Bluejay Therapeutics Receives U.S. FDA Breakthrough Therapy Designation for Brelovitug (BJT-778) for the Treatment of Chronic Hepatitis Delta

- Posted on January 21, 2025

Breakthrough Therapy Designation is designed to expedite the development and review of therapies that may show significant improvement over available treatments for serious conditions

REDWOOD CITY, Calif., Jan. 21, 2025 (GLOBE NEWSWIRE) — Bluejay Therapeutics, a clinical-stage biopharmaceutical company dedicated to developing potentially life-changing therapeutics for serious viral and liver diseases, today announced that its lead product candidate brelovitug (also known as BJT-778) has received U.S. Food and Drug Administration (FDA) Breakthrough Therapy designation for the treatment of chronic hepatitis delta (CHD). There are currently no approved treatments for chronic hepatitis D in the United States and most countries around the world.

“Chronic hepatitis delta is the most aggressive form of viral hepatitis and the lack of approved treatments in the United States creates a major unmet need for patients,” said Keting Chu, M.D., Ph.D., Founder and Chief Executive Officer of Bluejay Therapeutics. “Breakthrough Therapy designation recognizes the potential of brelovitug to transform the lives of people living with CHD. We look forward to initiating a global pivotal trial as soon as possible to meet our goal of improving patients’ lives.”

FDA Breakthrough Therapy designation is intended to expedite the development and regulatory reviews of investigational therapies for serious conditions that demonstrate promising preliminary clinical evidence and potential improvement over existing therapies.

Brelovitug has previously received Orphan and PRIME designation from the European Medicines Agency.

About Brelovitug (also known as BJT-778)

Brelovitug is a high potency, fully human immunoglobulin G1 (IgG1) monoclonal antibody (mAb) that targets the surface antigen (anti-HBsAg) of the hepatitis B virus. Brelovitug is designed to neutralize and remove hepatitis B and hepatitis D virions and deplete HBsAg-containing subviral particles, which makes brelovitug a potentially safe and highly efficacious treatment for CHD, a condition with urgent unmet medical need. In addition, brelovitug has also shown immunomodulatory functions in CHB patients, which may help to reconstitute antiviral immunity and contribute to functional cure for CHB when combined with other agents.

About Bluejay Therapeutics

Bluejay Therapeutics is a clinical-stage biopharmaceutical company dedicated to developing potentially life-changing therapeutics for serious viral and liver diseases. The company is currently investigating brelovitug for the treatment of chronic hepatitis D and chronic hepatitis B virus infections. Additionally, Bluejay is advancing several innovative programs with the goal of developing a combination regimen to achieve a functional cure for chronic hepatitis B, including a proprietary TLR9 agonist (cavrotolimod) and a liver-targeted hepatitis B virus (HBV) transcript inhibitor (BJT-628). For more information on Bluejay Therapeutics, please visit the company’s website at www.bluejaytx.com or follow the company on LinkedIn.

Media Contact:
Dan Boyle
Orangefiery
media@orangefiery.com
818-209-1692

Investor Contact:
Peter Garcia
CFO, Bluejay Therapeutics
ir@bluejaytx.com
650-674-2480