ALX Oncology Presents First Evorpacept Combination Data with an Antibody-Drug Conjugate from Phase 1 ASPEN-07 Clinical Trial in Patients with Advanced Bladder Cancer

June 2, 2024

- Evorpacept in combination with PADCEV®, an approved antibody-drug conjugate ("ADC"), demonstrated promising activity and was generally well tolerated
- Company to host conference call and webcast with Samuel A. Funt, M.D., of Memorial Sloan Kettering Cancer Center on Friday, June 7, 2024, at 1:00 PM ET

SOUTH SAN FRANCISCO, Calif., June 02, 2024 (GLOBE NEWSWIRE) -- ALX Oncology Holdings Inc., ("ALX Oncology" or "the Company") (Nasdaq: ALXO), an immuno-oncology company developing therapies that block the CD47 immune checkpoint pathway, today presented data from its Phase 1 ASPEN-07 clinical trial in a poster presentation (abstract #4575) at the 2024 American Society of Cancer Oncology ("ASCO") Annual Meeting being held in Chicago from May 31-June 4, 2024. These findings represent the first evorpacept combination data with an ADC from ASPEN-07's ongoing, open-label, single-arm, clinical trial of evorpacept in combination with PADCEV (enfortumab vedotin or "EV") in patients with locally advanced or metastatic urothelial cancer ("la/m UC"). Evorpacept is a CD47 blocker with an inactivated Fc effector domain that is designed to minimize associated toxicity.

Key results as of the data cut-off date of April 3, 2024:

Initial patient demographics

- Twenty-eight EV-naïve patients were enrolled with 29% having received three or more prior lines of therapy.
- All patients had disease that progressed after platinum chemotherapy and checkpoint inhibition.
- Approximately 93% of patients had metastatic disease.

The combination was generally well-tolerated in a heavily pre-treated patient population

- No maximum tolerated dose was reached, and the maximum administered evorpacept dose was 30 mg/kg Q2W.
- There were no treatment-related deaths in the study.
- The most frequent adverse events due to any cause were low-grade fatigue, dysgeusia, nausea, diarrhea, hyperglycemia, and pruritis.

Initial activity showed tumor reduction in the majority of evaluable patients

- ASCO poster presentation data-cut reported an unconfirmed overall response rate ("ORR") of 59% (n=22) with evorpacept plus EV (EV single agent ORR benchmark is 41%[1]).
- Following the April data cut-off, four additional response evaluable patients yielded an unconfirmed ORR of 61% (n=26) including two confirmed complete responses and six confirmed partial responses.
    - To date, 58% of evaluable patients remain in the study.
- Continued follow-up for patients who are EV-naïve on ASPEN-07 is ongoing and, enrollment of a new cohort of patients who have received prior EV has begun.

"We are encouraged by the preliminary safety data and clinical activity of evorpacept combined with PADCEV in patients with advanced bladder cancer," said Sophia Randolph, M.D., Ph.D., Chief Medical Officer of ALX Oncology. "To our knowledge, these data are the first demonstration of anti-tumor activity with a CD47 blocker and an ADC in a heavily pre-treated patient population in the clinical setting. With these promising early results, we are evaluating clinical development options in both PADCEV-naïve and experienced patient populations."

"This emerging dataset reported favorable potential for evorpacept to be combined with an ADC in a patient population that has exhausted many treatments," said Jason Lettmann, Chief Executive Officer of ALX Oncology. "We are especially hopeful because of the two patients with confirmed complete responses, which further exhibited this combination is active and that responses could improve over time in more patients. Heading further into the year, we will continue the momentum for ASPEN-07 as we gear up to share multiple, randomized, Phase 2 clinical data readouts where evorpacept is combined with anti-cancer antibodies and checkpoint inhibitors."

The poster can be found on the Publications section of the ALX Oncology website here.

Company Event with ASPEN-07 Principal Investigator and ALX Oncology Management

The Company is hosting a virtual event with key opinion leaders on Friday, June 7, 2024, at 1:00 PM ET. The event will feature leading ASPEN-07

principal investigator and bladder cancer expect, Samuel A. Funt, M.D., from Memorial Sloan Kettering Cancer Center, along with the management team of ALX Oncology. The discussion will cover details of the first promising initial dose escalation data from the Phase 1 ASPEN-07 clinical trial of evorpacept in combination with EV in patients with la/m UC, and how ASPEN-07 could fit into the treatment paradigm of this indication.

Samuel A. Funt, M.D., is a genitourinary oncologist at Memorial Sloan Kettering Cancer Center in New York, NY, where he is also Director of the Inpatient Genitourinary Oncology Service, Director of Bladder Cancer Clinical Trials Operations, and member of the Data Safety Monitoring Committee. Dr. Funt has practiced medicine and been involved in clinical trials for over 10 years. His top areas of clinical expertise are Bladder and Testicular Cancers. Dr. Funt has co-authored over 60 peer-reviewed articles and been awarded research grants from the National Institutes Health, American Society of Clinical Oncology, and the American Cancer Society. His research focuses on the development of more personalized and effective treatments and novel biomarkers of therapeutic response and resistance.

The event will be webcast live and can be accessed by visiting the Investors section of ALX Oncology's website at www.alxoncology.com and selecting Events under News and Events. To participate in the live event, please register using this link: https://edge.media-server.com/mmc/p/ct2fpmxb. An archived webcast will be available following the event.

About the Phase 1 Clinical Trial Investigating Evorpacept plus EV in Advanced Bladder Cancer

The Phase 1 clinical trial is an ongoing, open-label, single arm is designed to evaluate the safety, tolerability, and efficacy of evorpacept in combination with EV in patients with la/m UC (NCT05524545). This dose escalation clinical trial has enrolled cohorts receiving 20 mg/kg Q2W or 30 mg/kg Q2W evorpacept plus standard EV treatment. The study is sponsored and conducted by ALX Oncology.

About Bladder Cancer and UC

As estimated by the National Cancer Institute, bladder cancer is the sixth most common cancer type in the United States. UC is the most common type of bladder cancer and accounts for approximately 90% of all bladder cancer cases. Roughly 83,000 new cases of bladder cancer will be diagnosed in the United States in 2024 with about 16,800 deaths. The five-year survival for patients with metastatic bladder cancer is less than 8%. Worldwide, over 614,000 new cases of bladder cancer and over 220,000 deaths occurred in 2022 according to The Global Cancer Observatory.

About ALX Oncology

ALX Oncology is a publicly traded, clinical-stage immuno-oncology company focused on helping patients fight cancer by developing therapies that block the CD47 immune checkpoint inhibitor and bridge the innate and adaptive immune system. ALX Oncology's lead product candidate, evorpacept, is a next generation CD47 blocking therapeutic that combines a high-affinity CD47 binding domain with an inactivated, proprietary Fc domain. To date, evorpacept has been dosed in over 500 subjects and has demonstrated promising activity and favorable tolerability profile across a range of hematologic and solid malignancies in combination with various leading anti-cancer antibodies. ALX Oncology is currently focusing on combining evorpacept with anti-cancer antibodies, ADCs, and PD-1/PD-L1 immune checkpoint inhibitors.

Evorpacept's Unique Profile: Anchored by a Rational Design and Triple Development Pillars

Rationally engineered with an inactive Fc effector function, evorpacept's clinical data to date has demonstrated a substantially improved safety profile over other anti-CD47 molecules in the clinic with an active Fc (i.e., binding the Fc gamma receptor on macrophages). This best-in-class safety profile allows for higher dosage with minimal overlapping toxicity in the combination treatment setting. CD47 expressed on cancer cells binds to its receptor SIRP alpha, which is predominantly expressed on two cell types: macrophages and dendritic cells. The Company's pipeline of therapeutic candidates with standard-of-care agents include:

- **Anti-cancer antibodies and ADCs (the "*don't eat me* " signal):** evorpacept enables Fc-mediated antibody-dependent phagocytosis by macrophages in combination with anti-cancer antibodies (e.g., Herceptin®) and ADCs (e.g., PADCEV and ENHERTU®) with an active Fc domain, which is otherwise impaired by CD47 expression on cancer cells binding to SIRP alpha on macrophages. Additionally, ADCs target the delivery of a chemotherapeutic payload to tumor cells to exert cytotoxic effects.
- **PD-1/PD-L1 immune checkpoint inhibitors (the "*don't activate T-cells* " signal)**: evorpacept enables T-cell activation by dendritic cells that are constitutively inhibited by CD47 expression on cancer cells binding to SIRP alpha on dendritic cells. Activated dendritic cells present neoantigens to T-cells that once activated will kill cancer cells when the PD-1/PD-L1 inhibitory interaction is blocked by T-cell checkpoint inhibitors.

References

- [1] Powles, et al, NEJM 2021; Powles, et al, Genitourinary Cancer Symposium 2021

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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