Apexigen Announces New Data from a Phase 1/2 Trial Evaluating its CD40 Antibody, Sotigalimab, in Combination with Pembrolizumab in Patients with First-Line Metastatic Melanoma at the SITC 2022 Annual Meeting

November 11, 2022

- The combination of intratumoral sotigalimab and systemic pembrolizumab was well-tolerated and demonstrated an improved clinical response rate relative to the standard of care, pembrolizumab monotherapy-

-Activation of antigen-presenting cells stimulated broad innate and adaptive anti-tumor responses in both local as well as distant tumor lesions-

SAN CARLOS, Calif., Nov. 11, 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 new data from an ongoing Phase 2 investigator-sponsored trial evaluating intratumoral sotigalimab (sotiga), Apexigen's CD40 agonist antibody, in combination with systemic pembrolizumab (anti-PD-1 antibody) in first-line metastatic melanoma. Results showed that the combination therapy was well-tolerated in the trial and an improved best overall response rate (ORR) was observed relative to the standard of care, pembrolizumab monotherapy. Broad innate and adaptive immune activation was observed in both local and distant (non-injected) lesions. The data were featured in an oral presentation at the Society for Immunotherapy of Cancer's (SITC) 37 th Annual Meeting, taking place in Boston, Massachusetts from November 8-12, 2022.

"While checkpoint inhibitors are the current standard of care for metastatic melanoma, many patients are unresponsive or develop resistance after initial tumor regression," said Adi Diab, M.D., Associate Professor of Melanoma Medical Oncology at The University of Texas MD Anderson Cancer Center and Principal Investigator of the study. "Results from the ongoing Phase 2 trial of intratumoral sotigalimab and the PD-1 inhibitor pembrolizumab showed a promising ORR including responses achieved in PD-L1 negative tumors. Moreover, this encouraging anti-tumor activity correlated with treatment-induced immunologic changes, such as activated myeloid dendritic cells and macrophages, which support the mechanism of action and differentiated activity of sotigalimab – ultimately leading to inflammatory immune responses in the local injected tumor as well as distant non-injected lesions."

Frank Hsu, M.D., Chief Medical Officer of Apexigen commented, "We are encouraged by the emerging data that suggest sotiga-based combinations may address the need for improved treatments for advanced and metastatic melanoma patients, bringing us one step closer to paving the way for novel strategies to optimize anti-tumor immune responses and improve clinical benefits. The intratumoral administration of sotiga further validates its ability to turn an inflammatory 'cold' tumor to one that is 'hot ' and demonstrates the induction/expansion of T-cell clones in both the injected and distal tumors – indicating a systemic effect and the possible expansion of the repertoire of antitumor responses. This encouraging work indicates that sotiga may be an effective and well-tolerated method of in situ vaccination that can lead to improved clinical benefit for patients with cancer."

Key data and conclusions featured in the SITC presentation include:

- **Safety and tolerability:** Intratumoral administration of sotiga in combination with pembrolizumab was well-tolerated. The most common adverse events were injection site reactions. Grade 3 immune-related adverse events were observed at a frequency similar to that reported with anti-PD-1 therapy alone. There were no dose limiting toxicities and no discontinuations or deaths due to treatment-related events. No immunosuppressive therapy was needed.
- **Efficacy:** The objective response rate (ORR) was 47% (n=32) in all patients, including patients enrolled in the dose escalation portion of the trial. At the recommended Phase 2 dose of sotiga the ORR was 50% (n=24), which compares favorably to standard of care of pembrolizumab alone (34%). Clinical responses were achieved in both PD-L1 negative tumors and patients with elevated LDH
- **Immune Priming:** Effects included rapid increases in activated macrophages and dendritic cells and an early upregulation of genes associated with antigen-presenting cells 24 hours post sotiga administration followed by T-cells activation and expansion in the tumor microenvironment (TME) in local and distant tumor sites.
- **Immune changes in the TME correlate with clinical response:** Post treatment analyses revealed increases in activated macrophages, dendritic cells and CD8+ T-cells correlated with clinical response.

Details of the SITC presentation and its corresponding abstract are as follows:

- Presentation Title: *Intratumoral sotigalimab with pembrolizumab activates antigen-presenting cells and induces local and distant anti-tumor responses in first-line metastatic melanoma: Results of a phase I/II study*
- Presentation number: 782
- Presenter: Salah-Eddine Bentebibel, Ph.D., MD Anderson

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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