Xencor Presents Clinical Data from the Phase 1 Study of Tidutamab in Neuroendocrine Tumors at NANETS' Multidisciplinary NET Medical Virtual Symposium

November 3, 2021

MONROVIA, Calif.--(BUSINESS WIRE)--Nov. 3, 2021-- Xencor, Inc. (NASDAQ:XNCR), a clinical-stage biopharmaceutical company developing engineered monoclonal antibodies and cytokines for the treatment of cancer and autoimmune diseases, today announced updated clinical data from a Phase 1 study of tidutamab, an SSTR2 x CD3 bispecific antibody, in patients with neuroendocrine tumors (NETs). The data will be presented during the North American Neuroendocrine Tumor Society's 2021 Multidisciplinary NET Medical Virtual Symposium (NANETS).

"The Phase 1 study of tidutamab in patients with neuroendocrine tumors informed our view that an XmAb® CD3 bispecific antibody is generally well tolerated in solid tumors, with a low incidence and severity of CRS, and can induce meaningful biological activity in a challenging disease setting," said Allen Yang, M.D., Ph.D., senior vice president and chief medical officer at Xencor. "Importantly, we identified a recommended dose for continued study, and a Phase 1b/2 study has been opened to evaluate tidutamab as a potential treatment option for patients with Merkel cell carcinoma and small cell lung cancer, SSTR2-expressing tumor types known to be responsive to immunotherapy."

A poster with data from the study is available in the NANETS Virtual Poster Hall, and it will be made available under Archived Scientific Presentations on the Events & Presentations page in the Investors section of www.xencor.com. In addition to the poster, these results will be presented during the Clinical Abstracts session, which begins at 1:25 p.m. ET on Saturday, November 6, 2021.

Key Highlights

The primary objectives of the Phase 1 study were to determine the safety and tolerability profile of tidutamab in patients with advanced, well-differentiated NETs of pancreatic, gastrointestinal, lung and undetermined origin, and to identify the maximum tolerated dose and/or recommended dosing regimen for continued study, which was determined to be a 0.3 mcg/kg priming dose followed by 1.0 mcg/kg on subsequent dosing days.

At data cut-off in August 2021, 41 patients with neuroendocrine tumors, with the initial lesion location in the pancreas (46%), intestine (22%), lung (20%), and other GEP-NET or unknown (12%), received doses of tidutamab ranging from 0.1 to 2.0 mcg/kg. Dosing in the study included a lower priming dose, followed by a higher repeated dose on subsequent dosing days. The 20 patients in the expansion cohort received the recommended dosing regimen. Patients had a median age of 64 years and a median of four prior lines of systemic therapies. Fifty percent of patients received prior peptide receptor radionuclide therapy.

Tidutamab was generally well tolerated at the 0.3/1.0 mcg/kg dose identified for the expansion portion of the study. All 41 patients treated were included in the safety analysis. The most common treatment-related Grade 3 or Grade 4 adverse events across all doses were lymphopenia (29%), gamma-glutamyl transferase increases (20%), transaminase increases (20%) and vomiting (17%). In addition, Grade 3 esophageal dysmotility was observed in 7% of patients. CRS of any grade was observed in 41% of patients. The majority of CRS was limited to Grade 1 and Grade 2 and to the first two doses. Grade 3 CRS was observed in two patients (5%) upon the first dose. All patients experiencing CRS fully recovered.

Analysis of peripheral blood biomarkers indicated that tidutamab induced acute and sustained T-cell activation at the recommended dose for expansion. CD8-positive effector T cells showed a dose-dependent increase in proliferation (Ki67) and activation (PD-1) markers that began within 48 hours of the first dose and persisted at least seven weeks, as measured at cycle 2, day 22.

The best overall response was stable disease, with a disease control rate of 27%. Higher tumor PD-L1 expression was associated with a shorter time on study, and the patients with prolonged stable disease were most likely to have low or absent PD-L1 expression, suggesting a potential beneficial effect from the combination of tidutamab with PD-L1 inhibitors.

About Tidutamab

Tidutamab is a tumor-targeted bispecific antibody that contains both an SSTR2 binding domain and a T-cell binding domain (CD3). An XmAb® bispecific Fc domain serves as the scaffold for the two antigen binding domains and confers long circulating half-life, stability and ease of manufacture on tidutamab. SSTR2 (somatostatin receptor 2) is an antigen highly expressed on some solid tumors, and engagement of CD3 by tidutamab activates T cells for highly potent and targeted killing of SSTR2-expressing tumor cells. Tidutamab is being evaluated in an ongoing Phase 1b/2 study, which is enrolling patients with Merkel cell carcinoma and small cell lung cancer, SSTR2-expressing tumor types known to be responsive to immunotherapy.

About Xencor, Inc.

Xencor is a clinical-stage biopharmaceutical company developing engineered monoclonal antibodies and cytokines for the treatment of cancer and

autoimmune diseases. Currently, 22 candidates engineered with Xencor's XmAb® technology are in clinical development internally and with partners. Xencor's XmAb antibody engineering technology enables small changes to the structure of proteins resulting in new mechanisms of therapeutic action. For more information, please visit www.xencor.com.

Xencor Forward-Looking Statements

Certain statements contained in this press release may constitute forward-looking statements within the meaning of applicable securities laws. Forward-looking statements include statements that are not purely statements of historical fact, and can generally be identified by our use of words such as “potential,” “can,” “will,” “plan,” “may,” “could,” “would,” “expect,” “anticipate,” “seek,” “look forward,” “believe,” “committed,” “investigational,” and similar terms, or by express or implied discussions relating to the clinical trial data for tidutamab generally, the quotations from Xencor’s senior vice president and chief medical officer; and other statements that are not purely statements of historical fact. Such statements are made on the basis of the current beliefs, expectations, and assumptions of the management of Xencor and are subject to significant known and unknown risks, uncertainties and other factors, including the ability of publicly disclosed clinical trial data to support continued clinical development and regulatory approval for specific treatments, that may cause actual results, performance or achievements and the timing of events to be materially different from those implied by such statements, and therefore these statements should not be read as guarantees of future performance or results. Such risks include, without limitation, the risks associated with the process of discovering, developing, manufacturing and commercializing drugs that are safe and effective for use as human therapeutics and other risks described in Xencor's public securities filings. For a discussion of these and other factors, please refer to Xencor's annual report on Form 10-K for the year ended December 31, 2020 as well as Xencor's subsequent filings with the Securities and Exchange Commission. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. This caution is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, as amended to date. All forward-looking statements are qualified in their entirety by this cautionary statement and Xencor undertakes no obligation to revise or update this press release to reflect events or circumstances after the date hereof, except as required by law.

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