



Apexigen Announces Positive Interim Results from Phase 2 Trial Evaluating its CD40 Antibody, Sotigalimab, in Combination with Doxorubicin in Patients with Liposarcoma

November 14, 2022

-Patients with liposarcoma (LPS) demonstrated prolonged median PFS (mPFS) relative to historical controls treated with standard of care of doxorubicin-

-Encouraging PFS data from the ongoing investigator sponsored trial in collaboration with Columbia University supports expansion of the LPS cohort to inform a potential phase 3 registration-enabling trial-

-Apexigen to host investor call with sarcoma expert and principal investigator, Gary Schwartz, M.D. at Columbia University, today, November 14, at 8:00 a.m. ET-

SAN CARLOS, Calif., Nov. 14, 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 topline data from an ongoing Phase 2 investigator sponsored trial in collaboration with Columbia University, evaluating sotigalimab, Apexigen's agonist antibody targeting CD40, in combination with standard of care doxorubicin (dox), in patients with advanced soft tissue sarcoma (STS). In the subgroup of patients with liposarcoma (LPS), the second most common STS, treatment with sotigalimab combined with dox resulted in a median progression-free survival (mPFS) of 12.45 months relative to the historically observed mPFS of less than 5 months in patients treated with dox monotherapy.

"While the incidence of soft tissue sarcoma continues to rise, efforts to improve upon the standard of care treatment have largely stalled and remained largely unchanged for years," said Gary Schwartz, M.D., Chief of Columbia University Medical Center's Division of Hematology and Oncology and Principal Investigator of the study. "In contrast, results from the ongoing Phase 2 trial showed the subgroup of patients with LPS treated with sotigalimab in combination with dox achieved a mPFS more than double than historically seen with dox alone. With the favorable safety observed in these patients, the encouraging results support future evaluation of sotigalimab-based combinations while speaking to the potential of sotigalimab in the maintenance therapy setting."

Frank Hsu, M.D., Chief Medical Officer of Apexigen commented, "In collaboration with Columbia University, we are very pleased to have successfully completed enrollment of the LPS cohort and are encouraged by the promising clinical results to date. This impressive increase in PFS is an improvement of clinical benefit that builds on the standard of care treatment of this disease. We now plan to expand enrollment with an additional 10 patients with LPS. This expansion cohort will supplement the growing dataset suggesting sotigalimab in combination with dox may provide superior clinical benefit compared to emerging treatment approaches and currently approved standard of care chemotherapy. Further, these results could inform a potential Phase 3 registration-enabling study for patients with LPS in the first-line setting."

The objective of this ongoing study is to evaluate the efficacy of this novel combination and to further characterize the safety and feasibility of the combination of sotigalimab with dox. More information about the study is available [here](#) (NCT03719430).

Interim efficacy results:

- Sotigalimab combined with dox led to encouraging PFS in the completed LPS cohort consisting of dedifferentiated liposarcomas.
 - As of September 27, 2022, of the 10 evaluable patients with LPS, the mPFS was 12.45 months (range: 1.4 to 25.3 months), which compares favorably to the historically observed mPFS of LPS patients treated with dox alone (<5 months).
 - Results support the initiation of an expansion cohort with an additional 10 patients to inform a potential phase 3 registration-enabling trial in first-line LPS patients.

Conference Call at 8:00 a.m. ET Today

Apexigen will host a video conference call and webcast for investors and analysts today at 8:00 a.m. ET to discuss the most recent clinical data. Gary Schwartz, M.D., Chief of Columbia University Medical Center's Division of Hematology and Oncology and Principal Investigator of the study, as well as members of Apexigen's senior management team, will lead the discussion on the study results. The live webcast and replay can be accessed in the "Investors" section of our website (apexigen.com), under "Events & Presentations" or by clicking [here](#).

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 Apexigen's lead candidate sotigalimab, including in combination with doxorubicin and in patients with LPS; Apexigen's plans, timelines and expectations with respect to its ongoing Phase 2 investigator sponsored trial in collaboration with Columbia University, including expanded enrollment in patients with LPS and the expectation that it is a potential registration-enabling study; and statements made by Apexigen's Chief Medical Officer and Columbia University Medical Center's Chief of the Division of Hematology and Oncology. 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 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 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.

Investor Contact:

Bruce Mackle
LifeSci Advisors
+1-646-889-1200
bmackle@lifesciadvisors.com

Apexigen Contact:

William Duke
Chief Financial Officer
Apexigen, Inc.
+1-650-931-6236
ir@apexigen.com



Source: Apexigen