

Dogwood Therapeutics Announces Enrollment of First Fifty Patients in Ongoing Halneuron® Phase 2b Trial

- Halneuron[®] Chemotherapy-Induced Neuropathic Pain ("CINP") Phase 2b study interim data readout remains on track as projected for Q4 2025 -
- Low discontinuation rate (6%) due to adverse events amongst the first 35 patients completing the trial suggests Halneuron[®] and placebo treatment have been generally well tolerated -

ATLANTA, Aug. 07, 2025 (GLOBE NEWSWIRE) -- Dogwood Therapeutics, Inc. (Nasdaq: DWTX) (the "Company"), a development-stage biotechnology company developing new medicines to treat pain and fatigue-related disorders, today announced it has enrolled the first 50 patients in its ongoing Phase 2b CINP trial and remains on track to execute its planned interim analysis on approximately 100 patients who will have completed the four week trial during the fourth quarter of this year.

"There has been increasing interest in the role of Na_v 1.7 and Na_v 1.8 sodium channel inhibition as alternatives for pain treatment over the past few years," said Greg Duncan, Chief Executive Officer of Dogwood Therapeutics. "We believe the novelty of Halneuron's specificity and potency for Na_v 1.7 sodium channel inhibition, as well as the uniqueness of the cancer and chemotherapy related neuropathic pain disease targets differentiates our program from other sodium channel research programs."

"Positive data from prior Halneuron[®] cancer pain and CINP clinical trials underpins both patient and research community interest in participating in this landmark study," said Michael Gendreau, MD, PhD, Chief Medical Officer of Dogwood Therapeutics. "Based on this interest, we continue to add qualified research sites to our study with the goal to deliver full results from the Phase 2b trial in mid-2026."

Halneuron® CINP Phase 2b Trial ("HALT-CINP") Overview (NCT06848348)

HALT-CINP is a randomized, phase 2b clinical trial evaluating the safety and effectiveness of Halneuron[®] vs placebo in cancer patients with established neuropathy due to a platinum or taxane based chemotherapy regimen. Participants receive 8 once daily sub-cutaneous doses of Halneuron[®] or placebo over 14 days and will be followed for 28 days for safety and effectiveness. The primary endpoints for this study will assess overall safety and the change from baseline in the weekly average of daily 24-hour recall pain intensity over the course of

four weeks of treatment with either Halneuron[®] or placebo. We expect that the study will be conducted across 25 sites in the U.S. Secondary measures will assess Halneuron's[®] treatment effect on sleep, fatigue and overall patient health. Interim data from approximately 100 patients completing the trial will be used to determine the final Phase 2b trial sample size in Q4 2025.

About Halneuron®

Our lead product candidate, Halneuron[®], is in Phase 2b development as a non-opioid, Na_V 1.7 inhibitor to treat pain conditions including the neuropathic pain associated with chemotherapy treatment. Halneuron[®] has been granted fast track designation from the Food and Drug Administration ("FDA") for the treatment of CINP.

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 chemotherapy-induced neuropathic pain ("CINP"). Interim data from the ongoing Halneuron[®] Phase 2 CINP study are expected in Q4 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 IMC-2 LC research.

For more information, please visit <u>www.dwtx.com</u>.

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 Annual Report on Form 10-K for the year ended December 31, 2024, which has been 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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Source: Dogwood Therapeutics, Inc.