Labcorp Receives FDA Approval for First Companion Diagnostic for Use with Pfizer's Newly Approved Gene Therapy to Treat Patients with Hemophilia B

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Assay expands company's leadership in precision medicine and cell and gene therapy

BURLINGTON, N.C., April 29, 2024 /PRNewswire/ -- Labcorp (NYSE: LH), a global leader of innovative and comprehensive laboratory services, today announced the U.S. Food and Drug Administration (FDA) has approved its nAbCyte™ Anti-AAVRh74var HB-FE Assay, a companion diagnostic (CDx) to determine patient eligibility for treatment with BEQVEZ ™ (fidanacogene elaparvovec-dzkt), Pfizer's recently FDA-approved hemophilia B gene therapy.

The nAbCyte cell-based neutralizing antibody assay is a component of Pfizer's program to target recombinant adeno-associated virus (rAAV)-based gene therapies to the appropriate patient population. Before infusion with BEQVEZ, patients will require testing for preexisting anti-AAVRh74var antibodies. Labcorp's nAbCyte cell-based neutralizing antibody assay will allow for the accurate detection of preexisting neutralizing antibodies (nAbs), which could impact patient safety and/or efficacy of the one-time treatment.

"At Labcorp, we are committed to advancing cell and gene therapy and driving innovation that assists clinicians in making well-informed treatment decisions," said Dr. Brian Caveney, Labcorp's President, Early Development Research Laboratories and Chief Medical and Scientific Officer. "Labcorp is proud to offer the first cell-based, companion diagnostic to receive FDA approval, which represents a pioneering breakthrough in the field of companion diagnostics and will help transform the therapeutic landscape and the lives of patients living with rare, genetically inherited conditions."

An estimated 6,000 people in the United States are living with hemophilia B, which is a rare inherited bleeding disorder that prevents normal blood clotting due to a deficiency in Factor IX (FIX), which causes those with the disease to bleed more frequently and longer than others. It is estimated that as many as 60% of the American population have preexisting anti-AAV antibodies, which could interfere with rAAV gene delivery, demonstrating the essential need for nAbCyte CDx testing prior to treatment with BEQVEZ.

"The approval of the nAbCyte companion diagnostic represents a first for a gene therapy that treats eligible patients with hemophilia B, helping to bring clarity to physicians and patients who are considering BEQVEZ as a treatment option," said Dr. Sonal Bhatia, M.D., Head of U.S. Specialty Care Medical Affairs, Pfizer. "We believe this companion diagnostic is an important tool for evaluating patients who may be suitable for gene therapy as the treatment paradigm advances with the introduction of gene therapies like BEQVEZ."

The results from the nAbCyte test will be reported qualitatively as negative (not detected) or positive (detected). A negative test result indicates that an individual with moderate to severe hemophilia B can be considered for BEQVEZ therapy.

The FDA approval of nAbCyte Anti-AAVRh74var HB-FE CDx builds on Labcorp's comprehensive cell and gene therapy solutions, including specialized pre-clinical toxicology, biomarker and CDx development, and post-commercialization capabilities.

This assay is authorized by federal law for use as a companion diagnostic in the selection of patients to receive the Pfizer hemophilia B gene therapy, BEQVEZ (fidanacogene elaparvovec). The effectiveness of this device for this use has not been demonstrated.

About Labcorp
Labcorp (NYSE: LH) is a global leader of innovative and comprehensive laboratory services that helps doctors, hospitals, pharmaceutical companies, researchers and patients make clear and confident decisions. We provide insights and advance science to improve health and improve lives through our unparalleled diagnostics and drug development laboratory capabilities. The company's more than 67,000 employees serve clients in approximately 100 countries, provided support for 84% of the new drugs and therapeutic products approved in 2023 by the FDA, and performed more than 600 million tests for patients around the world. Learn more about us at www.labcorp.com.

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Media: Kimbrel Arculeo, 336-436-8263, Media@Labcorp.com; or Investors: Christin O'Donnell, 336-436-5076, Investor@Labcorp.com