

December 2, 2025



Dogwood Therapeutics Files New Synthetic Halneuron(R) Intellectual Property Protection Projected to Extend Exclusivity Period Up to 2045

- New Composition of Matter Intellectual Property ("IP") Filing Centered on First-in-Class, Fully Synthetically Manufactured Halneuron® -

- New Synthetic Process to be Used for Phase 3 Development Provides Higher Manufacturing Yields and Reduces Costs Versus Naturally Harvested Halneuron® -

ATLANTA, GA / [ACCESS Newswire](#) / December 2, 2025 / Dogwood Therapeutics, Inc. (Nasdaq:DWTX) (the "Company"), a development-stage biotechnology company developing new medicines to treat pain and neuropathy, today announced it has filed for new intellectual property protection for synthetic Halneuron®. If granted, the IP's exclusivity period will extend to 2045, before additional patent term restoration extensions.

"We plan to use synthetically manufactured Halneuron® in both Phase 3 development and commercialization," said Greg Duncan, Dogwood Therapeutics Chief Executive Officer. "This new synthetic process builds on our proprietary and best-in-class manufacturing know-how, with potential to reset our exclusivity period for 20 years, thus providing ample opportunity to deliver Halneuron's® full commercial potential."

About Halneuron®

Our lead product candidate, Halneuron®, is in Phase 2b development as a non-opioid, Na_v1.7 inhibitor to treat pain conditions including the neuropathic pain associated with chemotherapy treatment ("CINP"). 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 the 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 (LRP1) agonist 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.

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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