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NEWS RELEASE

BlueRock Therapeutics announces FDA clearance of IND application for investigational iPSC-derived cell therapy 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
- 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
- BlueRock plans to conduct a Phase 1/2a clinical study in the U.S.

Cambridge, MA USA, September 3, 2024 - BlueRock Therapeutics LP, a clinical stage cell therapy company and wholly owned, independently operated subsidiary of Bayer AG, today announced the clearance of its Investigational New Drug (IND) application by the U.S. Food and Drug Administration (FDA) for OpCT-001, an investigational induced pluripotent stem cell (iPSC)-derived cell therapy for the treatment of primary photoreceptor diseases.

“We are pleased with the immense progress we have made to date and thrilled that the FDA has cleared our IND application to initiate clinical testing for OpCT-001," said Amit Rakhit, Chief Development and Medical Officer at BlueRock Therapeutics. "We believe that OpCT-001 has potential to restore vision in people living with primary photoreceptor diseases and look forward to working with the ophthalmology community in initiating our Phase 1/2a clinical study.”

OpCT-001 is the first investigational iPSC-derived cell therapy to be clinically evaluated for the treatment of primary photoreceptor diseases. Initiation activities to support a Phase 1/2a study are underway. The Phase 1/2a study is designed as a first-in-human study to evaluate the safety and tolerability of subretinal administration of OpCT-001 in people with primary photoreceptor diseases as well as evaluate the effect of OpCT-001 on retinal structure, visual function and functional vision. The study will assess several dose levels of OpCT-001 and is expected to enroll participants in sites across the U.S.

Primary photoreceptor diseases are a subgroup of inherited retinal disorders that includes retinitis pigmentosa and cone-rod dystrophy. These diseases affect the

structure and function of the photoreceptor cells in the retina, leading to irreversible vision loss in both children and adults. Primary photoreceptor diseases affect an estimated 110,000[1] people in the U.S. and only limited treatment options exist for this population. OpCT-001 aims to restore vision loss caused by these diseases by replacing degenerated cells in the retina with functional cells.

OpCT-001 was exclusively licensed from FUJIFILM Cellular Dynamics and Opsis Therapeutics in January 2024 as part of the strategic R&D and clinical manufacturing collaboration between BlueRock Therapeutics, FUJIFILM Cellular Dynamics, and Opsis Therapeutics forged in 2021. As part of the collaboration, FUJIFILM Cellular Dynamics supported BlueRock Therapeutics via research, development and the execution of critical IND-enabling activities including the clinical manufacturing of OpCT-001 at their cGMP[2] facility in Madison, Wisconsin.

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 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, ophthalmic, cardiovascular and immunological diseases. Two of our novel investigational cell therapies, bemdaneprocel (BRT-DA01) for the treatment Parkinson's disease and OpCT-001 for the treatment of primary photoreceptor disease are clinical stage programs. Bemdaneprocel has RMAT (Regenerative Medicine Advanced Therapy) and Fast Track designation from the US FDA (Food and Drug Administration); has completed Phase 1 clinical trial and is progressing to the next stage of clinical development. OpCT-001 has been cleared by the FDA to begin phase 1 clinical testing. 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 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.

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**.

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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,” “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.

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[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

[2] Current good manufacturing practices are regulations enforced by the FDA.