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News Release

Not intended for UK Media

BlueRock Therapeutics announces first patient receives investigational therapy in Phase 1/2a clinical trial of OpCT-001 for the treatment of primary photoreceptor diseases

- OpCT-001 is the first iPSC-derived investigational cell therapy to be clinically tested for treating primary photoreceptor diseases
- Phase 1/2a trial, CLARICO, is a first-in-human, multisite, 2-part interventional trial to evaluate the safety, tolerability, and the effect on clinical outcomes of OpCT-001
- Primary photoreceptor diseases are a subgroup of inherited retinal disorders that affect the structure and function of the photoreceptor cells in the retina, leading to irreversible vision loss in children and adults

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Berlin, Germany, and Cambridge, MA, USA, July 8, 2025 – Bayer AG and BlueRock Therapeutics LP, a clinical-stage cell therapy company and wholly owned subsidiary of Bayer AG, today announced that the first patient received the investigational therapy in CLARICO, a Phase 1/2a clinical trial of OpCT-001, an investigational induced pluripotent stem cell (iPSC)-derived cell therapy for the treatment of primary photoreceptor diseases. OpCT-001 is the first iPSC-derived investigational cell therapy to be clinically tested for treating primary photoreceptor (PR) diseases, which are a subgroup of inherited retinal disorders that includes retinitis pigmentosa and cone-rod dystrophy.

“The initiation of the CLARICO trial represents a key milestone for the OpCT-001 program,” said Amit Rakhit, MD, MBA, BlueRock’s Chief Development and Medical Officer. “We believe OpCT-001 holds significant promise as a novel therapeutic approach for restoring vision in people living with primary photoreceptor diseases, and we look forward to assessing its safety and tolerability profile as we advance this important program in our pipeline.”

CLARICO is a Phase 1/2a first-in-human, multisite, 2-part interventional study to evaluate the safety, tolerability, and the effect on clinical outcomes of OpCT-001 in up to approximately 54 adults with primary photoreceptor disease. Phase 1 will focus on safety and includes a dose-escalation design. Phase 2 is designed to gather additional safety data and assess the effect of OpCT-001 on measures of visual function, functional vision, and anatomic measures of engraftment in different clinical subgroups.

“We aim to transform treatment options for patients facing irreversible vision loss. OpCT-001, our investigational iPSC-derived cell therapy, has the potential to restore vision for individuals with primary photoreceptor disease,” said Christian Rommel, Executive Vice President and Global Head of Research and Development of the Pharmaceuticals Division at Bayer. “We are excited to announce the first patient in the CLARICO trial, the first-ever clinical trial for an iPSC-derived treatment in this field.”

Primary photoreceptor diseases affect the structure and function of the photoreceptor cells in the retina, leading to irreversible vision loss in both children and adults. OpCT-001 aims to restore vision in patients with primary photoreceptor diseases by replacing degenerated cells in the retina with functional cells. Limited treatment options currently exist for treating primary photoreceptor diseases which affect an estimated 110,000 people in the U.S.[1]

OpCT-001 is an investigational cell therapy that has not been approved by any regulatory authority, and its efficacy and safety have not been established or fully evaluated.

About CLARICO

CLARICO is a Phase 1/2a first-in-human, multisite, 2-part interventional study to evaluate the safety, tolerability, and the effect on clinical outcomes of OpCT-001 in up to approximately 54 adults with primary photoreceptor disease. Phase 1 will focus on safety and features a dose-escalation design. Phase 2 is designed to gather additional safety data and assess the effect of OpCT-001 on measures of visual function, functional vision, and anatomic measures of engraftment in different clinical subgroups. Phase 1 will include 4 planned dose levels to be administered across 4 cohorts (Cohorts 1 through 4). Dose escalation in Phase 1 will be conducted using a standard 3+3 scheme in which a

[1] https://www.ncbi.nlm.nih.gov/books/NBK519518/; https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1808442/; https://www.nidcd.nih.gov/health/usher-syndrome#b

total of 12 to 24 legally blind participants (~3 to 6 per cohort) will receive OpCT-001. Phase 2 is planned to enroll a maximum of 15 participants in 2 cohorts (Cohorts 5 and 6) to evaluate 2 dose levels of OpCT-001 that will be selected based on Phase 1 safety and tolerability data. Phase 2 participants will be randomized 1:1 to either Cohort 5 or Cohort 6. Phase 2 participants and the investigator/study site personnel outside of the surgical team will be masked to OpCT-001 dose assignments. Further details of the trial can be found at www.clinicaltrials.gov (NCT06789445).

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 3 clinical trial, exPDite-2. OpCT-001 has Fast Track designation from the FDA and is being tested in a Phase 1 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 BlueRock Therapeutics
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,” “plan,” 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 initiation, timing, progress, activities, goals and reporting of results of any preclinical programs and clinical trials and research and development programs, the potential benefits, timing and future operation of the agreements with FUJIFILM Cellular Dynamics and Opsis Therapeutics, the ability to advance therapies into, and successfully initiate, enroll and complete clinical trials, the potential clinical utility of product candidates, the regulatory pathway of, and the timing or likelihood of any regulatory filings and approvals for, any product candidates, and the ability to, and extent of, potentially commercializing any product candidate, are forward looking. 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 BlueRock’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.

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. The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.