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Dogwood Therapeutics Announces Commencement of Halneuron® Chemotherapy Induced Neuropathic Pain Phase 2b Long Term Extension Study

New study to assess Halneuron® pain reduction effect over three months of treatment, additional safety data to bolster planned end of Phase 2 FDA submission package

Patients completing the ongoing Halneuron® 4-week CINP Phase 2b study are now eligible to enroll in the new 12-week open-label follow-on trial

ALPHARETTA, Ga., May 18, 2026 (GLOBE NEWSWIRE) -- Dogwood Therapeutics, Inc. (NASDAQ: DWTX) ("Dogwood" or the "Company"), a biopharmaceutical company developing first-in-class, non-opioid medicines to treat pain and neuropathy, today announced commencement of a new Halneuron® chemotherapy induced neuropathic pain ("CINP") phase 2b extension study. Based on a positive interim assessment demonstrating a Halneuron® 4-week treatment effect versus placebo, Dogwood previously submitted plans to FDA to support commencement of a Halneuron® 12-week follow-on open-label extension study for patients completing the 4-week double-blinded treatment period. Several patients have already been enrolled in the new study that will assess the safety and efficacy of continued Halneuron® treatment for an additional 3 months, using various dosing regimens. Data from the forthcoming extension trial will add to the data package the Company plans to submit to the FDA to support its planned Phase 3 development program, presently projected to start in the first half of 2027.

Dogwood Therapeutics previously announced that a pre-planned interim analysis of the double-blinded Halneuron® CINP Phase 2b study supported continuation of the study, with a sample size in the 210-240 range to achieve 80% power. This recommendation by an independent group of statisticians was based on the observed treatment difference between Halneuron®-treated and placebo-treated patients amongst the 97 patients completing the trial. The double-blinded portion of the ongoing CINP study is expected to meet enrollment objectives to support release of top-line results in the fall of 2026. The current overall study dropout rate of under 5% is far below rates typically observed during other FDA-approved chronic pain clinical studies. Patients completing the ongoing CINP Phase 2b trial will be eligible to receive Halneuron® for an additional 12 weeks to control their moderate-to-severe pain following chemotherapy treatment. A review of the demographics of the patients included in the interim analysis revealed that the mean duration of CINP for study enrollees exceeded five years, demonstrating the extraordinary medical need for novel new medicines to improve care for patients suffering from CINP. Currently, there are no FDA-approved

treatments for CINP patients.

“Neuropathic pain is a difficult to treat chronic condition, as evidenced by the five-year mean duration of symptoms for the patients enrolling in our current Halneuron® CINP Phase 2b trial,” commented R. Michael Gendreau, MD, Chief Medical Officer of Dogwood. “This new 12-week long term extension will generate important additional data on how best to optimize Halneuron® maintenance treatment for our planned Phase 3 program and potential commercialization.”

About Dogwood Therapeutics:

Dogwood Therapeutics (Nasdaq: DWTX) is a development-stage biopharmaceutical company focused on developing new medicines to treat pain and neuropathic disorders. The Dogwood research pipeline includes two first-in-class development candidates, Halneuron® and SP16.

Our lead product candidate, Halneuron®, is in Phase 2b development to treat pain conditions including the neuropathic pain associated with chemotherapy treatment. Halneuron® has been granted fast track designation from the FDA for the treatment of CINP. Halneuron ® is a non-opioid, Na_V 1.7 analgesic 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. SP16 IV is a low-density lipoprotein receptor related protein-1 agonist (LRP1) with potential to treat neuropathy and prevent or repair nerve damage following chemotherapy. SP16 acts as an LRP1 agonist that in turn provides alpha-1-antitrypsin-like activity. Consistent with alpha-1-antitrypsin anti-inflammatory and immunomodulatory actions, SP16 preclinically demonstrated anti-inflammatory (analgesic) action via potential reductions in IL-6, IL-8, IL1B and TNF-alpha levels, as well as potential to repair damaged tissue via increases in pAKT and pERK that regulate fundamental processes like growth, proliferation and survival. The forthcoming SP16 IV Phase 1b chemotherapy-induced pain and peripheral neuropathy trial is fully funded by the National Cancer Institute.

Dogwood Therapeutics’ largest shareholder is a member of CK Life Sciences Int’l., (Holdings) Inc., which is listed on the Hong Kong Stock Exchange (Stock code: 0775). For more information, please visit www.dwtx.com.

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 most recently filed Annual Report on Form 10-K, 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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