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News Release

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AskBio's Viralgen to Supply Commercial-Scale Drug Product for REGENERATE-PD Investigational Gene Therapy Phase II Trial for Parkinson's Disease

Ametefgene parvec (AB-1005) manufactured at Viralgen commercial manufacturing facility with next-generation process to deliver high-purity product with greater efficiency

Berlin, Germany, and Durham, N.C., USA, April 20, 2026 – AskBio Inc. (AskBio), a gene therapy company wholly owned and independently operated as a subsidiary of Bayer AG, today announced that it has introduced its proprietary, commercially ready manufacturing process to supply ametefgene parvec (AB-1005), an investigational gene therapy for the treatment of Parkinson's disease (PD) and multiple system atrophy-parkinsonian type (MSA-P), following submission of a United States Food and Drug Administration (FDA) Investigational New Drug Application (IND) amendment.

This enables AskBio to now advance its REGENERATE-PD Phase II clinical trial in the United States with the material produced at the commercial manufacturing facility of AskBio's wholly owned subsidiary, Viralgen, with other trial sites to follow, using an intensified, high-efficiency, next-generation large-scale suspension manufacturing process that provides a consistently high purity product.

"Today's news marks another important advancement in our Parkinson's program," said Canwen Jiang, MD, PhD, Chief Development Officer and Chief Medical Officer at AskBio. "We are initiating supply with our manufacturing platform, to deliver our investigational gene therapy to participants in our ametefgene parvec trials, including our REGENERATE-PD trial, which recently saw the randomization of our first participants in Germany. The trial is currently enrolling participants in Poland, the United Kingdom, and the United States."

“Manufacturing efficiency of our AAV gene therapy-based drug product is mission critical for our Phase II Parkinson’s disease trial,” said Christian Rommel, PhD, Global Head of Research and Development for Bayer’s Pharmaceuticals Division. “It underscores the innovation of our production technology and reflects our continued commitment to meet high regulatory standards.”

In December 2025, AskBio was granted Pioneering Regenerative Medical Product designation (SAKIGAKE) in Japan for ametefgene parvec, and in February 2025 the company was granted Regenerative Medicine Advanced Therapy (RMAT) designation from the FDA.[1,2] Prior to that, AskBio received FDA Fast Track designation and the Innovation Passport, the United Kingdom Medicines and Healthcare products Regulatory Agency (UK MHRA) innovative medicine designation.[3] All designations were for PD.

AskBio is also exploring ametefgene parvec in participants in the United States with the parkinsonian subtype of MSA-P in a fully enrolled Phase I clinical trial to assess the preliminary safety, tolerability, and efficacy for this rapidly progressing neurodegenerative condition.[4]

Ametefgene parvec is an investigational gene therapy that has not been approved by any regulatory authority, and its efficacy and safety have not been established or fully evaluated.

About Parkinson’s disease

Parkinson’s disease (PD) is a progressive neurodegenerative disease.[5] It has a significant impact on a person’s daily life.[5] In PD, the progressive death of dopamine producing nerve cells in the brain leads to the continuous loss of motor function.[6] Symptoms include tremors, muscle rigidity, and slowness of movement.[7] Additionally, people with PD experience non-motor symptoms, including fatigue and lack of energy, cognitive issues, and depression.[7] Symptoms typically intensify over time and make everyday tasks increasingly demanding.[7] The prevalence of PD has doubled over the past 25 years.[5] Today, more than 10 million people worldwide are estimated to be living with PD.[8] This makes it the world’s second most prevalent neurodegenerative disease.[9] It is also the most frequent movement disorder.[5,10] At present there is no cure, and current treatment options lack the holistic management of symptoms, so there is an urgent need for new therapies.[11]

About Parkinsonian subtype of multiple system atrophy

The parkinsonian subtype of multiple system atrophy (MSA-P) can initially be difficult to distinguish from Parkinson's disease and is marked by slow movement, lack of coordination, imbalance, dizziness, and fainting, among other symptoms.[12] Individuals experience increasing difficulty with movement and autonomic dysfunction as a result of progressive loss of nerve cells in the brain and spinal cord.[12] Affecting approximately 400,000 people worldwide, MSA-P is a rare disease, and its exact cause is unknown.[12,13,14] Symptoms usually start to develop around the age of 50, followed by rapid progression within 5–10 years.[12] At present there is no cure and no approved treatments for MSA-P, so there is an urgent need for new therapies.[12]

About REGENERATE-PD

REGENERATE-PD is a Phase II, randomized, double-blind, surgery controlled trial of the efficacy and safety of intraputaminal ametefgene parvec (AB-1005) in the treatment of adults (45–75 years) with moderate-stage Parkinson's disease.[15] The trial will include an estimated number of 127 participants with trial sites located in Germany, Poland, the United Kingdom, and the United States.[15] For more information about the REGENERATE-PD clinical trial, visit clinicaltrials.gov (NCT06285643), or visit askbio.com.

About ametefgene parvec (AB-1005)

Ametefgene parvec (AB-1005) is an investigational gene therapy intended to slow disease progression and improve motor outcomes in people with Parkinson's disease (PD). Composed of an adeno-associated viral vector containing the human glial cell line-derived neurotrophic factor (GDNF) transgene, ametefgene parvec allows for stable and continuous expression of GDNF in localized regions of the brain after direct neurosurgical injection with convection-enhanced delivery.[16,17] In nonclinical studies, GDNF has been shown to promote the survival and morphological differentiation of dopaminergic neurons, which could aid in the preservation and restoration of dopaminergic neuronal circuitries normally lost in the disease.[17,18] GDNF has long been evaluated as a potential disease-modifying treatment for diseases, such as PD which are marked by progressive degeneration of midbrain dopaminergic neurons.[18] Through a combination of an investigational gene therapy and innovative neurosurgical delivery approach, building on the promising outcomes of the open-label Phase 1b trial, we can now test the GDNF hypothesis by getting this neurotrophic factor to these degenerating nigrostriatal neurons in a well-controlled clinical study to understand the effects of GDNF in a moderate PD population.[19]

About AskBio

AskBio Inc., a wholly owned and independently operated subsidiary of Bayer AG, is a fully integrated gene therapy company dedicated to steering gene therapy into a new era where it can transform the lives of a wider range of people living with rare and more common diseases. The company maintains a portfolio of clinical programs across a range of disease indications related to a single gene or multiple factors across cardiovascular, central nervous system, and neuromuscular conditions, with a clinical-stage pipeline that includes investigational therapeutics for congestive heart failure, limb-girdle muscular dystrophy, multiple system atrophy, Parkinson's disease, and Pompe disease. AskBio's end-to-end gene therapy platform includes our Pro10™ technology and Aava™ manufacturing platform, which make gene therapies more accessible by making research and commercial grade manufacturing more affordable. With global headquarters in Research Triangle Park, North Carolina, the company has generated hundreds of proprietary capsids and promoters, several of which have entered pre-clinical and clinical testing. An early innovator in the gene therapy field with over 900 employees in five countries, the company holds more than 600 patents and patent applications in areas such as AAV production and chimeric capsids. Learn more at http://www.askbio.com or follow us on LinkedIn.

About Viralgen

Viralgen is a leading contract development and manufacturing organization (CDMO) specializing exclusively in adeno-associated virus (AAV)–based gene therapies. Founded in 2017 as a subsidiary of AskBio Inc. within the Bayer AG group, Viralgen provides end-to-end support from early development through large-scale commercial production. Leveraging its proprietary Pro10™ suspension cell line and Aava™ manufacturing platform, Viralgen achieves industry-leading, high-yield, scalable manufacturing across all AAV serotypes. Located in San Sebastián, Spain, its state-of-the-art facility includes three cGMP suites with 2,000-liter capacity each, certified by the AEMPS/EMA, and integrates services such as plasmid production, process optimization, fill-finish, and in-house QC testing. With more than 1,200 AAV batches produced, Viralgen delivers reliable, efficient solutions that help bring life-changing gene therapies to patients with greater speed and consistency. For more information, visit https://viralgen.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 2025, the Group employed around 88,000 people and had sales of 45.6 billion euros. R&D expenses amounted to 5.8 billion euros. For more information, go to www.bayer.com.

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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.

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Forward-Looking Statements AskBio

This press release contains "forward-looking statements." Any statements contained in this press release that are not statements of historical fact may be deemed to be forward-looking statements. Words such as "believes," "anticipates," "plans," "expects," "will," "intends," "potential," "possible," and similar expressions are intended to identify forward-looking statements. These forward-looking statements include, without limitation, statements regarding AskBio's clinical trials. These forward-looking statements involve risks and uncertainties, many of which are beyond AskBio's control. Known risks include, among others: AskBio may not be able to execute on its business plans and goals, including meeting its expected or planned clinical and regulatory milestones and timelines, its reliance on third-parties, clinical development plans, manufacturing processes and plans, and bringing its product candidates to market, due to a variety

of reasons, including possible limitations of company financial and other resources, manufacturing limitations that may not be anticipated or resolved in a timely manner, potential disagreements or other issues with our third-party collaborators and partners, and regulatory, court or agency feedback or decisions, such as feedback and decisions from the United States Food and Drug Administration or the United States Patent and Trademark Office. Any of the foregoing risks could materially and adversely affect AskBio's business and results of operations. You should not place undue reliance on the forward-looking statements contained in this press release. AskBio does not undertake any obligation to publicly update its forward-looking statements based on events or circumstances after the date hereof.