Whitehawk Therapeutics Advances to Clinical Stage with IND Clearance for HWK-007 and Announces IND Submission for HWK-016

January 8, 2026

Actively recruiting Phase 1 trial for PTK7-targeted antibody-drug conjugate (ADC) HWK-007

IND submitted mid-December 2025 for MUC16-targeted ADC HWK-016, anticipated Phase 1 start this quarter

Initial clinical data from both programs anticipated in early 2027

MORRISTOWN, N.J., Jan. 8, 2026 /PRNewswire/ -- Whitehawk Therapeutics, Inc. (Nasdaq: WHWK), a clinical-stage oncology therapeutics company applying advanced technologies to established tumor biology to efficiently deliver improved antibody drug conjugate (ADC) cancer treatments, today announced that the U.S. Food and Drug Administration (FDA) has cleared the Investigational New Drug (IND) application for HWK-007, its PTK7-targeted ADC. Whitehawk's Phase 1 trial for HWK-007 is now actively recruiting and will initially evaluate activity in lung and ovarian cancers, two PTK7-expressing tumor types with established precedent data, as well as endometrial cancer, one of the highest PTK7-expressing tumor types.

The company also announced the submission of an IND for HWK-016, its MUC16-targeted ADC, to the FDA in December 2025. A Phase 1 trial is anticipated to start recruiting this quarter and is expected to initially evaluate activity in two high MUC16-expressing gynecologic cancers, ovarian and endometrial.

Both next-generation ADC programs leverage Whitehawk's advanced ADC technology platform consisting of a highly stable yet cleavable linker that delivers a DNA Topoisomerase I (TOP1) inhibitor payload. Whitehawk expects to report initial clinical data from these trials in early 2027.

"These are important regulatory and execution milestones, underscoring the strength of our preclinical data and our ability to advance multiple programs in parallel," said Dave Lennon, PhD, President and CEO of Whitehawk Therapeutics. "At Whitehawk, we are taking a unique approach to the development of next-generation ADCs, combining validated tumor biology with a differentiated ADC architecture. Our platform's design features are intended to maximize tumor targeting while minimizing off-target toxicity, enabled by highly selective antibodies, a stabilizing bioconjugation strategy that includes carbon-bridge cysteine re-pairing, and controlled delivery of a potent TOP1 inhibitor payload. As our lead programs enter the clinic, our focus will be on efficient clinical execution to generate data that validates this approach with meaningful outcomes for patients."

About HWK-007
HWK-007 is a differentiated next-generation ADC targeting Protein Tyrosine Kinase 7 (PTK7). PTK7 is an oncofetal transmembrane pseudokinase that drives early embryonic development, has restricted expression in adult tissues and frequent overexpression in a wide range of cancers. PTK7 is the third most highly expressed tumor marker among clinically validated and emerging ADC targets, present in ~70% of tumors. There are no approved PTK7-directed ADCs.

HWK-007-101 is a Phase 1, multicenter, open-label study in adult participants that will employ a sequential dose-escalation and expansion design to evaluate the safety, pharmacokinetics and preliminary antitumor activity of HWK-007 in participants with advanced or metastatic solid tumors that are refractory to standard therapies.

About HWK-016
HWK-016 is a differentiated next-generation ADC targeting the membrane-bound portion of Mucin 16 (MUC16). MUC16 is a glycoprotein with low level of expression in normal adult tissues, and broad overexpression in gynecological tumors including ovarian, cervical and endometrial. In ovarian cancer, for example, MUC16 is present at rates up to 3-10 times higher than clinically validated and emerging ADC targets.

Shed MUC16 (CA125) is a validated biomarker for cancer screening and disease monitoring in gynecologic cancers. When ADCs bind to this cleaved portion of the MUC16 protein in circulation, it is cleared from the patient systemically rather than reaching the tumor. HWK-016 is designed to overcome this by directly targeting the membrane-bound, non-shed portion of MUC16.

HWK-016-101 is a planned Phase 1, multicenter, open-label study in adult participants that will employ a sequential dose-escalation and expansion design to evaluate the safety, tolerability, pharmacokinetics and preliminary antitumor activity of HWK-016 in participants with advanced or metastatic solid tumors that are refractory to standard therapies.

About Whitehawk Therapeutics
Whitehawk Therapeutics is a clinical-stage oncology therapeutics company applying advanced technologies to established tumor biology to efficiently deliver improved cancer treatments. Whitehawk's advanced three-asset ADC portfolio is engineered to overcome the limitations of first-generation predecessors to deliver a meaningful impact for patients with difficult-to-treat cancers. These assets are in-licensed from WuXi Biologics under an exclusive development and global commercialization agreement. More information on the Company is available at www.whitehawktx.com and connect with us on LinkedIn.

Forward-Looking Statements
This press release contains certain forward-looking statements regarding the business of Whitehawk Therapeutics that are not a description of historical facts within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are based on the Company's current beliefs and expectations and may include, but are not limited to, statements relating to: the potential therapeutic value and market opportunity for the Company's ADC portfolio; our plans related to the Company's development of its portfolio of ADC assets, including the anticipated timing of the initiation, enrollment and data releases of clinical trials for HWK-007 and HWK-016 and the planned trial design of such clinical trials; expectations regarding the beneficial characteristics, design features, safety, efficacy, therapeutic effects and the size of the potential targeted markets with respect

to the Company's ADC assets; and the sufficiency of the Company's existing capital resources and the expected timeframe to fund the Company's future operating expenses and capital expenditure requirements. Actual results could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation, uncertainties associated with preclinical and clinical development of the ADC portfolio, including potential delays in the commencement, enrollment and completion of clinical trials; failure to demonstrate the efficacy of the ADC portfolio in preclinical and clinical studies; the risk that unforeseen adverse reactions or side effects may occur in the course of testing of the ADC assets; and risks related to the Company's estimates regarding future expenses, capital requirements and need for additional financing.

Additional risks and uncertainties that could cause actual outcomes and results to differ materially from those contemplated by the forward-looking statements are included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2024, including under the caption "Item 1A. Risk Factors," and in Whitehawk's subsequent Quarterly Reports on Form 10-Q, and elsewhere in Whitehawk's reports and other documents that Whitehawk has filed, or will file, with the SEC from time to time and available at www.sec.gov.

All forward-looking statements in this press release are current only as of the date hereof and, except as required by applicable law, Whitehawk undertakes no obligation to revise or update any forward-looking statement, or to make any other forward-looking statements, whether as a result of new information, future events or otherwise. All forward-looking statements are qualified in their entirety by this cautionary statement. This cautionary statement is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

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