

News Release

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BlueRock Therapeutics reports positive 36-month results from Phase I trial of bemdaneprocel for treating Parkinson's disease

- Investigational cell therapy bemdaneprocel continues to demonstrate a favorable safety profile at 36 months in Phase I trial participants
- Secondary clinical efficacy endpoints related to motor outcomes remain stable compared to 24 months and continue to show positive trends from baseline
- Data were presented on October 6th at the International Congress of Parkinson's Disease and Movements Disorders®

Berlin, Germany and Cambridge, MA, USA, October 7, 2025 – Bayer AG and its wholly owned, independently operated subsidiary BlueRock Therapeutics LP, a clinical stage cell therapy company, today announced positive 36-month data from exPDite, a Phase I clinical trial of bemdaneprocel, an investigational cell therapy for the treatment of Parkinson's disease (PD). The data were presented on October 6th at the International Congress of Parkinson's Disease and Movements Disorders.

“Bemdaneprocel represents a new approach to restoring the dopamine inputs that are lost in Parkinson's, and leverages substantial advances in stem cell technology,” said Claire Henchcliffe, MD, chair of the UC Irvine School of Medicine's Department of Neurology at the University of California, Irvine and one of the study's Principal Investigators. “The new 3-year data is a critical next step to evaluate longer term safety. While there is a need for caution in interpreting the positive trends in clinical outcomes, initial signals are there, particularly in the higher dose cohort and the upcoming exPDite-2 clinical trial should shed further light on potential benefits.”

Bemdaneprocel's safety profile at 36 months is consistent with earlier findings, demonstrating that it continues to be well tolerated by patients, with no adverse events

reported related to the therapy or surgical procedure. F-Dopa imaging suggests that transplanted cells continue to survive and engraft in the brain after discontinuing immunosuppression therapy at 12 months as outlined in the study's protocol. In addition, secondary clinical endpoints related to motor symptoms continue to show positive trends from baseline through the duration of follow-up, with more encouraging trends in the high dose cohort than those in the low dose cohort. These were assessed by the MDS-Unified Parkinson's Disease Rating Scale Part II and III (MDS-UPDRS Part II & III) and the Parkinson's disease Diary, tools used to assess Parkinson's disease severity in motor symptoms.

"The 36-month data from this Phase I study underscores our hope that bемdaneprocеl could be a potentially meaningful and durable therapeutic option for treating people living with Parkinson's disease," said Gabi Belfort, MD, PhD, Senior Vice President and Bemdaneprocеl Product Lead at BlueRock Therapeutics. "We are excited to share these data with the Parkinson's disease community and are committed to advancing bemdaneprocеl through the next stage of clinical testing."

In the high dose cohort (n=7), the 36-month measurement of the effects of bemdaneprocеl on motor symptoms using the MDS-UPDRS Part III measured in the "OFF"-medication state, showed a mean reduction of 17.9 points compared with baseline. The low dose cohort (N=4) showed a mean decrease of 13.5 points. Both are considered to be clinically meaningful.¹

Using the PD Diary, which categorizes patients as being in the "ON" state when their symptoms are well controlled and in the "OFF" state when they experience a worsening of their symptoms, participants in the high dose cohort showed a mean increase of 1 hour in time spent in the "Good ON" state (without troublesome dyskinesias) compared with baseline after 36 months. Two participants in the high dose cohort did not submit a 36-month PD Diary. Time spent in the "OFF" state showed a mean decrease of - 0.93 hours from baseline after 36 months. The participants in the low dose cohort showed a mean increase of 0.23 hours in the "Good ON" state time compared with baseline and a corresponding mean decrease of -1.15 hours in "OFF" state time.

In the high dose cohort, the 36-month measurement of the effects of bemdaneprocеl on activities of daily living using the MDS-UPDRS Part II measured a mean reduction of -4.3

points compared with baseline. The low dose cohort showed a mean increase of 0.2 points. Participants in both cohorts continue in the long term Continued Evaluation Study.

“The results for bemdaneprocel after 36 months mark another motivating milestone,” said Christian Rommel, Global Head of Research and Development of the Pharmaceuticals Division at Bayer. “They reinforce our commitment to developing urgently needed new treatment options for Parkinson's patients.”

About bemdaneprocel (BRT-DA01)

Bemdaneprocel (BRT-DA01) is an investigational cell therapy designed to replace the dopamine producing neurons that are lost in Parkinson's disease. These dopaminergic neuron precursors are derived from human embryonic pluripotent stem cells that continue developing into mature dopamine neurons after implantation. In a surgical procedure, these neuron precursors are implanted into the brain of a person with Parkinson's disease. When transplanted, they have the potential to re-form neural networks that have been severely affected by Parkinson's disease and to potentially restore motor and non-motor function to patients. In 2021 bemdaneprocel received Fast Track Designation and in 2024 a Regenerative Medicine Advanced Therapy (RMAT) designation from the FDA. A pivotal Phase III trial to assess the efficacy, safety and overall impact of bemdaneprocel compared to sham surgery control is currently enrolling participants. Bemdaneprocel has not been approved for treatment of any disease or medical condition by any health authority.

About Parkinson's disease

Parkinson's disease (PD) is a progressive neurodegenerative disease. It has a significant impact on a person's daily life. In PD, the death of dopamine producing nerve cells in the brain leads to the continuous loss of motor function. Symptoms include tremors, muscle rigidity, and slowness of movement. Additionally, people with PD experience non-motor symptoms, including fatigue and lack of energy, cognitive issues, and depression. Symptoms typically intensify over time and make everyday tasks demanding. The prevalence of PD has doubled over the past 25 years. Today, more than 10 million people worldwide are estimated to be living with PD. This makes it the world's second most prevalent neurodegenerative disease. It is also the most frequent movement disorder. At present there is no cure, and current treatment options are inadequate and lack holistic management of symptoms so there is an urgent need for new therapies.

About BlueRock Therapeutics LP

BlueRock Therapeutics LP is a clinical stage cell therapy company focused on creating cellular medicines to treat devastating diseases. We are harnessing the power of cell therapy to create a pipeline of new medicines for people suffering from neurological and ophthalmic diseases. Two of our novel investigational cell therapies, bemdaneprocel (BRT-DA01) for the treatment of Parkinson's disease and OpCT-001 for the treatment of primary photoreceptor diseases are clinical stage programs. Bemdaneprocel has RMAT (Regenerative Medicine Advanced Therapy) and Fast Track designation from the US FDA (Food and Drug Administration) and is being tested in a Phase III clinical trial, exPDite-2. OpCT-001 has Fast Track designation from the FDA and is being tested in a Phase I clinical trial, Clarico. BlueRock was 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. 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.

About Bayer

Bayer is a global enterprise with core competencies in the life science fields of health care and nutrition. In line with its mission, "Health for all, Hunger for none," the company's 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 2024, the Group employed around 93,000 people and had sales of 46.6 billion euros. R&D expenses amounted to 6.2 billion euros. For more information, go to www.bayer.com.

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Forward-Looking Statements

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¹ Hauser RA, Gordon MF, Mizuno Y, Poewe W, Barone P, Schapira AH, Rascol O, Debieuvre C, Fräßdorf M. Minimal clinically important difference in Parkinson's disease as assessed in pivotal trials of pramipexole extended release. *Parkinsons Dis.* 2014;2014:467131. doi: 10.1155/2014/467131. Epub 2014 Apr 1. PMID: 24800101; PMCID: PMC3995302.