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Dogwood Therapeutics Announces FDA Acceptance of SP16 Investigational New Drug Application for the Treatment of Chemotherapy Induced Pain and Neuropathy

Dogwood licensed SP16 to treat cancer-related pain from partner and regulatory sponsor Serpin Pharma

The SP16 Phase 1b trial fully funded by the National Cancer Institute; Patient enrollment expected to commence in the middle of 2026 at the University of Virginia

ALPHARETTA, Ga., April 15, 2026 (GLOBE NEWSWIRE) -- Dogwood Therapeutics, Inc. (NASDAQ: DWTX) ("DWTX", "Dogwood" or "the Company"), a company that focuses on developing new non-opioid medicines to treat pain and neuropathy, today announced FDA acceptance of an Investigational New Drug ("IND") application for its development candidate SP16, administered intravenously ("IV"), for the treatment of chemotherapy-induced pain and peripheral neuropathy ("CIPPN").

SP16 is administered via IV infusion with two hypothesized actions: anti-inflammatory actions via reduction of IL-6, IL-8, IL-1β and TNF-alpha, and tissue repair via increases in pAKT and pERK that regulate and promote fundamental processes like growth, proliferation, and survival. The Company and its partner Serpin Pharma anticipate patient enrollment in the SP16 Phase 1b trial to begin in the middle of 2026. Serpin Pharma has been awarded a $2.5 million grant from the National Cancer Institute ("NCI"), which will fully fund the forthcoming SP16 Phase 1b CIPPN clinical trial.

"FDA acceptance of our SP16 IND filing represents an important step in expanding our pipeline as we advance a second development candidate into the clinic to treat chemotherapy-induced neuropathy and pain," said Greg Duncan, Chairman and Chief Executive Officer of Dogwood Therapeutics. "SP16 compliments our lead candidate, Halneuron®, by not only targeting neuropathic pain but also addressing additional debilitating symptoms of neurotoxic chemotherapy, including numbness, tingling and impaired motor function."

Incidence of CIPPN is high, affecting approximately 30-40% of patients six months after receiving neurotoxic chemotherapy, and can persist long-term in many patients. Key risk factors for the development of these symptoms include use of platinum or taxane containing drugs, higher chemotherapeutic doses, and underlying diabetes. Common symptoms associated with CIPPN are numbness, tingling, and pain, symptoms that directly impact

quality of life in these cancer survivors.

In September 2025, Dogwood secured the SP16 royalty-free, global license to develop and commercialize Serpin Pharma's IV formulation of SP16 to manage CIPPN. Serpin Pharma is the holder of the IND and the regulatory sponsor of the program.

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 CIPPN 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 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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Source: Dogwood Therapeutics, Inc.