Apexigen Announces New Phase 2 Data Evaluating Sotigalimab, its CD40 Agonist Antibody, at ASCO Gastrointestinal Cancers Symposium 2023

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-Results demonstrate sotigalimab's ability to turn immunologically "cold" tumors "hot" to increase anti-tumor immune responses for increased therapeutic effect in patients with esophageal/gastro-esophageal junction and rectal cancers-

SAN CARLOS, Calif., Jan. 19, 2023 (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 Phase 2 multicenter clinical trials evaluating sotigalimab (sotiga), Apexigen's agonist antibody targeting CD40, in two poster presentations at the ASCO Gastrointestinal Cancers Symposium, being held both virtually and in San Francisco, California from January 19-21, 2023.

"We are excited to present new data at ASCO demonstrating sotiga's differentiated mechanism of action and ability to expand anti-tumor immune responses by modulating the tumor microenvironment (TME) for increased therapeutic effect," said Frank Hsu, M.D., Chief Medical Officer of Apexigen. "In patients with esophageal/gastro-esophageal junction (E/GEJ) cancer, single-agent sotiga turned immunologically "cold" tumors "hot" by inducing significant inflammatory responses in the TME. Following a single dose of sotiga monotherapy there was an increase in T cell density, particularly activated and memory cytotoxic T cells and macrophages. Although patient sample numbers are small, pathologic complete responses were associated with an increased density of T cells following a single dose of sotiga. In a separate study, results demonstrated that adding sotiga to short-course radiation therapy (SCRT) led to increased activation of anti-cancer immune cells, including T cells, B cells and dendritic cells in the TME of rectal cancer patients compared to SCRT alone. We believe sotiga has the potential to provide meaningful clinical benefit across multiple solid tumor indications and become a backbone of combination therapy to address the need for innovative treatment options. We look forward to providing further updates as we advance our clinical program."

The posters are accessible on-demand through the ASCO Congress portal and additional details are provided below.

Poster (#K16), titled "Use of High-dimensional and Spatial Immune Profiling to Explore Sotigalimab (CD40 Agonist) Activation of Antigen Presenting Cells and T Cells in the Tumor Microenvironment in Patients with Esophageal/Gastroesophageal Junction Cancer," is being presented by Bridget P. Keenan, M.D., Ph.D., Assistant Professor, Division of Hematology/Oncology, Department of Medicine, at the University of California, San Francisco.

Presentation Highlights
Key Takeaways:

- Single-agent sotiga induced infiltration and activation of myeloid cells, including dendritic cells and macrophages in the TME. Sotiga also induced infiltration of CD8+ T cells while decreasing the frequency of CD4+ regulatory T cells in the TME.
- T cell composition and density in the TME at baseline is associated with tumor response, potentially identifying patients more likely to respond to treatment.
- The ability to modify the immune microenvironment from "cold" to "hot" further validates sotiga's mechanism of action.

Poster (#K13) titled "Tissue assessment of therapeutic responses to neoadjuvant SCRT with and without anti-CD40 immunotherapy sotigalimab (sotiga) in rectal cancer," is being presented by Todd Aguilera, M.D., Ph.D., Assistant Professor of Radiation Oncology at UT Southwestern Medical Center.

Presentation Highlights
Key Takeaways:

- Sotiga in combination with SCRT induces immune activation in the TME, with the potential to improve clinical responses and avoid the need for surgery.
- Single-cell RNA sequencing performed on tumor biopsies taken pre- and post- sotiga in combination with SCRT demonstrated induction of robust immune responses.
- The addition of sotiga to SCRT induced greater antigen presenting cells and CD8+ T cell activation compared to SCRT alone.
- Immune changes were observed with SCRT alone but were more robust with the addition of sotiga. In the SCRT with sotiga group there was a greater induction of genes associated with M1-like macrophages, with no change in M2 genes. In lymphocytes, sotiga treatment led to an induction of genes related to Th1 and B cell response.
- These emerging data highlight the potential of combining sotiga, an agent that induces robust immune responses, with SCRT to treat rectal cancer patients.

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 Apexigen's ability 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; Apexigen's pursuit of strategic partnerships; Apexigen's plans with respect to its clinical trials; Apexigen's cash runway. 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 Apexigen's management in light of their respective experience and their perception of historical trends, current conditions and expected future developments and their potential effects on Apexigen, as well as other factors they believe are appropriate in the circumstances. There can be no assurance that future developments affecting Apexigen will be those that Apexigen has anticipated. These forward-looking statements involve a number of risks, uncertainties (some of which are beyond Apexigen'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, including Apexigen's early stages of clinical drug development, Apexigen's ability to achieve successful clinical results or commercial adoption of sotigalimab, Apexigen's competitors developing and marketing products that are more effective, safer, or less expensive than Apexigen's product candidates, delays or difficulties in the enrollment of patients in Apexigen's clinical trials, or that Apexigen will have sufficient capital 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 Apexigen'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 Apexigen 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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