ALX Oncology Announces New Data Demonstrating Evorpacept in Combination with Zanidatamab Generates Promising Antitumor Activity in Advanced Breast Cancer

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- Data from Phase 1b/2 clinical trial to be presented at 2024 San Antonio Breast Cancer Symposium (SABCS) show encouraging clinical activity in patients with heavily pretreated HER2-positive breast cancer who had received multiple HER2-targeted agents, including fam-trastuzumab deruxtecan-nxki (ENHERTU®)
- Combination therapy was well tolerated with a manageable safety profile consistent with prior experience with each investigational agent
- Data contribute to growing evidence supporting evorpacept activity in combination with anti-HER2-targeted agents among patients with HER2-positive cancers

SOUTH SAN FRANCISCO, Calif., Dec. 10, 2024 (GLOBE NEWSWIRE) -- ALX Oncology Holdings Inc. (“ALX Oncology” or “the Company”) (Nasdaq: ALXO), a clinical-stage biotechnology company advancing therapies that boost the immune system to treat cancer and extend patients’ lives, announced results from a Phase 1b/2 clinical trial demonstrating the company’s investigational CD47-blocker evorpacept in combination with Jazz Pharmaceuticals’ zanidatamab generates promising anti-tumor activity in patients with both HER2-positive and HER2-low advanced breast cancer. The findings, which are the first from a clinical trial evaluating the safety and efficacy of evorpacept and zanidatamab in heavily pretreated patients with metastatic breast cancer (mBC), will be presented on Thursday, December 12 in a poster spotlight presentation (#PS8-09) at the 2024 San Antonio Breast Cancer Symposium (SABCS).

“These data suggest that HER2-positive patients whose cancer has been heavily pretreated may benefit from CD47 inhibition via evorpacept’s unique mechanism when combined with a HER2-targeted agent,” said Alberto J. Montero, M.D., MBA, Clinical Director, Breast Cancer Medical Oncology Program, Case Western Reserve University, and the study’s principal investigator. “New therapeutic options with better safety profiles are desperately needed for these patients, and this is particularly true once disease progresses following advanced, standard-of-care therapies such as ENHERTU.”

The Phase 1b/2 open-label, multi-center clinical trial (NCT05027139) evaluated the potential of evorpacept, a highly differentiated, investigational CD47 blocker, in combination with zanidatamab, a dual HER2-targeted bispecific antibody, as a novel treatment for patients with previously treated inoperable, locally advanced, or metastatic HER2-expressing breast cancer and other cancers.

Part one of the trial evaluated the safety and recommended doses for the combination; part two assessed the anti-tumor activity of the resulting combination. The SABCS poster presentation will include efficacy findings from all three of the part-two trial cohorts: Cohort 1 (n=21) consisted of patients with HER2-positive breast cancer who had received a median of six prior systemic therapies in the metastatic setting. Notably, all patients in Cohort 1 had received prior fam-trastuzumab deruxtecan-nxki (ENHERTU®). Patients were enrolled based on local assessment of tumor samples or central assessment. Of the 21 patients enrolled in Cohort 1, nine were found to be HER2-positive based on central assessment. Cohort 2 (n=15) consisted of patients with HER2-low breast cancer who had received a median of five prior systemic therapies. Cohort 3 (n=8) consisted of patients with other HER2-expressing cancers.

Key trial results to be shared at SABCS 2024 include:

- HER2-positive by central assessment mBC: Patients in Cohort 1 who were HER2-positive by central assessment (n=9) showed the greatest anti-tumor activity with a confirmed objective response rate (cORR) of 55.6% and a median progression free survival (mPFS) of 7.4 months.
- HER2-positive mBC: Overall, patients in Cohort 1 (n=21) had a confirmed cORR and mPFS of 33.3% and 3.6 months, respectively.
- HER2-low mBC: Responses were also observed in Cohort 2 (cORR: 20.0%; mPFS: 1.9 months).
- As of the August 2024 data cutoff, median follow-up was 9.6 months, with six patients still on treatment. The median duration of response was not reached for Cohort 1 patients (range: 3.6-25.9 months) and was 5.5 months for Cohort 2 patients (range: 3.6-11.0 months), with responses ongoing, including the longest observed response, in each cohort.

Most treatment-related adverse events were grade 1 or 2. The most frequent adverse events due to any cause were fatigue, nausea, diarrhea, and infusion-related reactions. There were no treatment-related deaths in the study and no non-infectious pulmonary toxicities. These safety findings are consistent with those observed in the >700 patients treated with evorpacept to date.

“This study adds to the growing body of evidence suggesting that evorpacept can treat HER2-positive cancers after patients progress on multiple conventional HER2-directed therapies, given that the encouraging response rate of 55 percent in this population would not be expected,” said Jason Lettmann, Chief Executive Officer at ALX Oncology. “The data that will be presented this week also further validate our biomarker strategy, showing that confirmed HER2-expression drove the largest benefit for patients. Collectively, these findings provide us with the proof of concept necessary to accelerate our clinical plans to advance evorpacept in HER2-positive breast cancer.”

A copy of the poster presentation will be available on the Publications section of ALX Oncology's website at the start of the presentation at SABCS on December 12, 2024.

About ALX Oncology

ALX Oncology (Nasdaq: ALXO) is a clinical-stage biotechnology company advancing therapies that boost the immune system to treat cancer and extend patients' lives. ALX Oncology's lead therapeutic candidate, evorpacept, has demonstrated potential to serve as a cornerstone therapy upon which the future of immuno-oncology can be built. Evorpacept is currently being evaluated across multiple ongoing clinical trials in a wide range of cancer indications. More information is available at www.alxoncology.com and on LinkedIn @ALX Oncology.

Cautionary note regarding forward-looking statements

This press release contains forward-looking statements that involve substantial risks and uncertainties. Forward-looking statements include statements regarding future results of operations and financial position, business strategy, product candidates, planned preclinical studies and clinical trials, results of clinical trials, research and development costs, regulatory approvals, timing and likelihood of success, plans and objects of management for future operations, as well as statements regarding industry trends. Such forward-looking statements are based on ALX Oncology's beliefs and assumptions and on information currently available to it on the date of this press release. Forward-looking statements may involve known and unknown risks, uncertainties and other factors that may cause ALX Oncology's actual results, performance or achievements to be materially different from those expressed or implied by the forward-looking statements. These and other risks are described more fully in ALX Oncology's filings with the Securities and Exchange Commission (SEC), including ALX Oncology's Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and other documents ALX Oncology files with the SEC from time to time. Except to the extent required by law, ALX Oncology undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

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