February 2, 2026

Dogwood Therapeutics Announces 50% Enrollment in Ongoing Halneuron® Phase 2b Trial, Top Line Results Anticipated in Q3 2026

- Low early termination rate (4.3%) among the first 116 patients completing the study suggests Halneuron® treatment to be well tolerated -

ATLANTA, Feb. 02, 2026 (GLOBE NEWSWIRE) -- Dogwood Therapeutics, Inc. (Nasdaq: DWTX) (the "Company"), a development-stage biotechnology company developing new medicines to treat pain and neuropathy, today announced it has achieved over 50% of the planned enrollment in its ongoing HAL-CINP-203 Phase 2b chemotherapy induced neuropathic pain ("HALT-CINP") trial. HALT-CINP remains on track for top line results to be available during the third quarter of 2026.

"If the HALT-CINP study is successful, Halenuron® would represent a new therapeutic agent for treating chemotherapy-induced neuropathic pain, a condition for which there are currently no approved therapies. There remains a great need for treatment options for the millions of patients suffering from chemotherapy-induced neuropathic pain and we continue to be encouraged by the rate of enrollment, interim outcomes and safety profile," said Dogwood Therapeutics Chief Medical Officer R. Michael Gendreau, M.D., Ph.D., "Against a history of failed clinical trials, the ongoing Halneuron® clinical trial has the potential to be the first statistically significant trial treating chemotherapy-induced neuropathic pain patients under FDA chronic pain study guidance."

In December 2025, Dogwood announced encouraging results from an interim analysis of 97 patients who had completed treatment in the HALT-CINP study. An 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. This preliminary evidence of a Halneuron® treatment effect is noteworthy as patients in the interim analysis population presented with an average duration of chemotherapy-induced neuropathic pain of 5 years. The overall study dropout rate of approximately 4.0% is far below rates typically observed in studies of other FDA approved chronic pain medicines.

The study is designed to provide statistical power of approximately >80% to detect a Halneuron® treatment difference versus placebo upon study unblinding in the third quarter of 2026.

Halneuron® CINP Phase 2b Trial 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 previous platinum or taxane-based chemotherapy regimen. Participants receive 8 sub-cutaneous doses of Halneuron® or placebo over a 14-day period and are followed for a total of 28 days for safety and effectiveness. The primary endpoint for this study is the change in the weekly average of daily 24-hour recall pain intensity scores from baseline to week four. The study is being conducted at approximately 30 sites in the U.S. Secondary measures will assess Halneuron's® treatment effects on sleep, fatigue, neuropathy symptoms and overall patient health. Final HALT-CINP Phase 2b trial results are projected for the third quarter of 2026.

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 chemotherapy induced neuropathic pain ("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 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 chemotherapy induced peripheral neuropathy 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.

Investor Relations:

CORE IR
(516) 222-2560
IR@dwtx.com

DOGWOOD
THERAPEUTICS

Source: Dogwood Therapeutics, Inc.