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Dogwood Therapeutics Announces Dosing of First Patient in Phase 2b Trial Evaluating Halneuron® in Patients with Chemotherapy-Induced Neuropathic Pain

Opioid-free and addiction-free pain treatment therapy could address $1.5B worldwide CINP market

ATLANTA, March 18, 2025 (GLOBE NEWSWIRE) -- Dogwood Therapeutics, Inc. (Nasdaq: DWTX) ("Dogwood" or the "Company"), a development-stage biopharmaceutical company focused on advancing first-in-class, non-opioid, treatments for chronic and acute pain, announces the 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® for the treatment of neuropathic pain associated with prior chemotherapy treatment ("CINP").

"Halneuron® is being developed to specifically inhibit the Na_V 1.7 sodium channel, given the well-established role of this target in pain transmission," said Greg Duncan, Dogwood's Chairman and Chief Executive Officer. "We believe Halneuron's® inherent specificity and potency may enable physicians to use very low doses of Halneuron® to both reduce pain and minimize the off-target effects that have limited prior Na_V 1.7 development candidates."

Halneuron® is a first-in-class, Na_V 1.7 specific voltage gated sodium channel inhibitor being developed as an alternative to chronic pain treatment with opioids. Patients treated with Halneuron® 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 and shows no signs of addiction potential.

"Our goal is to recruit 100 patients with CINP by the fourth quarter of 2025, which should allow us to execute an interim analysis on the HALT-CINP trial in the fourth quarter of 2025," commented R. Michael Gendreau, M.D., Ph.D., Dogwood's Chief Medical Officer. "This proposed interim analysis will inform our adaptive trial design, enabling changes to the study, if necessary, to improve trial outcomes."

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, Na_V 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 the second half of 2025.

Dogwood's 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-controlled 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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