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News Release

Not intended for UK Media

BlueRock Therapeutics investigative cell therapy bemdaneprocel for treating Parkinson's disease receives Pioneering Regenerative Medical Product designation in Japan

- Designation enables preferred procedural treatment and review consultation by Japan's Ministry of Health, Labor and Welfare
- Parkinson's disease affects approximately 10 million people worldwide and 250,000 in Japan

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Berlin, Germany and Cambridge, MA, USA, December 17. 2025 – Bayer AG and its wholly owned, independently operated subsidiary BlueRock Therapeutics LP, a clinical stage cell therapy company, today announced that the investigative cell therapy bemdaneprocel, has received Pioneering Regenerative Medical Product designation (SAKIGAKE) from Japan's Ministry of Health, Labor and Welfare (MHLW.) A drug candidate that receives Sakigake designation may be eligible for more frequent interaction with the MHLW to discuss the drug candidate's development plan as well as eligibility for accelerated approval and priority review, if relevant criteria are met.

"We are honored that bemdaneprocel has received Sakigake designation in Japan, recognizing the urgent need for new and innovative treatment options for people living with this debilitating condition," said Gabi Belfort, MD PhD and Bemdaneprocel Product Lead at BlueRock Therapeutics. "This designation will allow us to work closely with Japan's regulators to advance our therapy as efficiently as possible and bring new hope to people living with Parkinson's disease and their families."

Parkinson's disease is the world's second leading neurodegenerative disease, affecting approximately 10 million people worldwide and 250,000 in Japan.

“Receiving the Sakigake designation for bemdaneprocel highlights its potential to change how we approach Parkinson’s disease treatment,” said Christian Rommel, PhD and Global Head of Research and Development for Bayer's Pharmaceuticals Division. “Our collaboration with the Japanese regulatory authority reflects our dedication to partnering with healthcare systems and regulators worldwide. Together, we aim to improve patient access to innovative therapies and make strides in enhancing patient outcomes.”

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 clinical trial (exPDite-2) 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 exPDite-2

exPDite-2 is the first Phase III pivotal clinical trial for an investigational allogeneic pluripotent stem cell derived therapy to treat Parkinson’s disease. In a Phase I study with 12 participants, bemdaneprocel was well tolerated, with no serious adverse events related to drug product at 36 months post-surgery. In addition, encouraging trends were observed in secondary endpoints related to motor impairments at 36 months post-surgery. Building on these results, exPDite-2 is a multicenter, double-blind trial that will assess the efficacy, safety and overall impact of bemdaneprocel compared to sham surgery control. The trial is designed to enroll approximately 102 participants with Parkinson’s disease in US, Canada, and Australia. The primary endpoint of the Phase III study is change from baseline to week 78 in PD motor diary measure of ON-time without troublesome dyskinesia, adjusted for a 16-hour waking day. In addition, the trial will incorporate secondary endpoints designed to assess objective measures of movement, non-motor

symptoms, safety and tolerability, and instruments that capture activities of daily living and quality of life.

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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