



Carisma Therapeutics Announces Clinical & Pre-Clinical Updates

November 11, 2022

New data from Phase 1 clinical trial of CT-0508 presented at SITC

Early pre-clinical data on CT-1119 and preliminary insights from novel immunotherapy platform also presented

PHILADELPHIA, Nov. 11, 2022 /PRNewswire/ -- [Carisma Therapeutics Inc.](#) (Carisma Therapeutics), a clinical stage biopharmaceutical company focused on discovering and developing innovative immunotherapies, presented today at the Society for Immunotherapy of Cancer (SITC) 37th Annual Meeting additional findings from its CT-0508 chimeric antigen receptor macrophage (CAR-M) clinical trial for patients with advanced metastatic human epidermal growth factor receptor 2 (HER2) overexpressing solid tumors, supporting a favorable safety profile and manufacturing feasibility of its proprietary engineered cell therapy platform.

The findings in the abstract, "[A phase 1, first-in-human \(FIH\) clinical trial of the anti-HER2 CAR macrophage CT-0508 in participants with HER2 overexpressing solid tumors](#)," demonstrate that CT-0508 has been successfully manufactured using macrophages obtained from heavily pre-treated, advanced solid tumor patients and has shown high chimeric antigen receptor (CAR) expression, viability, and purity. In this clinical trial, CT-0508 has been generally well-tolerated after infusion with no dose-limiting toxicities reported to date from the nine participants enrolled in Group 1. The clinical trial data provide early clinical validation of the CAR-M mechanism of action, demonstrating that CT-0508 can be detected within the tumor microenvironment (TME), lead to remodeling and activation of the TME, and induce anti-tumor adaptive immunity. The data is drawn from the ongoing clinical trial led by Kim A. Reiss, MD, principal investigator of the Phase 1 clinical trial and an Assistant Professor of Hematology-Oncology at the Abramson Cancer Center at the University of Pennsylvania (Penn).

"The data from Group 1 of our first-in-human CAR-M clinical trial provides evidence that CAR-M therapy is feasible and generally well-tolerated by patients with certain late-stage metastatic cancers," said Michael Klichinsky, Pharm.D., Ph.D., Co-Founder and Chief Scientific Officer at Carisma Therapeutics. "The translational data collected from these patients is highly encouraging. We look forward to advancing CT-0508 into Group 2 of the monotherapy safety trial, as well as in a combination sub-study with the T cell checkpoint inhibitor pembrolizumab."

Additionally, in the abstract, "[Pre-clinical development of CT-1119, a mesothelin targeting chimeric antigen receptor macrophage \(CAR-M\), for solid tumor immunotherapy](#)," the presented data demonstrate that CT-1119, an autologous human anti-mesothelin CAR-M, can mediate phagocytosis, tumor cell killing, and pro-inflammatory cytokine release and control tumor growth in pre-clinical lung cancer models. This data demonstrates that CAR-M may be a feasible and differentiated approach that could be tested in the treatment of mesothelin expressing solid tumors such as lung cancer, mesothelioma, ovarian cancer, pancreatic cancer, and other solid tumors.

Also presented for the first time is a novel immunotherapy platform that harnesses macrophages as "living converters" to locally regulate the inflammatory state of tissues. The platform has potential for both oncology and inflammatory disease applications. In the abstract, "[Macrophages engineered to express synthetic cytokine switch receptors act as living microenvironment converters](#)," Carisma Therapeutics demonstrated a novel approach wherein macrophages expressing novel synthetic cytokine receptors are utilized to convert inflammatory signals into immunosuppressive responses or vice versa, offering modularity in controlling the inflammatory status of tissue microenvironments without systemic cytokine antagonism.

Details of Carisma Therapeutics' data also accepted for presentation at the SITC 37th Annual Meeting:

- "[Characterization of CT-0508, an anti-HER2 chimeric antigen receptor macrophage \(CAR-M\), manufactured from patients enrolled in the phase 1, first in human, clinical trial of CT-0508](#)," Friday, November 11 at 12:18pm EST
- "[Chimeric antigen receptor macrophages \(CAR-M\) sensitize solid tumors to anti-PD1 immunotherapy](#)," Thursday, November 10
- "[A Phase 1, First in Human \(FIH\) study of autologous macrophages containing an anti-HER2 chimeric antigen receptor \(CAR\) in participants with HER2 overexpressing solid tumors](#)," Thursday November 10
- "[Pre-clinical development of a CAR Monocyte platform for cancer immunotherapy](#)," Friday, November 11

Presentation and posters will be available on the [SITC 37th Annual Meeting portal](#) for registered attendees.

About CT-0508

CT-0508 is a human epidermal growth factor receptor 2 (HER2) targeted chimeric antigen receptor macrophage (CAR-M). It is being evaluated in a landmark Phase 1 multi-center clinical trial that focuses on patients with recurrent or metastatic HER2-overexpressing solid tumors whose cancers do not have approved HER2-targeted therapies or who do not respond to treatment. Carisma Therapeutics is selecting participants who have tumors of any anatomical origin, but with the commonality of overexpressing the HER2 receptor on the cell surface, which is the target for its CAR-M. The Phase 1 clinical trial is first-of-its-kind, marking the first time that engineered macrophages are being studied in humans. The trial continues to enroll patients at five U.S. sites, including Abramson Cancer Center at The University of Pennsylvania; the University of North Carolina Lineberger Comprehensive Cancer Center in Chapel Hill; City of Hope in Duarte, California; University of Texas MD Anderson Cancer Center in Houston, Texas; and Sarah Cannon Research Institute at Tennessee Oncology – Nashville.

About Carisma Therapeutics

Carisma Therapeutics Inc. is a biopharmaceutical company dedicated to developing a differentiated and proprietary cell therapy platform focused on engineered macrophages, cells that play a crucial role in both the innate and adaptive immune response. The first applications of the platform, developed in collaboration with the University of Pennsylvania*, are autologous chimeric antigen receptor (CAR)-macrophages for the treatment of solid tumors. Carisma Therapeutics is headquartered in Philadelphia, PA. For more information, please visit www.carismatx.com

*Carisma Therapeutics has licensed certain Penn-owned intellectual property from the University of Pennsylvania, and Penn's Perelman School of Medicine receives sponsored research and clinical trial funding from the company. Penn may also be entitled to receive additional financial benefits from technologies licensed and optioned to Carisma Therapeutics in the future. In addition, Penn is a co-founder of the company and holds equity interests in Carisma Therapeutics.

Cautionary Note on Forward-Looking Statements

Any statements in this press release about future expectations, plans and prospects for Sesen Bio, Inc. (Sesen Bio), Carisma Therapeutics or the combined company, Sesen Bio's, Carisma Therapeutics' or the combined company's strategy or future operations, and other statements containing the words "anticipate," "believe," "contemplate," "expect," "intend," "may," "plan," "predict," "target," "potential," "possible," "will," "would," "could," "should," "continue," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. For example, statements concerning the proposed transaction, the concurrent financing, the contingent value rights and other matters, including without limitation: statements relating to the satisfaction of the conditions to and consummation of the proposed transaction, the expected timing of the consummation of the proposed transaction and the expected ownership percentages of the combined company, Sesen Bio's and Carisma Therapeutics' respective businesses, the strategy of the combined company, future operations, advancement of the combined company's product candidates and product pipeline, clinical development of the combined company's product candidates, including expectations regarding timing of initiation and results of clinical trials of the combined company, the ability of Sesen Bio to remain listed on the Nasdaq Stock Market, the completion of the concurrent financing, and the receipt of any payments under the contingent value rights are forward-looking statements. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including without limitation: (i) the risk that the conditions to the closing of the proposed transaction are not satisfied, including the failure to obtain stockholder approval of matters related to the proposed transaction in a timely manner or at all; (ii) uncertainties as to the timing of the consummation of the proposed transaction and the ability of each of Sesen Bio and Carisma Therapeutics to consummate the proposed transaction, including completing the concurrent financing; (iii) risks related to Sesen Bio's ability to correctly estimate its expected net cash at closing and Sesen Bio's and Carisma Therapeutics' ability to correctly estimate and manage their respective operating expenses and expenses associated with the proposed transaction; (iv) risks related to Sesen Bio's continued listing on the Nasdaq Stock Market until closing of the proposed transaction; (v) the risk that as a result of adjustments to the exchange ratio, Sesen Bio stockholders or Carisma Therapeutics stockholders could own less of the combined company than is currently anticipated; (vi) the risk that the conditions to payment under the contingent value rights will not be met and that the contingent value rights may otherwise never deliver any value to Sesen Bio stockholders; (vii) risks associated with the possible failure to realize certain anticipated benefits of the proposed transaction, including with respect to future financial and operating results; (viii) uncertainties regarding the impact any delay in the closing would have on the anticipated cash resources of the combined company upon closing and other events and unanticipated spending and costs that could reduce the combined company's cash resources; (ix) the occurrence of any event, change or other circumstance or condition that could give rise to the termination of the merger agreement; (x) the effect of the announcement, pendency or completion of the merger on Sesen Bio's or Carisma Therapeutics' business relationships, operating results and business generally; (xi) costs related to the merger; (xii) the outcome of any legal proceedings that may be instituted against Sesen Bio, Carisma Therapeutics or any of their respective directors or officers related to the merger agreement or the transactions contemplated thereby; (xiii) the ability of Sesen Bio or Carisma Therapeutics to protect their respective intellectual property rights; (xiv) competitive responses to the proposed transaction and changes in expected or existing competition; (xv) the success and timing of regulatory submissions and pre-clinical and clinical trials; (xvi) regulatory requirements or developments; (xvii) changes to clinical trial designs and regulatory pathways; (xviii) changes in capital resource requirements; (xix) risks related to the inability of the combined company to obtain sufficient additional capital to continue to advance its product candidates and its preclinical programs; (xx) legislative, regulatory, political and economic developments; and (xxi) other factors discussed in the "Risk Factors" section of Sesen Bio's Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and other reports filed with the SEC. In addition, the forward-looking statements included in this communication represent Sesen Bio's and Carisma Therapeutics' views as of the date hereof. Sesen Bio and Carisma Therapeutics anticipate that subsequent events and developments will cause the respective company's views to change. However, while Sesen Bio may elect to update these forward-looking statements at some point in the future, Sesen Bio specifically disclaims any obligation to do so, except as required under applicable law. These forward-looking statements should not be relied upon as representing Sesen Bio's views as of any date subsequent to the date hereof.

Important Additional Information

In connection with the proposed transaction between Carisma Therapeutics and Sesen Bio, on October 14, 2022, Sesen Bio filed with the Securities and Exchange Commission (SEC) a registration statement on Form S-4, which includes a preliminary proxy statement of Sesen Bio and which also constitutes a prospectus of Sesen Bio with respect to shares of Sesen Bio's common stock to be issued in the proposed transaction (Preliminary Proxy Statement/Prospectus). The Preliminary Proxy Statement/Prospectus is not final and may be amended. The definitive proxy statement/prospectus (if and when available) will be delivered to Sesen Bio's stockholders. Sesen Bio may also file other relevant documents regarding the proposed transaction with the SEC. INVESTORS AND SECURITY HOLDERS ARE URGED TO READ THESE MATERIALS, INCLUDING THE REGISTRATION STATEMENT, THE DEFINITIVE PROXY STATEMENT/PROSPECTUS, AND ALL OTHER RELEVANT DOCUMENTS THAT ARE OR WILL BE FILED WITH THE SEC IN CONNECTION WITH THE PROPOSED TRANSACTION, INCLUDING ANY AMENDMENTS OR SUPPLEMENTS TO THESE MATERIALS, BECAUSE THEY CONTAIN OR WILL CONTAIN IMPORTANT INFORMATION ABOUT THE PROPOSED TRANSACTION AND THE PARTIES TO THE PROPOSED TRANSACTION. Investors and security holders are able to obtain the Preliminary Proxy Statement/Prospectus, the definitive proxy statement/prospectus (when it becomes available) and other documents that are filed or will be filed by Sesen Bio with the SEC free of charge from the SEC's website at www.sec.gov or from Sesen Bio at the SEC Filings section of www.sesenbio.com.

No Offer or Solicitation

This press release shall not constitute an offer to sell or the solicitation of an offer to buy any securities, nor shall there be any sale of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction. No offering of securities shall be made except by means of a prospectus meeting the requirements of Section 10 of the Securities Act of 1933, as amended. Subject to certain exceptions to be approved by the relevant regulators or certain facts to be ascertained, a public offer will not be made directly or indirectly, in or into any jurisdiction where to do so would constitute a violation of the laws of such jurisdiction, or by use of the mails or by any means or instrumentality (including without limitation, facsimile transmission, telephone or internet) of interstate or foreign commerce, or any facility of a national securities exchange, of any such jurisdiction.

Participants in the Solicitation

Sesen Bio and Carisma Therapeutics and their respective directors, executive officers and other members of management may be deemed to be participants in the solicitation of proxies in respect of the proposed transaction. Information about Sesen Bio's directors and executive officers is available in Sesen Bio's Annual Report on Form 10-K for the fiscal year ended December 31, 2021, its definitive proxy statement dated April 28, 2022 for its 2022 Annual Meeting of Stockholders and its Current Report on Form 8-K filed with the SEC on August 31, 2022. Other information

regarding the participants in the proxy solicitation and a description of their interests in the proposed transaction, by security holdings or otherwise, is included in the Preliminary Proxy Statement/Prospectus and other relevant materials that are or will be filed with the SEC regarding the proposed transaction. Investors should read the definitive proxy statement/prospectus carefully (when it becomes available) before making any voting or investment decisions. You may obtain free copies of these documents from Sesen Bio or the SEC's website as indicated above.

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