Tempest Receives Orphan Drug Designation from the FDA for TPST-1495 to Treat Patients with FAP

April 21, 2025

BRISBANE, Calif., April 21, 2025 (GLOBE NEWSWIRE) -- Tempest Therapeutics, Inc. (Nasdaq: TPST), a clinical-stage biotechnology company developing first-in-class[1] targeted and immune-mediated therapeutics to fight cancer, today announced that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation (ODD) to TPST-1495, the company's novel dual receptor inhibitor of prostaglandin (PGE2) signaling, for the treatment of patients with Familial Adenomatous Polyposis (FAP).

"Receiving orphan drug designation for TPST-1495, our second clinical program, is a significant milestone in our mission to bring innovative therapies to patients with unmet medical need," said Stephen Brady, President and CEO of Tempest. "This designation for the treatment of FAP underscores Tempest's mission to make a meaningful difference in the lives of patients and builds on the momentum from prior designations received for amezalpat in hepatocellular carcinoma."

A Phase 2 study evaluating TPST-1495 in patients with FAP is set to begin this year, conducted by the Cancer Prevention Clinical Trials Network and funded by the National Cancer Institute (NCI) Division of Cancer Prevention. Data from this study are expected in 2026.

About Familial Adenomatous Polyposis

FAP is a high-risk inherited syndrome associated with the development of cancer in affected patients and has no approved medical therapies. In the US, the disease affects approximately one in 5,000 to 10,000 individuals[2]. FAP is caused by autosomal dominant inactivating mutations in the tumor suppressor gene APC. Patients with FAP develop large numbers of adenomatous polyps throughout the gastrointestinal tract, often starting in their teenage years. These growths have a high risk of malignant transformation and can give rise to invasive cancers of the colon, stomach, duodenum, rectum, and other tissues. Standard of care treatment for patients with FAP is surgical removal of the colon (colectomy) early in life to reduce the likelihood of cancer development. Even after colectomy, patients must receive careful surveillance for development of cancer elsewhere in the GI tract throughout their lifetime. While surgical management and surveillance have improved the prognosis for patients with FAP, cancer remains a major cause of death for patients with FAP.

1 If approved by the FDA

2 Rarediseases.org/rare-diseases/familial-adenomatous-polyposis/

About Orphan Drug Designation

The FDA's Orphan Drug Designation program provides orphan status to therapies intended for the treatment, diagnosis, or prevention of rare diseases that affect fewer than 200,000 people in the United States. This designation provides certain benefits, including tax credits for qualified clinical testing, waiver or partial payment of FDA application fees and seven years of market exclusivity, if approved.

About Tempest Therapeutics

Tempest Therapeutics is a clinical-stage biotechnology company advancing a diverse portfolio of small molecule product candidates containing tumor-targeted and/or immune-mediated mechanisms with the potential to treat a wide range of tumors. The company's novel programs range from early research to later-stage investigation in a randomized global study in first-line cancer patients. Tempest is headquartered in Brisbane, California. More information about Tempest can be found on the company's website at www.tempesttx.com.

Forward-Looking Statements

This press release contains forward-looking statements, as that term is defined under the federal securities laws, that are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These statements may be identified by the use of forward-looking terminology such as "may," "will," "should," "would," "could", "expect," "anticipate," "plan," "likely," "believe," "estimate," "project," "intend," and other similar expressions. Forward-looking statements contained in this press release include but are not limited to statements relating to: the initiation, timing and results of the Phase 2 study for TPST-1495; and the ability of TPST-1495 to benefit from the ODD designation, including potential tax credits and market exclusivity. Any forward-looking statements in this press release are based on Tempest Therapeutics' current expectations, estimates and projections about its industry as well as management's current beliefs and expectations of future events only as of today and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to, risks relating to: changes in the regulatory environment resulting in potentials delays in the clinical development and regulatory approval of our product candidates, including TPST-1495; the volatility and uncertainty in the capital markets for biotechnology companies; and our ability to raise additional capital or other pursue our plan to identify and complete a strategic transaction on attractive terms or at all. These and other factors that may cause actual results to differ from those expressed or implied are discussed in greater detail in the "Risk Factors" section of the company's Annual Report on Form 10-K for the year ended December 31, 2024, filed with the Securities and Exchange Commission (SEC) on March 27, 2025, as well as in other filings the company may make with the SEC in the future. Except as required by applicable law, Tempest Therapeutics undertakes no obligation to revise or update any forward-looking statement, or to make any other forward-looking statements, whether as a result of new information, future events or otherwise. These forward-looking statements should not be relied upon as representing Tempest Therapeutics' views as of any date subsequent to the date of this press release and should not be relied upon as prediction of future events. In light of the foregoing, investors are urged not to rely on any forward-looking statement in reaching any conclusion or making any investment decision about any securities of Tempest Therapeutics.

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