November 18, 2024

# Dogwood Therapeutics, Inc. Announces Low Dose IMC-2 Treatment Reduces Long-COVID Related Fatigue and Sleep Disturbance in an Investigator-Initiated Study

*- IMC-2 treatment, dosed as valacyclovir 750 mg + celecoxib 200 mg twice daily, demonstrated clinically meaningful reduction in Long-COVID related fatigue and sleep disturbance as compared to placebo –*

*- Top-line results from the Bateman Horne Center's Long-COVID study provide key insights into final design of Dogwood's planned Phase 2 study, projected to enroll approximately 200 participants -*

ATLANTA, Nov. 18, 2024 (GLOBE NEWSWIRE) -- Dogwood Therapeutics, Inc. (Nasdaq: DWTX) (the "Company"), a development-stage biotechnology company advancing new medicines to treat pain and fatigue-related disorders, today announced top line data from the recently completed BHC IMC-2 Long-COVID study. The study was conducted via an investigator-initiated, investigational research grant provided to the Bateman Horne Center ("BHC"). The study demonstrated that the low dose combination antiviral therapy IMC-2 treated patient cohort (valacyclovir 750 mg + celecoxib dosed 200 mg twice daily) exhibited clinically meaningful reductions in Long-COVID associated fatigue and sleep disturbance, as compared with the placebo treated cohort. The high dose IMC-2 treated cohort (valacyclovir 1500 mg + celecoxib 200 mg dosed twice daily) did not exhibit clinically meaningful differences versus placebo, believed to be related to higher levels of gastrointestinal (GI) adverse events associated with the higher dose regimen.

"To date, there are no FDA approved medicines to treat Long-COVID symptoms," said Lucinda Bateman, MD, Founder and Chief Medical Officer of the Bateman Horne Center and the study's principal investigator. "This trial provides evidence that IMC-2 has the potential to improve fatigue and sleep symptoms associated with Long-COVID illness on a scale not previously observed in Long-COVID research. I believe this finding warrants further investigation of IMC-2 in larger scale, multi-center Long-COVID studies."

"The primary goals of this trial were to determine the IMC-2 treatment effect size versus placebo and the associated patient sample size to design our planned IMC-2 Phase 2 Long-COVID study in a manner that maximizes probability of success," said R. Michael Gendreau, MD, Chief Medical Officer of Dogwood Therapeutics, Inc. "IMC-2 demonstrated a robust reduction in fatigue, the primary endpoint agreed with the Food & Drug Administration to advance IMC-2 into Phase 2 development. We look forward to finalizing these plans and

providing further information on next steps in the coming months."

**IMC-2 Long-COVID Development Program Summary:**

BHC Study 201: Investigator-initiated, open-label, matched control study assessing IMC-2 treatment versus patients matched by age, duration of effect, vaccination status and gender. In this study, completed in 2023, the combination of valacyclovir and celecoxib exhibited statistically significant reductions in Long-COVID related fatigue, orthostatic intolerance, pain and anxiety, while improving overall patient health. The dosage used in this study was valacyclovir 1500 mg + celecoxib 200 mg dosed twice daily.

BHC Study 202: This recently completed study was designed as an investigator-initiated, double-blinded, placebo controlled follow-on study to BHC 201. While not statistically significant given the small sample size recruited for this trial (14-15 per group), the study demonstrated that the low dose combination antiviral therapy IMC-2 exhibited clinically meaningful improvements in fatigue and sleep disruption as compared to placebo treated patients. Overall, the IMC-2 adverse event profile was favorable in this study. The high dose IMC-2 treatment (valacyclovir 1500 mg + celecoxib 200 mg dosed twice daily) resulted in more GI related adverse events compared to the low dose and placebo cohorts.

**Additional Assets in Dogwood Therapeutics Proprietary Pipeline:**

- **Halneuron®** is in Phase 2b development as a non-opioid, Nav 1.7 inhibitor to treat the neuropathic pain resultant from chemotherapy treatment. Halneuron® has been granted Fast Track Designation from the FDA for the treatment of Chemotherapy-Induced Neuropathic Pain (CINP).

  Next milestone: Interim data from the ongoing Phase 2 CINP study are expected in the second half of 2025.

- **IMC-1 (famciclovir + celecoxib)** is Phase 3 development ready as a combination antiviral treatment for fibromyalgia (FM). IMC-1 has been granted fast track designation by the FDA as a treatment for FM.

  Next milestone: Dogwood is exploring partnerships for IMC-1 to execute the Phase 3 FM program as agreed with the FDA.

**About Dogwood Therapeutics**

Dogwood Therapeutics (Nasdaq: DWTX) is a development-stage biopharmaceutical company focused on developing new medicines to treat pain and fatigue-related disorders. The Dogwood research pipeline includes two separate mechanistic platforms with a non-opioid analgesic program and an antiviral program. The proprietary non-opioid, Nav 1.7 analgesic program is centered on lead development candidate, Halneuron® which is a voltage-gated sodium channel blocker, a mechanism known to be effective for reducing pain. Halneuron® treatment has demonstrated pain reduction of both general cancer related pain and CINP. Interim data from the forthcoming Phase 2 CINP study are expected in 2H 2025. The antiviral program includes IMC-1 and IMC-2, which are novel, proprietary, fixed dose combinations of nucleoside analog, anti-herpes antivirals and the anti-inflammatory agent,

celecoxib, for the treatment of illnesses believed to be related to reactivation of previously dormant herpes viruses, including FM and LC. IMC-1 is poised to progress into Phase 3 development as a treatment for FM and is the focus of external partnership activities. For more information, please visit www.dwtx.com.

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**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 Amended Annual Report on Form 10-K/A for the year ended December 31, 2023 and the Company’s quarterly report on Form 10-Q for the quarterly period ended September 30, 2024, which are 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.

**Contact:**

IR@dwtx.com


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