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News Release

Not intended for US and UK Media

Bayer's AskBio initiates Phase II GenePHIT trial in Congestive Heart Failure (CHF)

GenePHIT, which is now enrolling, will study AB-1002 in adults with NYHA Class III Heart Failure and non-ischemic cardiomyopathy[1]

Berlin, Germany/Research Triangle Park, North Carolina, USA, January 11, 2024 – Bayer AG and Asklepios BioPharmaceutical, Inc. (AskBio), a gene therapy company wholly owned and independently operated as a subsidiary of Bayer AG, have announced the initiation of GenePHIT (Gene PHosphatase Inhibition Therapy), a Phase II trial of AB-1002 (also known as NAN-101) for the treatment of congestive heart failure (CHF). GenePHIT is an adaptive, double-blind, placebo-controlled, randomized, multicenter trial to evaluate the safety and efficacy of a single intracoronary infusion of AB-1002 in adults with non-ischemic cardiomyopathy classified as New York Heart Association (NYHA) Class III Heart Failure who have been medically stable for at least 4 weeks.[1] The advancement of AB-1002 into Phase II marks a significant milestone for the development of this novel investigational gene therapy for patients with CHF who have high unmet medical need.

GenePHIT will include between 90 and 150 adults with left ventricle ejection fraction between 15 and 35%, who continue to suffer from heart failure symptoms despite guideline recommended therapy. The primary efficacy endpoint at 52 weeks is a modified win ratio of several clinically meaningful assessments.[1]

"AskBio is excited to initiate GenePHIT under the leadership of Roger Hajjar, MD, Scientific Chair CHF, and Lothar Roessig, MD, Integrated Product Team Lead CHF," said Jude Samulski, PhD, Co-Founder and Chief Scientific Officer, AskBio. "We believe this trial will help determine the potential of AB-1002 as a treatment for one of the world's most devastating diseases, and we look forward to learning more about this important investigational cardiac gene therapy. Our hope is that one day AB-1002 will potentially help patients suffering from congestive heart failure."

The GenePHIT trial, which includes 52-week safety and primary efficacy and four-year long-term follow-up periods, is currently recruiting. AskBio plans to conduct the trial in the U.S. and multiple countries in Europe.[1] For more information, please visit clinicaltrials.gov (NCT#05598333) or visit askbio.com.

AB-1002 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. AB-1002 is manufactured by Viralgen Vector Core, a wholly owned and independently operated subsidiary of AskBio.

About Congestive Heart Failure

Heart failure occurs when the heart cannot pump blood efficiently enough to meet the body's needs, including providing sufficient oxygen to the organs.[2] Congestive heart failure results in the slowing of the blood flow out of the heart, which causes the blood returning to the heart through the veins to back up.[3] This causes congestion in the body's tissues. Symptoms include swelling in the legs and ankles. Sometimes, fluid collects in the lungs and interferes with breathing. Approximately 26 million people worldwide are living with congestive heart failure.[4]

About AskBio

Asklepios BioPharmaceutical, Inc. (AskBio), a wholly owned and independently operated subsidiary of Bayer AG, is a fully integrated gene therapy company dedicated to developing life-saving medicines and changing lives. The company maintains a portfolio of clinical programs across a range of neuromuscular, central nervous system, cardiovascular, and metabolic disease indications with a clinical-stage pipeline that includes therapeutics for congestive heart failure, Huntington's disease, limb-girdle muscular dystrophy, multiple system atrophy, Parkinson's disease, and Pompe disease. AskBio's gene therapy platform includes Pro10™, an industry-leading proprietary cell line manufacturing process, and an extensive capsid and promoter library. With global headquarters in Research Triangle Park, North Carolina, and European headquarters in Edinburgh, Scotland, 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 800 patents and patent applications in areas such as AAV production and chimeric capsids. Learn more at www.askbio.com or follow us on LinkedIn.

About Viralgen Vector Core

Viralgen is a Contract Development and Manufacturing Organization (CDMO) founded in 2017 and exists as an independently operated subsidiary of AskBio, which is wholly owned and independently operated as a subsidiary of Bayer AG. As a manufacturer of Current Good Manufacturing Practice (cGMP) certified AAV, Viralgen offers the Pro10™

based suspension manufacturing platform, a technology licensed from AskBio and developed by Chief Technical Officer Josh Grieger, PhD, and Co-Founder R. Jude Samulski, PhD, at University of North Carolina. The Pro10™ platform has been found to increase scalability, performance, and yield of AAV therapies.[5] Located in Spain, in the Gipuzkoa Science and Technology Park, Viralgen produces AAV gene therapy treatments for pharmaceutical and biotech companies with the aim of accelerating the delivery of new treatments that may improve patients' lives.

The company's clinical facilities have four cGMP manufacturing suites, with 250-liter and 500-liter bioreactors. In 2020, Viralgen expanded within the Scientific Park by constructing a new building with three modules for large-scale commercial manufacturing. Each module of the state-of-the-art space includes three cGMP suites with a manufacturing capacity of >2,000 liters. The first module, which includes a suite dedicated to fully automated fill and finish operations, has received cGMP certification by the Spanish Agency for Medicines and Medical Devices (AEMPS) as part of the EMA network. For more information, visit viralgenvc.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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Bayer 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.

AskBio Forward-Looking Statements
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.

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[1] Phosphatase Inhibition by Intracoronary Gene Therapy in Subjects With Non-Ischemic NYHA Class III Heart Failure (GenePHIT). Available at: https://classic.clinicaltrials.gov/ct2/show/NCT05598333. Accessed January 2024.
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