Apexigen Announces Phase 2 Data Evaluating Sotigalimab, its CD40 Agonist Antibody, in Combination with Doxorubicin in Patients with Advanced Soft Tissue Sarcoma Presented at the American Society of Clinical Oncology (ASCO) 2023 Annual Meeting

June 3, 2023

- Marked increases in overall survival observed across soft tissue sarcoma patients -

- Demonstrated improvement of median progression free survival in patients with dedifferentiated liposarcoma (DDLPS) -

- DDLPS expansion cohort enrolling to inform a potential Phase 3 registration trial -

SAN CARLOS, Calif., June 03, 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 a Phase 2 investigator-sponsored trial in collaboration with Columbia University, evaluating sotigalimab (sotiga), Apexigen's agonist antibody targeting CD40, in combination with standard-of-care doxorubicin (dox), in patients with advanced soft tissue sarcoma (STS). These data were presented in a poster presentation on June 3, 2023 at the ASCO Annual Meeting being held both virtually and in person in Chicago, IL.

Sotiga combined with dox was safe and well tolerated and indicated increases in overall survival (OS) with a median OS of 35.6 months across all STS patients evaluated, which is markedly higher than the historical OS of 12.8 to 20 months of dox alone across STS subtypes. Moreover, subtype-specific analysis demonstrated improvement in median progression-free survival (mPFS) of 10.95 months in patients with dedifferentiated liposarcoma (DDLPS) which is markedly higher than the historical mPFS of 4 months in patients with DDLPS.

"We are excited to present new data at ASCO from the Phase 2 trial in patients with advanced STS that supports further development of sotiga-based combinations and underscores the significant opportunity to provide patients with meaningful clinical benefit characterized by rapid, deep and durable responses with a favorable safety profile," said Xiaodong Yang, M.D., Ph.D., Chief Executive Officer of Apexigen. "Notably, we are encouraged by the median overall survival results across sarcoma subtypes and the data demonstrating that the subgroup of patients with DDLPS treated with sotiga in combination with dox achieved a mPFS, more than double that seen historically with dox alone. We look forward to building on these impressive findings with our DDLPS expansion cohort, which will potentially inform a Phase 3 registration study in DDLPS."

Key Takeaways: The open-label, single-arm, multicenter Phase 2 trial enrolled patients with advanced STS, including DDLPS, leiomyosarcoma (LMS), and undifferentiated pleomorphic sarcoma (UPS) and treated patients with a combination of sotiga and dox. The primary endpoint was objective response rate (ORR), and secondary endpoints were progression-free survival and safety.

- Interim results indicated marked increases in OS across STS subtypes compared to historical standard-of-care dox monotherapy with a median OS of 35.62 months (n=32), which is remarkably higher than the historical OS of 12.8 to 20 months across STS subtypes.
- Subtype-specific analysis demonstrated an mPFS of 10.95 months for DDLPS patients (n=9), which is remarkably higher than the historical mPFS of 4 months for standard-of-care dox in patients with DDLPS.
- The interim ORR observed in the trial is comparable to the ORR of single-agent doxorubicin in the STS population. Durable objective responses and stable disease have been observed beyond what might be expected from single-agent doxorubicin.
- Overall, sotiga combined with dox was safe and well tolerated.
    - Grade 3/4 treatment-related adverse events (TRAEs) occurred in 56% (18/32) of patients – the most common grade 3/4 TRAEs were neutropenia (31%), febrile neutropenia (19%), and anemia (19%) and were consistent with the safety profile of doxorubicin monotherapy.
    - 3/32 (9.4%) withdrew study treatment for AEs.
    - Cytokine release syndrome was reported in 19% of patients – all grade 1/2.
    - There were no additive/synergistic or unexpected AEs observed with the combination.

More information about the study is available here (NCT03719430).

The abstract (#11565) is accessible on the ASCO Congress portal, and additional details are provided below.

- Title: A phase 2 trial with a safety lead-in to evaluate the addition of sotigalimab, a CD40 agonistic monoclonal antibody, to standard-of-care doxorubicin for the treatment of advanced sarcoma
- Format: Poster (Bd #499)
- Session Title: Sarcoma
- Session Date and Time: Saturday, June 3 from 1:15 p.m. to 4:15 p.m. CT

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; and Apexigen's beliefs with respect to the successful development of sotigalimab. 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 with 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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