November 23, 2026

Dogwood Therapeutics Announces Halneuron® Meets Primary Endpoint with Statistically Significant Pain Reduction vs. Placebo in Phase 2b Study of Chemotherapy-Induced Neuropathic Pain

- Primary endpoint achieved: 23.3% of Halneuron® patients achieved a 50% or greater reduction in pain vs. 9.2% on placebo (p=0.003) -

- Statistically significant improvements observed in neuropathic pain symptoms (p=0.027), numbness and tingling (p=0.025), and quality-of-life measures (p=0.006) -

- Halneuron® treatment demonstrated a statistically significant improvement over placebo in the proportion of CINP patients pain interference by 50% or greater with activities at work, leisure, or home over placebo (p=0.026) -

- Treatment benefit was observed in patients with an average CINP duration of approximately five years and whether used alone or with background pain medications -

- Halneuron® was generally well tolerated; 4.2% discontinuation rate, identical to placebo -

- Company to host investor call today at 8:30am Eastern Time -

ALPHARETTA, Ga., Nov. 23, 2026 (GLOBE NEWSWIRE) -- Dogwood Therapeutics, Inc. (Nasdaq: DWTX) ("Dogwood" or the "Company"), a company that focuses on developing potential first-in-class, new non-opioid medicines to treat pain and neuropathy, today announced positive top-line results from its randomized, double-blind, placebo-controlled Phase 2b trial evaluating Halneuron® administered subcutaneously in cancer survivors suffering from chemotherapy-induced neuropathic pain ("CINP"). The study met its prespecified primary endpoint, demonstrating a statistically significant increase in the proportion of patients achieving at least a 50% reduction from baseline in weekly average pain intensity at Week 4 as compared with placebo. The observed 50% pain reduction represents a treatment effect that is clinically meaningful in this difficult-to-treat condition for which there are no FDA-approved treatments. Notably, reduction in pain was observed when Halneuron® was used alone or when used on top of other approved chronic pain medications.

A total of 239 patients with moderate-to-severe CINP were randomized 1:1 to receive Halneuron® or placebo. Patients received eight subcutaneous injections of Halneuron® or

placebo over a two-week treatment period, with the primary endpoint at Week 4. The study enrolled patients with neuropathic pain secondary to prior treatment with neurotoxic chemotherapy agents, including platinum-based compounds and taxanes. Enrolled patients had experienced CINP for a mean duration of approximately 5.6 years for Halneuron®-treated patients and 4.4 years for placebo-treated patients. Halneuron® was generally well tolerated, with an overall dropout rate of 4.2%. Most adverse events ("AEs") were mild to moderate in severity.

"We are thrilled with the groundbreaking results of this landmark study and look forward to advancing Halneuron® toward registration trials in CINP. The long-standing promise of Na_V 1.7 inhibition delivering significant pain reduction has now been validated in patients suffering from CINP, a very difficult to treat illness for which there are no approved treatments," said Greg Duncan, Chief Executive Officer of Dogwood Therapeutics. "The pain reduction treatment benefits Halneuron® delivered, combined with what appears to be a best-in-class chronic pain medicine tolerability profile, suggest Halneuron® could represent the first new therapeutic agent for millions of CINP patients across the globe."

The treatment responder rates and the tolerability profile observed for Halneuron® in this trial represent a real breakthrough for CINP patients and suggest that selective Na_V 1.7 modulation has therapeutic relevance in treating multiple forms of neuropathic pain," said R. Michael Gendreau, M.D., Ph.D., Chief Medical Officer. "This study provides important clinical evidence validating the biological mechanism of Halneuron® and supports our planned Phase 3 development strategy in CINP and other neuropathic pain conditions."

Patient Demographics

PATIENT DEMOGRAPHICS	Halneuron® n=120	Placebo n=119
Age	65.4	64.9
% Female	83.3%	78.2%
Baseline Pain Score	6.1	6.0
On Any Background Concomitant Pain Medication	51.7%	57.1%
On duloxetine/TCAs	20.0%	21.8%
On gabapentinoids	39.2%	42.9%
On opioids	13.3%	10.9%
Years since CINP Onset	5.6	4.4
Platinum Chemotherapy Agent Induced CINP	38.3%	42.0%
Taxane Chemotherapy Agent Induced CINP	32.5%	34.4%
Both Platinum and Taxane	29.2%	23.5%

Halneuron® Phase 2b CINP Top-Line Results

The prespecified primary endpoint was the proportion of patients completing the full study and achieving a 50% or greater reduction from baseline in the weekly average of daily 24-hour recall pain intensity scores, as measured by the 11-point Numeric Pain Rating Scale (NPRS), at Week 4.

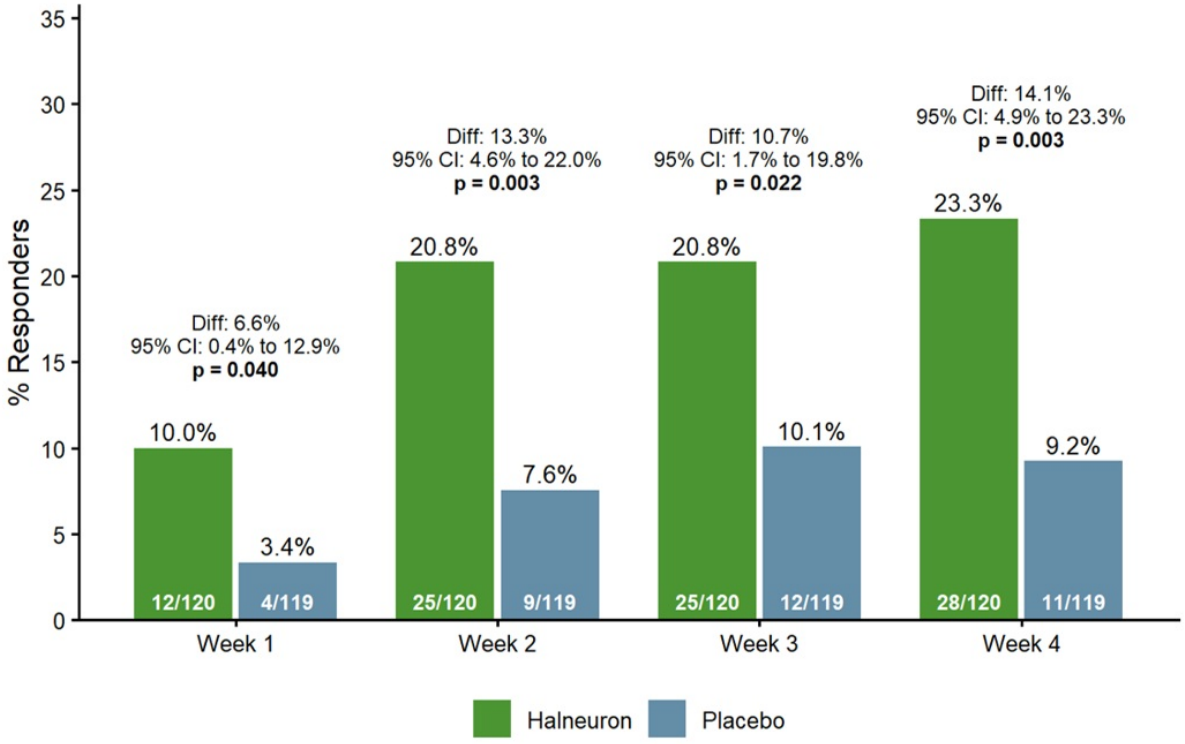
Primary Endpoint Result

Endpoint	Halneuron® (n=120)	Placebo (n=119)	Treatment Difference	p-value
≥ 50% NPRS responder rate at Week 4	23.3%	9.2%	14.1%	p=0.003

- Key findings included:**23.3%** of patients receiving Halneuron® achieved at least a 50% reduction in pain intensity compared with **9.2%** of patients receiving placebo (**p=0.003)**.

- Halneuron® treatment demonstrated a statistically significant improvement versus placebo on the primary endpoint at every study week.

Proportion of Patients Who Achieved ≥ 50% Reduction from Baseline in Average Weekly Pain Intensity at Week 4



Other Key Study Results

- Halneuron® treatment demonstrated statistically significant improvement on key secondary global assessment endpoints:
  - Neuropathic pain (p=0.027)
  - Numbness and tingling (p=0.025)
  - QoL measures (p=0.006)

- Halneuron® treatment demonstrated a statistically significant improvement of CINP patients' pain interference by 50% or greater with activities at work, leisure, or home over placebo (p=0.026).

- Halneuron® pain reduction was observed when used alone or on top of other chronic

pain medications, including opioids, gabapentinoids and duloxetine/TCAs, for patients suffering from moderate-to-severe CINP.

- Halneuron® was generally well tolerated, with an adverse event related dropout rate of 2.5%, compared to placebo (1.7%).

Detailed analyses of secondary endpoints will be reported following completion of ongoing statistical review.

Safety and Tolerability

Halneuron® was generally well tolerated. More than **95%** of randomized participants completed the study.

Treatment-emergent adverse events ("TEAEs") were reported in **90.0%** of patients receiving Halneuron® and **54.6%** of patients receiving placebo and were generally mild to moderate in severity.

The most frequently reported treatment-emergent adverse events were:

TEAE Preferred Term	Halneuron® (N=120)	Placebo (N=119)
Paraesthesia oral (lips, tongue, mouth tingling)	70.0%	7.6%
Hypoesthesia oral (numbness in oral cavity)	35.0%	1.7%
Paraesthesia	23.3%	8.4%
Headache	15.8%	9.2%
Nausea	15.0%	6.7%
Hypoesthesia	11.7%	2.5%
Fatigue	9.2%	1.7%
Dizziness	8.3%	3.4%
Blood pressure increased	6.7%	0.8%
Dysgeusia (taste distortion)	6.7%	1.7%
Somnolence	5.8%	0.8%

Most adverse events were mild to moderate in severity.

Discontinuations due to adverse events occurred in **2.5%** and **1.7%** of patients in the Halneuron® and placebo groups, respectively.

The safety profile observed in the Phase 2b study was generally consistent with that reported in previous clinical studies of Halneuron®.

About the Phase 2b Study

The Phase 2b study was a multicenter, randomized, double-blind, placebo-controlled clinical trial conducted at 27 sites in the United States evaluating Halneuron® in patients with chemotherapy-induced neuropathic pain.

Key Study Characteristics

- Enrollment: 239 patients
- Randomization: 1:1
- Study duration: 4 weeks
- Primary endpoint: Proportion of patients achieving ≥ 50% reduction in weekly average pain intensity at Week 4
- Assessment tool: 11-point Numeric Pain Rating Scale (NPRS)
- Mean CINP duration of 5.6 years for Halneuron®-treated patients and 4.4 years for placebo-treated patients.
- Mean baseline NPRS score: 6.1 for Halneuron® and 6.0 for placebo

About Chemotherapy-Induced Neuropathic Pain (CINP)

Chemotherapy-induced neuropathic pain is a chronic and potentially debilitating complication of cancer treatment resulting from damage to peripheral nerves caused by neurotoxic chemotherapy agents. Symptoms may include pain, numbness, tingling, burning sensations, and impaired physical function. CINP can persist long after completion of chemotherapy and may substantially affect quality of life and daily functioning. There are currently no FDA-approved therapies specifically indicated for the treatment of CINP.

Conference Call and Webcast

The Company will host a webcast presentation to discuss the top-line results today, November 23, 2026 at 8:30 a.m. Eastern Time.

Registration Details

Toll Free: 1-877-407-0784
International: 1-201-689-8560
Participant Access Code: 13763933
CallMe™: Click here
Webcast: Click here

A replay of the webcast will also be available via the investor website after the call's conclusion.

About Halneuron®

Halneuron® is an investigational, selective modulator of the Na_V 1.7 sodium channel being evaluated for the treatment of neuropathic pain conditions. Halneuron® has not been approved by the FDA or any other regulatory authority. Na_V 1.7 has been identified as a key regulator of pain signaling pathways, and the Company believes it is a promising biological target for pain modulation.

About Dogwood Therapeutics

Dogwood Therapeutics (Nasdaq: DWTX) is a development-stage biopharmaceutical company focused on developing potential first-in-class, non-opioid medicines to treat pain and neuropathic disorders. Dogwood's research pipeline includes two potential first-in-class development candidates, Halneuron® and SP16 IV.

Our lead product candidate 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. Halneuron® delivered clinically significant pain reduction of 50% or greater as compared with a placebo in a recently completed Phase 2b CINP study (n=239) of patients with a mean five-year duration of illness. Halneuron® has been granted Fast Track Designation from the FDA for the treatment of CINP. Halneuron ® treatment has also demonstrated pain reduction related to general cancer pain, including both neuropathic and non-neuropathic pain, as well as patients not treated with chemotherapy.

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 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 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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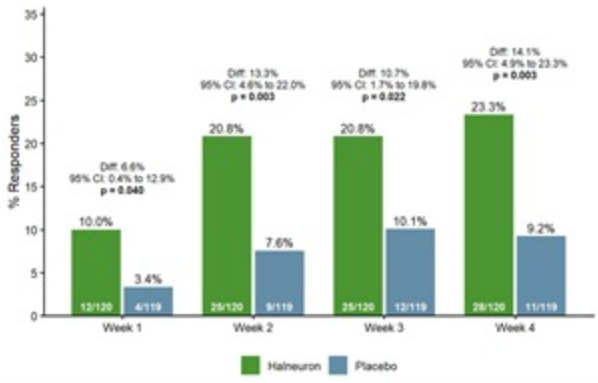
An infographic accompanying this announcement is available at https://www.globenewswire.com/NewsRoom/AttachmentNg/c315ecd6-6730-4531-9e36-771978be8ff7

DOGWOOD THERAPEUTICS

Source: Dogwood Therapeutics, Inc.

Proportion of Patients.....



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