



Crescent Biopharma Announces FDA Clearance of IND Application for CR-002, a PD-L1-targeted Topoisomerase Inhibitor ADC, for the Treatment of Solid Tumors

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Phase 1/2 APOLLO global clinical trial to evaluate CR-002 in multiple solid tumor types, including non-small cell lung cancer (NSCLC) and head and neck squamous cell carcinoma (HNSCC), on track to initiate in the fourth quarter of 2026

Initial clinical data expected in the second half of 2027

WALTHAM, Mass., Oct. 05, 2026 (GLOBE NEWSWIRE) -- [Crescent Biopharma, Inc.](#) ("Crescent" or the "Company") (Nasdaq: CBIO), a clinical-stage biotechnology company dedicated to rapidly advancing the next wave of therapies for cancer patients, today announced that the U.S. Food and Drug Administration (FDA) has cleared its Investigational New Drug (IND) application for CR-002, a topoisomerase inhibitor antibody drug-conjugate (ADC) targeting programmed cell death ligand 1 (PD-L1), being developed for the treatment of advanced solid tumors.

"FDA clearance of the CR-002 IND is an important milestone for Crescent and is the third distinct program in our portfolio to enter the clinic," said Ellie Im, M.D., chief medical officer of Crescent. "The strong scientific rationale and encouraging preclinical profile of CR-002 underscores its promise in addressing a range of solid tumors. We look forward to initiating the APOLLO trial this quarter and working with global investigators to generate important clinical insights and advance our mission of bringing new treatment options to patients living with difficult-to-treat cancers."

The Phase 1/2 APOLLO global clinical trial plans to enroll patients in the United States, Europe and Asia Pacific with advanced solid tumors, including non-small cell lung cancer (NSCLC), head and neck squamous cell carcinoma (HNSCC), and various gastrointestinal and gynecological tumors. The study's dose escalation and tumor-specific backfill cohorts are expected to enroll approximately 200 participants with the opportunity for additional participants in expansion cohorts. Crescent anticipates reporting initial clinical data from the APOLLO trial in the second half of 2027, including safety, pharmacokinetic and preliminary antitumor activity in multiple tumor types.

About CR-002

CR-002, internally developed in collaboration with Paragon Therapeutics, is a topoisomerase inhibitor ADC directed to PD-L1, a validated target known to have high expression in multiple solid tumors and comparatively limited expression in healthy tissue. CR-002 incorporates a PD-L1 antibody selected for high internalization to facilitate payload release in target cells and a linker designed for intracellular cleavage and high stability in circulation, an approach intended to concentrate payload delivery in tumor tissue. APOLLO, a global Phase 1/2 trial of CR-002 in patients with solid tumors, is anticipated to commence in the fourth quarter of 2026. Crescent also plans to evaluate CR-002 in combination with CR-001, its PD-1 x VEGF bispecific antibody, as part of its efforts to evaluate synergistic ADC and immuno-oncology combinations.

About Crescent Biopharma

Crescent Biopharma's vision is to build a world leading oncology company bringing the next wave of therapies for cancer patients. The Company's clinical-stage pipeline includes its lead program, a PD-1 x VEGF bispecific antibody, as well as novel antibody-drug conjugates (ADCs). By leveraging multiple modalities and established targets, Crescent aims to rapidly advance potentially transformative therapies as single agents and as part of combination regimens to treat a range of solid tumors. For more information, visit www.crescentbiopharma.com and follow the Company on [LinkedIn](#) and [X](#).

Forward-Looking Statements

Certain statements in this press release, other than purely historical information, may constitute "forward-looking statements" within the meaning of the federal securities laws, including for purposes of the "safe harbor" provisions under the Private Securities Litigation Reform Act of 1995. These forward-looking statements include, but are not limited to, express or implied statements relating to Crescent's expectations, beliefs, or strategies regarding the future of its pipeline and business including, without limitation: the initiation, design, timing, and success of the Phase 1/2 global APOLLO trial; the potential for CR-002 to treat a range of solid tumors; and anticipated timing of reporting proof-of concept data from the APOLLO trial. Forward-looking statements generally relate to future events or future financial or operating performance. The words "believe," "may," "will," "potentially," "estimate," "continue," "anticipate," "predict," "target," "intend," "could," "would," "should," "project," "plan," "expect" and similar expressions may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. These forward-looking statements are based on current expectations and beliefs concerning future developments and their potential effects and involve a number of risks, uncertainties or other assumptions that may cause actual

performance to be materially different from those expressed or implied by these forward-looking statements. Risks and uncertainties include, but are not limited to: the expected benefits of, and opportunities related to, the strategic partnership between Crescent and Kelun-Biotech may not be realized or may take longer to realize than anticipated; Crescent's limited operating history, including with respect to clinical trials; Crescent's historical losses and any future ability to generate revenue; Crescent's ability to raise capital to support its business plans; risks associated with clinical development and regulatory approval; risks related to Crescent's intellectual property; Crescent's reliance on third parties, including to help develop its product candidates, run its clinical trials, and manufacture its product candidates; significant disruptions of information technology systems or breaches of data security, litigation and regulatory risks; risks related to the current macroeconomic environment, including fluctuating interest rates, barriers to trade, changes to fiscal and monetary policy or government budget dynamics, geopolitical factors, including the ongoing conflicts in Iran and between Russia and Ukraine and the responses thereto, and supply chain disruptions, as well as those factors more fully described in Crescent's most recent filings with the Securities and Exchange Commission (including its Quarterly Report on Form 10-Q), and Crescent's other filings with the Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should any of Crescent's assumptions prove incorrect, actual results may vary in material respects from those projected in these forward-looking statements. Forward-looking statements in this press release speak only as of the date they are made and are qualified in their entirety by reference to the cautionary statements herein. Except as required by law, Crescent does not undertake or accept any duty to release publicly any updates or revisions to any forward-looking statements.

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