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Dogwood Enrolls First 200 Patients in Ongoing Halneuron® Phase 2b Chemotherapy Induced Neuropathy Trial; Top-line Data Expected in Fall 2026

- Continued low early termination rate (4.5%) among the first 200 patients enrolled in the study suggests Halneuron® and placebo treatment have been well tolerated -

ATLANTA, July 20, 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 successfully enrolled the first 200 patients in its ongoing HAL-CINP Phase 2b trial. HAL-CINP remains on track for top-line data readout from the four-week study in the fall of 2026.

"In December, an independent statistical review committee reviewed unblinded patient treatment data from the ongoing 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," said Greg Duncan, Chief Executive Officer of Dogwood Therapeutics. "The continued low dropout rate of 4.5% remains below rates typically observed in studies of other FDA-approved chronic pain medicines and is consistent with the encouraging safety and tolerability profile observed in prior Halneuron® clinical trials. We are very pleased to have reached this milestone and look forward to reporting top-line data in the fall of 2026."

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

HAL-CINP is a randomized, phase 2b clinical trial evaluating the efficacy and safety of Halneuron® compared with placebo in approximately 210 to 240 patients with moderate to severe neuropathic pain caused by prior platinum and/or taxane-based chemotherapy. 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 from baseline to week four in the weekly average of daily 24-hour recall pain intensity scores. The study is being conducted at approximately 25 sites in the U.S. Secondary measures will assess Halneuron's® treatment effects on sleep, fatigue, neuropathy symptoms and overall patient health.

About Dogwood Therapeutics

Dogwood Therapeutics (Nasdaq: DWTX) is a development-stage biopharmaceutical company focused on developing first-in-class, non-opioid 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, NaV 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 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's activity as an LRP1 agonist 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 CIPN 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, enrollment, design and results of current and future clinical studies relating to Dogwood's product candidates; whether interim or final clinical data will support continued development, regulatory submissions or approval; and Dogwood's ability to finance its operations. 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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