Apexigen Announces New Data from a Phase 2 Trial Evaluating its CD40 Antibody, Sotigalimab, in Combination with Pembrolizumab in Patients with Metastatic Melanoma Presented at the AACR Annual Meeting 2022

April 12, 2022

-The combination of intratumoral sotigalimab and systemic pembrolizumab induced broad innate and adaptive immune activation in local and distant tumors-

-Oral presentation on April 12, 2022 at 3:35 pm (CDT)-

SAN CARLOS, Calif., April 12, 2022 (GLOBE NEWSWIRE) -- Apexigen, Inc., a clinical-stage biopharmaceutical company focused on discovering and developing a new generation of antibody therapeutics for oncology, today announced the presentation of data from a Phase 2 clinical trial evaluating intratumoral sotigalimab (sotiga), Apexigen's monoclonal antibody targeting CD40, in combination with systemic pembrolizumab in anti-PD-L1 treatment-naïve patients with advanced or metastatic melanoma. Broad innate and adaptive immune activation was observed in both local and distant (non-injected) lesions. Encouraging anti-tumor activity was observed in patients with PD-L1-negative tumors as well as in patients with elevated LDH, a poor prognostic indicator for response to anti-PD-1 therapy. These data were featured in an oral presentation at the American Association for Cancer Research (AACR) Annual Meeting, taking place in New Orleans, Louisiana from April 8-13, 2022.

"We are encouraged by these exciting data demonstrating the clinical utility of sotiga, a potentially first- and best-in-class CD40 agonist with unique epitope specificity and Fc receptor engagement, and its ability to harness the innate and adaptive arms of the immune system for maximal therapeutic effect," said Frank Hsu, M.D., Chief Medical Officer of Apexigen. "These findings further support the potential to combine sotiga with other anti-cancer therapies across multiple indications to initiate and boost effective anti-tumor immunity and provide clinical benefit."

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, commented, "The results from this ongoing study show the combination of intratumoral sotiga and systemic pembrolizumab leads to increased immunologic activity and encouraging clinical responses with a favorable safety and tolerability profile. Further, this combination stimulated innate and adaptive immune responses in both local and distant lesions. Together, these results suggest sotiga-based combinations warrant further investigation for patients with metastatic melanoma and offer the potential to pave the way for novel strategies to improve immunologic activity and deliver sustained clinical benefit."

Key data and conclusions featured in the AACR presentation include:
The combination of intratumoral sotiga and systemic pembrolizumab, a PD-1 inhibitor, was reasonably well-tolerated and showed encouraging anti-tumor activity that correlated with treatment-induced immunologic changes in treatment-naïve melanoma patients. These findings further validate sotiga's mechanism of action targeting CD40 and ability to be combined in novel ways to induce anti-tumor immunity.

- The best overall response rate (ORR) was 50% (n=15/30) and 55% (n=12/22) at the recommended sotiga Phase 2 dose (10 mg).
- In all 30 evaluable Phase 1/2 patients, the disease control rate was 67% (n=20/30).
    - CR rate was 17% (n=5/30), PR was 33% (n=10/30) and SD was 17% (n=5/30).
- Clinical responses were observed in patients with PD-L1 negative tumors as well as in patients with elevated LDH.
- Effects included an upregulation of genes associated with antigen-presenting cells and T cells as well as an increase in T cell infiltration and clonality in local and distant tumor sites.
- Intratumoral administration of sotiga in combination with pembrolizumab was reasonably well-tolerated. The most common adverse events were injection site reactions. Six patients experienced grade 3 immune mediated adverse events, which were considered related to pembrolizumab alone or the combination. There were no dose limiting toxicities and no discontinuations or deaths due to treatment-related events.

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

- **Presentation Title:** Intratumoral CD40 agonist sotiga with pembrolizumab induces broad innate and adaptive immune activation in local and distant tumors in metastatic melanoma
- **Presentation number:** CT039
  Presenter: Salah-Eddine Bentebibel, Ph.D., The University of Texas MD Anderson Cancer Center
- **Session Title:** Immunotherapy Combination Strategies in Clinical Trials
- **Session Date and Time:** April 12, 2022, 3:35 pm (CDT)

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 that may 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 high-quality 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.

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