Dr. Harini Sarva, M.D. at Weill Cornell Medicine, Dr. Claire Henchcliffe, M.D., D.Phil., F.A.A.N., F.A.N.A. at the University of California, Irvine, and Dr. Alfonso Fasano, M.D., PhD., Chair in Neuromodulation and Multi-Disciplinary Care at the University Health Network (UHN) and UoT.

*Disclosure:*

*Memorial Sloane Kettering (MSK): Dr. Tabar has financial interests related to BlueRock. MSK has institutional financial interests related to BlueRock. Note the foregoing institutional disclosure language is included because the referenced study relates to MSK technology licensed to BlueRock.*

*University Health Network (UHN): UHN has institutional financial interests related to BlueRock.*

More information about the Phase I trial is available at [clinicaltrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT04802733) (NCT04802733).

**About BlueRock Therapeutics LP**

BlueRock Therapeutics LP is a clinical stage cell therapy company focused on creating cellular medicines to reverse devastating diseases. We are harnessing the power of cell therapy to create a pipeline of new medicines for patients suffering from neurological, cardiovascular, immunological, and ophthalmic diseases. Our lead clinical program, bemdaneprocel (BRT-DA01), is in Phase I clinical trials for Parkinson's disease. We were founded in 2016 as a joint venture of Versant Ventures and Leaps by Bayer, the impact investing arm of Bayer AG that invests in paradigm-shifting breakthrough innovation. In late 2019, BlueRock became a wholly owned, independently operated subsidiary of Bayer AG as a cornerstone of its newly formed Cell & Gene Therapy Platform. Our culture is defined by the courage to persist regardless of the challenge, the urgency to transform medicine and deliver hope, integrity guided by mission, and community-mindedness with

the understanding that we are all part of something bigger than ourselves. 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 the planet thrive by supporting efforts to master the major challenges presented by a growing and aging global population. Bayer is committed to driving sustainable development and generating 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 2022, the Group employed around 101,000 people and had sales of 50.7 billion euros. R&D expenses before special items amounted to 6.2 billion euros. For more information, go to [www.bayer.com](http://www.bayer.com).

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**Forward-Looking Statements**

This release may contain forward-looking statements based on current assumptions and forecasts made by Bayer management. Various known and unknown risks, uncertainties and other factors could lead to material differences between the actual future results, financial situation, development or performance of the company and the estimates given here. These factors include those discussed in Bayer's public reports which are available on the Bayer website at [www.bayer.com](http://www.bayer.com). The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.