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Dogwood Therapeutics Announces Patient Dosing in Phase 2b Trial Evaluating Halneuron® in Patients with Chemotherapy Induced Neuropathy (CINP) to Commence First Quarter of 2025

ATLANTA, Jan. 21, 2025 (GLOBE NEWSWIRE) -- Dogwood Therapeutics, Inc. (Nasdaq: DWTX) (the "Company"), a development-stage biopharmaceutical company focused on advancing first-in class, non-opioid, Nav 1.7 inhibitor treatments for chronic and acute pain, announced today that dosing of the first patient in its Phase 2b clinical trial, referred to as HALT-CINP (Halneuron® Treatment of Chemotherapy Induced Neuropathic Pain), evaluating Halneuron® to treat neuropathic pain associated with prior chemotherapy treatment ("CINP") is expected to occur in the first quarter of 2025.

Halneuron® is a first-in-class, Nav 1.7 specific voltage gated sodium channel inhibitor being developed as an alternative to pain treatment with opioids. Halneuron® treated patients demonstrated a statistically significant reduction in cancer-related pain in a previous Phase 2 clinical trial with an acceptable safety profile. Halneuron® has been evaluated in over 700 patients in a series of Phase 1 and Phase 2 studies, with no addiction potential.

"Chemotherapy is effective, but can be very challenging for patients given common side effects, including fever, fatigue, infection, hair loss, neuropathy and pain," commented R. Michael Gendreau, M.D., Ph.D., Chief Medical Officer of Dogwood Therapeutics, Inc. "Research suggests that one-in-three patients treated with certain chemotherapeutics including taxanes and platinum drugs develop chronic painful neuropathy. There are currently no approved treatments for chronic neuropathy, and off label treatment with available analgesics is generally not effective. Further, market data suggest that approximately one-in-three cancer patients are treated with opioids."

"The lead Halneuron® target indication in CINP represents an area of high unmet medical need and a market valued at approximately $1.5B," said Greg Duncan, Chairman and Chief Executive Officer of Dogwood Therapeutics, Inc. "The Dogwood executive team has established a track record of developing and/or commercializing blockbuster medicines, including the pain therapeutics Celebrex, Lyrica and Savella."

About Dogwood Therapeutics

Dogwood Therapeutics (Nasdaq: DWTX) is a development-stage biopharmaceutical company focused on developing new medicines to treat pain and fatigue-related disorders.

The Dogwood research pipeline includes two separate mechanistic platforms with a non-opioid analgesic program and an antiviral program. The proprietary non-opioid, Nav 1.7 analgesic program is centered on our lead development candidate, Halneuron® which is a highly specific voltage-gated sodium channel modulator, a mechanism known to be effective for reducing pain transmission. In clinical studies, Halneuron® treatment has demonstrated pain reduction in pain related to general cancer and in pain related to chronic CINP. Interim data from the forthcoming Phase 2 CINP study are expected in 2H 2025. The antiviral program includes IMC-1 and IMC-2, which are novel, proprietary, fixed dose combinations of anti-herpes antivirals and the anti-inflammatory agent, celecoxib. These combination antiviral approaches are being applied to the treatment of illnesses believed to be related to reactivation of previously dormant herpesviruses, including fibromyalgia ("FM") and Long-COVID ("LC"). IMC-1 is poised to progress into Phase 3 development as a treatment for FM and is the focus of external partnership activities. IMC-2 has been assessed in both active control and double-blind, placebo clinical trials and in both cases demonstrated successful reduction of the fatigue associated with LC. The company has reached an agreement with FDA on using reduction in fatigue as the primary endpoint for future LC research and is currently planning to advance IMC-2 into Phase 2b research.

For more information, please visit www.dwtx.com.

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Forward-Looking Statements

Statements in this press release contain "forward-looking statements," within the meaning of the U.S. Private Securities Litigation Reform Act of 1995, that are subject to substantial risks and uncertainties. All statements, other than statements of historical fact, contained in this press release are forward-looking statements. Forward-looking statements contained in this press release may be identified by the use of words such as "anticipate," "believe," "contemplate," "could," "estimate," "expect," "intend," "seek," "may," "might," "plan," "potential," "predict," "project," "suggest," "target," "aim," "should," "will," "would," or the negative of these words or other similar expressions, although not all forward-looking statements contain these words. Forward-looking statements are based on Dogwood's current expectations and are subject to inherent uncertainties, risks and assumptions that are difficult to predict, including risks related to the completion, timing and results of current and future clinical studies relating to Dogwood's product candidates. Further, certain forward-looking statements are based on assumptions as to future events that may not prove to be accurate. These and other risks and uncertainties are described more fully in the section titled "Risk Factors" in the Amended Annual Report on Form 10-K/A for the year ended December 31, 2023 and the Company's quarterly report on Form 10-Q for the quarterly period ended September 30, 2024, which are filed with the Securities and Exchange Commission. Forward-looking statements contained in this announcement are

made as of this date, and Dogwood undertakes no duty to update such information except as required under applicable law.

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