



Crescent Biopharma Announces Clinical Pipeline Momentum, including Enrolling Patients in Standard of Care Chemotherapy Combination Cohorts of Global Phase 1/2 ASCEND Trial of CR-001, a PD-1 x VEGF Bispecific Antibody, and Initiation of Additional ADC Combination Studies with CR-001

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More than 125 patients dosed in ASCEND across the United States, Europe and South Korea; dose escalation complete

On track to report initial monotherapy data from ASCEND in Q1 2027, including antitumor response for a first-line non-small cell lung cancer (NSCLC) cohort

Enrolling patients in CR-001 plus standard of care chemotherapy combinations from ASCEND expansion cohorts in several solid tumor types in treatment-naïve and previously treated patients, including first-line NSCLC, colorectal, biliary tract, gastric and endometrial cancers; on track to report initial data from hundreds of patients in mid-2027

Potential to start the first of multiple CR-001 Phase 3 studies in early 2028

Crescent and Kelun-Biotech rapidly advancing development of CR-001 as next generation immuno-oncology (IO) backbone: multiple sacituzumab tirumotecan (sac-TMT) + CR-001 Phase 2 studies ongoing in NSCLC and other solid tumors in more than 700 patients, with initial data expected in mid-2027; additional antibody-drug conjugate (ADC) combinations planned

Global Phase 1/2 APOLLO trial of CR-002, a PD-L1-targeted ADC, on track to commence dosing this quarter; initial data expected in the second half 2027

Phase 1/2 trial of CR-003 (SKB105), an ITGB6-targeted ADC, ongoing in China; initial data expected in Q1 2027

Anticipate more than 2,000 patients dosed across portfolio by mid-2027

WALTHAM, Mass., Oct. 15, 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 clinical pipeline momentum, including enrolling patients in cohorts combining CR-001, a PD-1 x VEGF bispecific antibody, plus standard of care chemotherapy regimens in its global Phase 1/2 ASCEND trial, as well as the initiation of additional antibody-drug conjugate (ADC) combination studies with CR-001.

"Our team's outstanding execution has enabled us to rapidly advance three programs into the clinic in 2026 and make significant progress in developing next-generation IO, ADC and combination therapies. Together with our partner, Kelun-Biotech, we have achieved seven IND clearances to date, and by mid-2027, we expect more than 2,000 patients to have been dosed across our portfolio. We remain focused on generating meaningful clinical data and expect to begin sharing results in the first quarter of 2027, including data from ASCEND, which is enrolling first-line NSCLC patients globally, including in the United States and Europe. We believe these data can support the initiation of the first of multiple Phase 3 studies of CR-001 in early 2028," said Joshua Brumm, chief executive officer of Crescent.

"Our partnership with Kelun-Biotech brings together two companies with a shared commitment to accelerating the development of potentially transformative therapies for people living with cancer. Multiple combination trials of CR-001 and sac-TMT are already underway in China, with additional ADC combination studies planned. In 2026, we established the foundation for the next phase of Crescent's growth: delivering multiple important clinical readouts across our IO and ADC portfolio, beginning early next year," said Mr. Brumm.

Clinical Execution Progress in ASCEND, a Global Phase 1/2 Trial of CR-001

On track to report initial monotherapy data from ASCEND in Q1 2027

- Crescent has completed dose escalation in the global Phase 1/2 ASCEND trial of CR-001, its investigational PD-1 x VEGF bispecific, developed in collaboration with Paragon Labs, with patients enrolled across several tumor types at clinical sites in the United States, Europe and South Korea.
- The Company plans to report initial monotherapy data from ASCEND in the first quarter of 2027, including:

- Preliminary antitumor response as measured by overall response rate (ORR) from a first-line NSCLC cohort of up to 12 patients.
- Safety, tolerability, pharmacokinetic and pharmacodynamic data from more than 125 treatment-naïve and previously-treated patients across multiple solid tumor types.

Enrolling patients in standard of care chemotherapy combination cohorts

- Enrollment has commenced in the standard of care chemotherapy combination expansion cohorts of ASCEND. Hundreds of participants are expected to enroll in this part of the study with various tumor types and chemotherapy regimens being evaluated, including:
 - **First-line (1L) NSCLC:** CR-001 + paclitaxel and carboplatin (squamous) or pemetrexed and carboplatin (non-squamous)
 - **1L mismatch repair proficient (pMMR) / microsatellite stable (MSS) colorectal cancer (CRC):** CR-001 + mFOLFOX6
 - **Third-line (3L) CRC:** CR-001 + trifluridine and tipiracil
 - **1L biliary tract cancer:** CR-001 + gemcitabine and cisplatin
 - **1L pMMR endometrial cancer:** CR-001 + carboplatin and paclitaxel
 - **1L programmed cell death ligand 1 (PD-L1)-expressing gastric/gastroesophageal junction (GEJ) cancer:** CR-001 + capecitabine and oxaliplatin
 - **Second-line (2L) PD-L1-expressing gastric/GEJ cancer:** CR-001 + paclitaxel
- Crescent plans to report initial data from the chemotherapy combination cohorts in mid-2027 (Q2/Q3).
- Data from these cohorts, along with monotherapy data from ASCEND, will inform future clinical development for CR-001. Pending results and further interactions with regulators, Crescent plans to initiate the first of multiple Phase 3 trials of CR-001 in early 2028.
- Trial in progress posters on the ASCEND study design will be presented during the European Society for Medical Oncology (ESMO) 2026 Congress being held October 23-27, 2026 in Madrid, Spain and at the Society for Immunotherapy of Cancer (SITC) 2026 Annual Meeting being held November 4-8, 2026 in Phoenix, Arizona.

Multiple Studies Evaluating CR-001 in Combination with Novel ADCs

- Under a collaboration agreement, Crescent granted Sichuan Kelun-Biotech Biopharmaceutical Co., Ltd., (“Kelun-Biotech”) exclusive rights to research, develop, and commercialize CR-001 (also known as SKB118) in Greater China. Both Kelun-Biotech and Crescent have rights to independently develop CR-001 in combinations, including with their respective ADC pipelines. Kelun-Biotech is conducting multiple trials in China evaluating CR-001 in combination with sacituzumab tirumotecan (sac-TMT), its TROP2-directed ADC, and additional ADC combination studies are planned.
 - A Phase 2 trial of CR-001 (SKB118) and sac-TMT in participants with locally advanced or metastatic NSCLC is ongoing with initial data expected in mid-2027 (Q2/Q3).
 - A Phase 2 trial of sac-TMT in combination with CR-001 (SKB118) is now enrolling participants with advanced solid tumors.
 - A Phase 2 trial of sac-TMT in combination with CR-001 (SKB118) is initiating in epidermal growth factor receptor (EGFR)-mutant locally advanced or metastatic non-squamous NSCLC who have failed EGFR tyrosine kinase inhibitor (EGFR-TKI) therapy.
 - A Phase 1/2 trial of CR-001(SKB118) in combination with CR-003 (also known as SKB105), an integrin-beta 6 (ITGB6)-directed ADC, is expected to commence in the first half of 2027.

Advancing a Differentiated ADC Pipeline

- Earlier this month, CR-002, Crescent’s topoisomerase inhibitor ADC targeting PD-L1, internally developed in collaboration with Paragon Labs, received Investigational New Drug (IND) clearance from the U.S. Food and Drug Administration. Crescent is on track to initiate the global Phase 1/2 APOLLO trial this quarter in patients with advanced solid tumors, including NSCLC, head and neck squamous cell carcinoma (HNSCC), and various gastrointestinal and gynecological tumors. Initial data are expected in the second half of 2027.
- Kelun-Biotech granted Crescent exclusive rights to research, develop, and commercialize CR-003 (SKB105), an ITGB6-targeted ADC, in the United States, Europe and all markets outside of Greater China. A Phase 1/2 trial of CR-003 (SKB105) in participants with advanced solid tumors conducted by Kelun-Biotech in China is ongoing and proof-of-concept data are expected in the first quarter of 2027. Crescent plans to leverage data generated in China to support the global clinical development of CR-003 (SKB105).

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 timing and success of clinical data from the ASCEND monotherapy and combination trials of CR-001; the potential initiation and success of Phase 3 studies of CR-001; the timing and success of the Phase 2 combination trials for CR-001 and sac-TMT, including the potential initiation of additional ADC combination studies by Kelun-Biotech; the expected timing for initiation, trial design, indication selection, and initial clinical data for the global Phase 1/2 APOLLO trial of CR-002; the timing and success of clinical data from the Phase 1/2 trial of CR-003 as generated by Kelun-Biotech in China; the expected benefits or opportunities with respect to CR-001, CR-002, and CR-003, including the anticipated number of patients dosed across the portfolio; and the potential for CR-002 and CR-003 to act as single agents and in combination with CR-001. 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 for the quarterly period ended June 30, 2026), 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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