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News Release

Not intended for US and UK Media

Bayer invests 250 million USD in new cell therapy manufacturing facility in the U.S.

- New plant will supply cell therapy products for late-stage clinical trials and future product launches
 - Supports clinical studies with BlueRock Therapeutics' investigational cell therapy for Parkinson's Disease bemdaneprocel (BRT-DA01)
 - New facility located in Berkeley, California, USA
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Berlin, October 10, 2023 – Bayer AG has opened a new cell therapy production plant in Berkeley, California, USA, to bring cell therapies to patients on a global scale. The USD 250 million investment will support the production of material required for clinical trials and potential commercial launch of BlueRock Therapeutics' bemdaneprocel (BRT-DA01), an investigational cell therapy currently in evaluation for treating Parkinson's Disease. BlueRock Therapeutics LP is a clinical stage cell therapy company and wholly owned, independently operated subsidiary of Bayer AG. The new facility will also support the future production of additional cell therapies as Bayer's cell therapy portfolio advances.

"This new facility ensures our investment in cell therapies can become a reality for patients around the world," said Stefan Oelrich, member of the Board of Management of Bayer AG and President of the company's Pharmaceuticals Division. "Cell therapies represent an important opportunity to treat diseases differently by targeting the underlying cause or enabling the human body to restore vital functions."

The new cell therapy facility is part of a transformation at the company's dedicated biotechnology site in Berkeley, California, where Bayer has invested around USD 500 million over the past five years.

"Manufacturing is an important element in taking the biopharmaceutical sector's pipeline of cell and gene therapies from the laboratory to patients, and this facility enables Bayer

to play a critical role in making that happen,” said Holger Weintritt, Member of the Executive Committee of Bayer’s Pharmaceuticals Division and Head of Product Supply of the Pharmaceuticals Division of Bayer AG. “We’re building on our capabilities in manufacturing the most complex protein therapeutics to drive forward platforms that further enable the industry to bring these new medicines to patients worldwide.”

Bayer’s global biotech organization supports pharmaceutical innovators to transfer their product candidates from the laboratory bench to patient care. The company’s biotech team provides its biologic development and manufacturing capabilities for Bayer’s larger biotherapeutics portfolio, including commercial products and late-stage protein and cell therapies in development. At the same time the company supports third party companies to enable patient trials and commercial launches through its BioPartnering Solutions offerings.

“Having access to this new cell therapy manufacturing facility is important to deliver impactful cell therapies from our development portfolio to patients in need,” said Seth Ettenberg, President and CEO of BlueRock Therapeutics. “Our team is excited to be working shoulder to shoulder with Bayer’s biotech scientists and manufacturing experts as we look to scale up manufacturing for our first investigational therapy, bemdaneprocel for treating Parkinson’s disease, as it advances through clinical trials.”

The new Cell Therapy Launch Facility is among several recent investments to advance Bayer’s biologic pipeline of protein therapeutics, cell and gene therapies including a new Cell Culture Technology Center and Cell Therapy Labs. The new Cell Therapy Launch Facility features flexible, modular space for cell culture, viral transduction and automated filling of cell therapies leveraging Biotech@Bayer expertise in iPSC and CAR-T characterization, process development, analytics and clinical to commercial production.

Beyond Berkeley, the company’s global biotech network includes biologic development, manufacturing science, industrialization and advanced manufacturing engineering teams in Wuppertal and Leverkusen, Germany; and Basel, Switzerland; with a full complement of laboratories and clinical production suites.

About bemdaneprocel and Parkinson’s Disease

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 pluripotent stem cells (PSC) that are human embryonic stem cells. 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 reform neural networks that have been severely affected by Parkinson's and restore motor and non-motor function to patients. Planning is underway for BlueRock Therapeutics' Phase II study that is expected to begin enrolling participants in H1 (first half) 2024.

Parkinson's disease is a progressive neurodegenerative disorder caused by the death of nerve cells 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. Even with medication, the symptoms of Parkinson's disease can fluctuate during the course of the day. 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 effectiveness of current treatments decreases over time.

About BioPartnering Solutions for Biotech Innovators in U.S. and Europe

Through Bayer's BioPartnering Solutions, innovators can leverage industry-leading biotech process development and biomanufacturing capabilities to make their therapeutic candidates a reality. Bayer's highly skilled Biotech teams and infrastructure – which includes preclinical, clinical and commercial launch scale manufacturing – are available to advance promising investigational cell therapy, monoclonal antibody and protein therapeutic candidates from the discovery bench to patients. Through BioPartnering Solutions, Bayer provides early-stage companies with a single source of IND- and BLA-enabling development; bioprocess and biochemical engineering; clinical and commercial manufacturing. A range of complementing support service functions such as supply chain management, procurement, quality, and CMC strategy support for regulatory filings are also available. For more information visit: <https://www.bayer.com/en/us/BioPartneringSolutions>.

About Bayer's Biotech Campus in Berkeley, CA

Bayer's 46-acre Biotech Campus is located in Berkeley, California, USA, where a team of about 1,000 employees drives the development and manufacturing of traditional protein therapeutics as well as novel cell and gene therapies.

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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