Apexigen Presents New Data from a Phase 2 Trial Evaluating its CD40 Antibody, Sotigalimab, in Combination with Neoadjuvant Chemoradiation in Patients with Resectable Esophageal and Gastroesophageal Junction Cancers at ESMO Congress 2022

September 10, 2022

-Sotigalimab in combination with neoadjuvant chemoradiation induced higher pathologic complete response rates, an important predictor of survival, in patients with both adenocarcinoma and squamous cell carcinoma-

SAN CARLOS, Calif., Sept. 10, 2022 (GLOBE NEWSWIRE) -- Apexigen, Inc. (NASDAQ: APGN) a clinical-stage company focused on developing innovative antibody-based therapeutics for the treatment of cancer with a focus on immuno-oncology, today announced the presentation of new data from a Phase 2 multicenter clinical trial evaluating sotigalimab (sotiga), Apexigen's agonist antibody targeting CD40, in combination with neoadjuvant chemoradiation for patients with resectable esophageal and gastroesophageal junction (GEJ) cancers. Encouraging pathologic complete response (pCR) rates were observed in patients with both adenocarcinoma (AC) and squamous cell carcinoma (SCC). These data were featured in a poster presentation at the European Society for Medical Oncology (ESMO) Congress, being held both virtually and in Paris from September 9-13, 2022.

"We are excited to present new data at ESMO that highlight the clinical utility of sotiga and the potential to improve outcomes in patients with resectable esophageal and GEJ cancers," said Andrew Ko, M.D., Professor of Clinical Medicine at the University of California San Francisco and Principal Investigator of the study. "The pathologic complete response rates, an important predictor of survival, compared favorably to historical pCR rates with standard of care treatment alone. Moreover, our study demonstrates that sotiga was able to be safely added to concurrent chemotherapy plus radiation. These results speak to the promise of sotiga-based combination therapies."

Frank Hsu, M.D., Chief Medical Officer of Apexigen commented, "The results from this ongoing study validate sotiga's differentiated mechanism of action, which has the potential to expand anti-tumor immune responses and modulate the tumor microenvironment for maximal therapeutic effect. We believe sotiga has the potential to become a backbone of combination therapy to address the need for innovative treatment options, as demonstrated by the encouraging rates of pCR in the overall patient population and across histologic subgroups of both adenocarcinoma and squamous cell carcinoma. Additionally, a single dose of sotiga alone induced an inflammatory response in the tumor, which was quantitatively higher in patients achieving a pCR. These important correlative findings further highlight sotiga's potential to turn cold tumors hot, and together with the emerging data across our broad Phase 2 development program, suggest there is significant opportunity for sotiga to provide meaningful clinical benefit across multiple solid tumor indications. We look forward to providing updates on our progress as we advance our clinical program."

Key data and conclusions featured in the ESMO presentation include:
The primary objective of this study was to assess the efficacy of this novel combination, as measured by the pCR rate, and to further characterize the safety and feasibility of the combination of sotiga with standard of care chemoradiation in the neoadjuvant setting for patients with resectable esophageal and GEJ cancers.

Safety:

- Sotiga combined with neoadjuvant chemoradiation for esophageal/GEJ cancers was generally safe and well tolerated.
  - The majority of patients had Grade 1-2 adverse events (AEs).
  - Six serious adverse events considered at least possibly related to sotiga included cytokine release syndrome observed in three patients, nausea and vomiting in one patient, dysphagia in one patient and Guillain-Barre Syndrome in one patient.
  - There were no patient withdrawals due to sotiga and no sotiga/neoadjuvant chemoradiation-related deaths.

Efficacy:

- Sotiga combined with neoadjuvant chemoradiation led to encouraging rates of pCR in the overall patient population and in the histologic subgroups of AC and SCC.
  - Of the 29 evaluable patients, 11 (38%) patients had a pCR and 19 (66%) patients had a mPR (major pathological response) with less than 10% of the residual tumor remaining after treatment.
  - By histology, the pCR rate was 33% (8/24) in patients with AC and 60% (3/5) in patients with SCC.
- The pCR rate was 41.2% for patients (n= 17) receiving four doses of sotiga versus 33.3% for patients (n= 12) receiving three doses.
- R0 resection was achieved in 86% (25/29) patients and progressive disease was only 7%.
- Paired biomarker analysis collected before and one to two weeks following a single run-in dose of sotiga alone demonstrated significantly increased tumor infiltration of activated dendritic cells, monocytes and both CD8 and CD4 T cells compared to baseline. The observed immune/inflammatory response in the tumor, changing the immune microenvironment from "cold" to "hot", further validates sotiga's mechanism of action.

The e-Poster (1229P) is accessible on the ESMO Congress portal and additional details are provided below.

- Title: A multicenter phase 2 study of sotigalimab (CD40 agonist) in combination with neoadjuvant chemoradiation for resectable esophageal and gastroesophageal junction (GEJ) cancers
- Presenting author: Andrew Ko, M.D., Professor of Clinical Medicine at the University of California San Francisco
- Poster Session Date and Time: Monday, September 12, 2022 at 12:00 p.m. CEST

About Apexigen

Apexigen is a clinical-stage biopharmaceutical company focused on discovering and developing a new generation of antibody therapeutics for oncology, with an emphasis on new immuno-oncology agents designed to harness the patient's immune system to combat and eradicate cancer. Sotigalimab and Apexigen's other programs were discovered using Apexigen's proprietary APXiMAB™ discovery platform. This platform has enabled Apexigen and its collaboration partners to discover and develop therapeutic antibodies against a variety of molecular targets, including targets that are difficult to drug with conventional antibody technologies. Multiple product candidates have been discovered using the APXiMAB platform, one of which is commercially available and the others are in clinical development, either internally by Apexigen or by its licensees. For more information, please visit www.apexigen.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, including statements regarding the transactions, such as the potential value for stockholders; the ability of the combined company to provide innovative oncology solutions, meet the needs of patients and provide meaningful clinical benefits; the potential attributes, uses and effectiveness of its lead candidate sotigalimab; the ability of the combined company to achieve value-creating milestones and pursue strategic partnerships; the combined company's plans with respect to its clinical trials; and the combined company's receipt of additional funds. Any statements contained herein that are not statements of historical fact may be deemed to be forward-looking statements. In addition, any statements that refer to projections, forecasts or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intends," "may," "might," "plan," "possible," "potential," "predict," "project," "should," "would" and similar expressions may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. The forward-looking statements contained in this press release are based on certain assumptions and analyses made by the management of Apexigen in light of their respective experience and their perception of historical trends, current conditions and expected future developments and their potential effects on the combined company, as well as other factors they believe are appropriate in the circumstances. There can be no assurance that future developments affecting the combined company will be those that the parties have anticipated. These forward-looking statements involve a number of risks, uncertainties (some of which are beyond the control of the parties) or other assumptions that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements, including the ability of the combined company to continue to meet the Nasdaq listing standards, achieve successful clinical results or commercial adoption of approved antibody candidates, or that the combined company will have sufficient capital following the transactions to operate as anticipated. Should one or more of these risks or uncertainties materialize, or should any of our assumptions prove incorrect, actual results may vary in material respects from those projected in these forward-looking statements. Additional factors that could cause actual results to differ are discussed under the heading "Risk Factors" and in other sections of the combined company's filings with the SEC, and in its current and periodic reports filed or furnished from time to time with the SEC. All forward-looking statements in this press release are made as of the date hereof, based on information available to the combined company, and Apexigen assumes no obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws.

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