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Dogwood Therapeutics Announces Positive Interim Phase 2b Clinical Trial Results in Chemotherapy Induced Neuropathic Pain

- Halneuron® treated patients separating from placebo on pain improvement assessment; Company expects top-line results availability in Q3 2026 -

- The overall study dropout rate of ~4.4% is far below rates typically observed with other FDA approved chronic pain medicines -

ATLANTA, Dec. 22, 2025 (GLOBE NEWSWIRE) -- Dogwood Therapeutics, Inc. (Nasdaq: DWTX) (the "Company"), a development-stage biotechnology company developing new medicines to treat pain and neuropathy, today announces positive results from an interim analysis of 97 patients who had completed treatment in the ongoing Halneuron® Phase 2b chemotherapy induced neuropathic pain ("CINP") study. The independent statistical review committee reviewed unblinded patient treatment data from the Phase 2b trial and concluded that Halneuron® treated patients are demonstrating separation from placebo treated patients in terms of pain improvement over the four-week study.

Based on the current Phase 2b trial enrollment pace and the interim assessment results, the Company continues to expect to have top-line results available during Q3 2026. Current study patient enrollment trends are projected to provide statistical power of approximately 80% to 85% to detect a Halneuron® treatment difference.

"We have long believed that Na_V 1.7 sodium channel inhibition holds great promise for treating both chronic and acute pain," said Greg Duncan, Dogwood Therapeutics Chief Executive Officer. "Extrapolation of the current Phase 2b study trends has the potential to represent the first statistically significant trial involving CINP patients under FDA chronic pain study guidance."

This preliminary evidence of a Halneuron® treatment effect is noteworthy as patients in the interim analysis population present an average duration of CINP of 5 years and 67% of patients that met entry criteria were also being treated with stable doses of other chronic pain medicines, including pregabalin, gabapentin, duloxetine, and opioids. In addition, the overall study dropout rate of approximately 4.4% is far below rates typically observed with other FDA approved chronic pain medicines. While still blinded, the Company believes these findings reaffirm the encouraging safety and tolerability profile of Halneuron® observed in previous clinical trials.

“There are currently no approved therapies to treat the moderate-to-severe neuropathic pain that occurs following chemotherapy treatment,” said Dr. R. Michael Gendreau, Chief Medical Officer of Dogwood Therapeutics. “We are hopeful that positive outcomes in this ongoing Phase 2b trial will set the stage for a Phase 3 registration program in CINP, providing a needed therapeutic option for this patient population of cancer survivors.”

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. Success in this Phase 2b study will serve as the basis for the Company engaging FDA to align on the Halneuron® Phase 3 development program requirements.

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 IV.

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 (“CINP”).

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 CINP trial is fully funded by the National Cancer Institute.

Dogwood Therapeutic’s 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 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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