Crescent Biopharma Announces Regulatory Clearances of IND Applications for CR-001, a PD-1 x VEGF Bispecific Antibody and CR-003, an ITGB6-targeted ADC, for the Treatment of Solid Tumors

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CR-001 IND cleared by U.S. FDA; Phase 1/2 ASCEND global clinical trial to evaluate CR-001 in first-line and previously treated patients on track to initiate in first quarter of 2026, with proof-of-concept data anticipated in first quarter of 2027

Crescent partner Kelun-Biotech receives IND approval for CR-003 (SKB105) by NMPA of China

Four clinical trials across portfolio expected to initiate in 2026

WALTHAM, Mass., Jan. 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 regulatory clearances of Investigational New Drug (IND) applications for CR-001, a PD-1 x VEGF bispecific antibody, and CR-003, an integrin beta-6 (ITGB6)-targeted antibody drug-conjugate (ADC), both being developed for the treatment of advanced solid tumors.

The U.S. Food and Drug Administration (FDA) has cleared Crescent’s IND for CR-001, and Crescent’s partner Sichuan Kelun-Biotech Biopharmaceutical Co., Ltd. (“Kelun-Biotech”) has received IND approval for CR-003 (also known as SKB105) from the Center for Drug Evaluation (CDE) of the National Medical Products Administration (NMPA) of China.

“With regulatory clearances for CR-001 and CR-003, we are excited to begin 2026 with strong momentum as we work to deliver next generation therapies for people living with cancer,” said Ellie Im, M.D., chief medical officer of Crescent. “We are on track to have four clinical trials initiate across our portfolio in 2026, starting with the ASCEND trial of CR-001 planned for this quarter. Based on its intentional design replicating a clinically validated approach and robust preclinical profile demonstrating cooperative pharmacology and anti-tumor activity, we believe CR-001 has the potential to be a best-in-class therapy and immuno-oncology backbone.”

The Phase 1/2 ASCEND global clinical trial plans to enroll both treatment-naïve and previously treated patients with multiple solid tumor types, including non-small cell lung cancer (NSCLC) and various gastrointestinal and gynecological tumors. The trial is expected to enroll up to 290 participants in the dose-escalation, back-fill and dose-optimization cohorts designed to enable robust assessment of the clinical profile of CR-001. Crescent anticipates reporting proof-of-concept clinical data from the ASCEND trial in the first quarter of 2027, including safety, pharmacokinetic, pharmacodynamic and early anti-tumor activity in first-line and previously treated patients.

In December 2025, Crescent announced a strategic collaboration with Kelun-Biotech for CR-001 and CR-003 (SKB105). Under the terms of the strategic collaboration, Kelun-Biotech granted Crescent exclusive rights to research, develop, and commercialize CR-003 (SKB105) in the United States, Europe and all markets outside of Greater China (including mainland China, Hong Kong, Macau and Taiwan). In addition, Crescent granted Kelun-Biotech exclusive rights to research, develop, and commercialize CR-001 (also known as SKB118) in Greater China.

About CR-001 (also known as SKB118)

CR-001 (SKB118) is a tetravalent bispecific antibody being developed for the treatment of solid tumors that combines two complementary, validated mechanisms in oncology via a blockade of PD-1 and VEGF. PD-1 checkpoint inhibition is aimed at restoring T cells’ ability to recognize and destroy tumor cells, and blocking VEGF is intended for reducing blood supply to tumor cells and inhibiting tumor growth. In preclinical studies, CR-001 demonstrated cooperative pharmacology with increased binding to PD-1 and signal blockade in the presence of VEGF as well as robust anti-tumor activity. ASCEND, a global Phase 1/2 trial of CR-001 in patients with solid tumors, is anticipated to commence in the first quarter of 2026. CR-001’s anti-VEGF activity may also normalize the vasculature at the tumor site, which has the potential to improve the localization and effectiveness of combination therapies, such as the administration of CR-001 with Crescent’s antibody-drug conjugates (ADCs) in development. The first Phase 1/2 ADC combination trial with CR-001 is expected to initiate in the second half of 2026.

About CR-003 (also known as SKB105)

CR-003 (SKB105) is a differentiated ADC targeting integrin beta-6 (ITGB6) with a topoisomerase 1 inhibitor payload. ITGB6 is

overexpressed in many solid tumors, but shows minimal to no expression in most normal tissues, thereby potentially reducing the risk of systemic toxicity and off-target effects. CR-003 (SKB105) incorporates proprietary Kthiol® irreversible conjugation technology, linking anti-ITGB6 fully human IgG1 monoclonal antibody to a clinically validated cleavable linker. The design aims to enhance stability and tumor-specific payload delivery while reducing adverse effects. In preclinical models, CR-003 (SKB105) demonstrated a favorable efficacy, safety, and pharmacokinetic (PK) profile.

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 either as single agents or 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, hopes, beliefs, intentions or strategies regarding the future of its pipeline and business including, without limitation, the initiation, design, and success of the ASCEND trial, including its ability to enable robust assessment of the clinical profile of CR-001, the opportunity for CR-001 to be a best-in-class immuno-oncology backbone therapy for people living with cancer, the potential for each of CR-001 and CR-003 (SKB105) to address multiple solid tumor types both as a monotherapy and in combination, the timing of initiation and success of clinical trials for the Company's other product candidates both as monotherapy and in combination, including the four clinical trials planned for 2026, anticipated timing of reporting proof-of-concept clinical data from the ASCEND trial, the timing and success of the first Phase 1/2 ADC combination trial with CR-001, the potential for CR-001 to be developed in additional combinations, including with other proprietary ADC pipeline assets, the opportunity for rapid and efficient clinical development of CR-001 as both first-in-class and in fast-follower solid tumor indications, the expected benefits or opportunities with respect to the strategic partnership for CR-001 between Crescent and Kelun-Biotech, and the potential for CR-001's anti-VEGF activity to normalize the vasculature at the tumor site to improve the localization and effectiveness of combination therapies. The words "opportunity," "potential," "milestones," "pipeline," "can," "goal," "strategy," "target," "anticipate," "achieve," "believe," "contemplate," "continue," "could," "estimate," "expect," "intends," "may," "plan," "possible," "project," "should," "will," "would" and similar expressions (including the negatives of these terms or variations of them) 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. There can be no assurance that future developments affecting Crescent will be those that have been anticipated. These forward-looking statements involve a number of risks, uncertainties (some of which are beyond Crescent's control) or other assumptions that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements. These risks and uncertainties include, but are not limited to, that the expected benefits of, and opportunities related to, CR-001 may change, that CR-001 may not receive regulatory approval and, if approved, may not be commercially successful, that Crescent has no clinical data regarding cancer patients that have been treated with CR-001, either as a monotherapy or in combination with ADCs, and there can be no assurance that Crescent's clinical trials will be completed successfully and/or produce results necessary to support regulatory approval for commercialization, that Crescent may not reach the anticipated milestones at the times outlined in this release or at all, that the expected benefits of, and opportunities related to, the strategic partnership between Crescent and Kelun-Biotech, including the success of CR-003 (SKB105), may not be realized by either party 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 and run its clinical trials, as well as to manufacture its product candidates, Crescent's dependence on key personnel, Crescent's estimates of market opportunity may prove to be inaccurate, significant disruptions of information technology systems or breaches of data security, litigation and regulatory risks, 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. Nothing in this press release should be regarded as a representation by any person that the forward-looking statements set forth herein will be achieved or that any of the contemplated results of such forward-looking statements will be achieved. You should not place undue reliance on forward-looking statements in this press release, which speak only as of the date they are made and are qualified in their entirety by reference to the cautionary statements herein. Crescent does not undertake or accept any duty to release publicly any updates or revisions to any forward-looking statements. This press release does not purport to summarize all of the conditions, risks and other attributes of an investment in Crescent.

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