Filings under Rule 425
under the Securities Act of 1933
and deemed filed under Rule 14a-12
of the Securities Exchange Act of 1934, as amended
Filing by: GTx, Inc.
Subject Company: GTx, Inc.
SEC File No.: 000-50549

Oncternal Therapeutics Announces Updated Interim Data from a Phase 1/2 Study of Cirmtuzumab in Combination with Ibrutinib

Data presented today at the
2019 American Society of Clinical Oncology Annual Meeting

SAN DIEGO, June 3, 2019 — Oncternal Therapeutics, Inc., a clinical-stage biotechnology company focused on developing potential first-in-class product candidates for cancers with critical unmet medical need, today announced updated interim data from an ongoing Phase 1/2 study of its investigational monoclonal antibody, cirmtuzumab, in combination with ibrutinib in patients with chronic lymphocytic leukemia (CLL). Results from the first 12 patients in the Phase 1 portion of the study showed that the combination was well tolerated, with an overall objective response rate (ORR) of 91.7%, including three patients with clinical or confirmed complete responses.

These data were presented today as part of a poster session at the 2019 American Society of Clinical Oncology (ASCO) Annual Meeting. The study is being conducted in collaboration with the California Institute for Regenerative Medicine (CIRM) and the University of California San Diego (UC San Diego) School of Medicine, and the CIRLL (Cirmtuzumab and Ibrutinib in Relapsed Leukemia and Lymphoma) Study Group.

“The cirmtuzumab and ibrutinib combination has demonstrated impressive clinical activity in this interim assessment of data from these patients with CLL,” said Michael Y. Choi, M.D., UC San Diego Moores Cancer Center, and an investigator in the study. “These results support our belief that the receptor tyrosine kinase-like orphan receptor 1 (ROR1)-Wnt5a signaling pathway remains active in ibrutinib-treated CLL and mantle cell lymphoma (MCL). In addition, we believe that inhibition of Bruton’s tyrosine kinase (BTK) in CLL cells increases dependence on ROR1 signaling, further enhancing the potential benefit of a ROR1 inhibitor such as cirmtuzumab.”

The Cirmtuzumab + Ibrutinib combination was well-tolerated

Among 18 CLL patients evaluated in the interim safety assessment of the study, the Cirmtuzumab + Ibrutinib combination was well-tolerated, with adverse events that were typical for those reported in the literature for patients receiving ibrutinib alone. No dose-limiting toxicities were attributed to cirmtuzumab. Two patients discontinued treatment: one patient due to worsening heart failure unrelated to the combination treatment; and one patient secondary to atrial fibrillation, pericardial effusion and tamponade, which was not attributed to cirmtuzumab.

On-treatment ORR was 91.7%

Twelve CLL patients received 24 weeks or more of treatment on the study, and so were evaluable for efficacy. The on-treatment ORR was 91.7%, with 11 of the 12 patients achieving a partial response (PR) or complete response (CR) as of the data cutoff of May 22, 2019. None of the patients experienced progressive disease (PD). Three patients completed the full one

year of treatment specified in the protocol, and one out of these three patients met all International Working Group CLL (iwCLL) criteria for a CR, including no enlarged lymph nodes or splenomegaly, an absolute lymphocyte count (ALC) in the normal range, and no evidence of a lymphoid infiltrate or increased lymphocytes in the bone marrow. Two patients experienced a clinical CR, one at 34 weeks and another at 42 weeks of treatment, including no enlarged lymph nodes or splenomegaly, and an ALC in the normal range, pending bone marrow assessment.

Patients treated with ibrutinib commonly experience a redistributive lymphocytosis, with a transient increase in ALC. The increase in ALC following cirmtuzumab + ibrutinib treatment was markedly blunted and fell to below baseline more rapidly compared to historical data for treatment with ibrutinib alone.

Preliminary signs of efficacy in Mantle Cell Lymphoma

Six patients with MCL have also been treated in a separate cohort of the Phase 1/2 study. Data from this cohort will be presented at a future medical conference. One patient with MCL who had relapsed following an allogeneic stem cell transplant experienced a confirmed complete response after 3 months of cirmtuzumab + ibrutinib treatment, including complete resolution of a large mediastinal mass. This CR has been confirmed at 6 and 9 months of combination therapy.

“These data presented today, taken together with an earlier Phase 1 study of cirmtuzumab as a monotherapy in relapsed/refractory CLL, give us increased confidence in the potential for cirmtuzumab as a treatment for patients with ROR1-expressing lymphoid malignancies, particularly in combination with ibrutinib as a potential treatment for patients with CLL and MCL. We believe that the data also help to validate the importance of ROR1 as a therapeutic target,” said James Breitmeyer, M.D., Ph.D., cofounder, president and CEO of Oncternal Therapeutics. “We are currently treating patients with CLL in an expansion cohort in the Phase 1/2 study, and expect to report updated results in the second half of 2019.”

The presentation entitled, “Phase 1/2 Trial of Cirmtuzumab and Ibrutinib: Planned Analysis of Phase 1 CLL Cohorts,” is available on Oncternal’s website at www.oncternal.com.

About the Study

The CIRLL Study (CIRM-0001) is a Phase 1/2 clinical trial evaluating cirmtuzumab in combination with ibrutinib and is actively enrolling patients with CLL or MCL. Part 1 is a dose-finding portion designed to determine the recommended dosing regimen (RDR), Part 2 is an expansion cohort to confirm the RDR, and Part 3 will randomize patients with CLL to receive either ibrutinib alone or ibrutinib plus cirmtuzumab. The data presented today are the results of a planned, interim assessment of the CLL patients enrolled in Part 1.

About Cirmtuzumab

Cirmtuzumab is an investigational, potentially first-in-class anti-ROR1 monoclonal antibody. Cirmtuzumab is currently in a Phase 1/2 clinical trial in combination with ibrutinib for the treatment of CLL and MCL, in a collaboration with the UC San Diego School of Medicine and CIRM. In addition, an investigator-initiated Phase 1 clinical trial of cirmtuzumab in combination with paclitaxel for women with metastatic breast cancer is being conducted at UC San Diego School of Medicine. CIRM has also provided funding to support the cirmtuzumab development program.

ROR1 is a survival factor for many cancers. Tumor cells that express ROR1 have tumor-initiating features that are associated with a dedifferentiated oncogenic state. When expressed by hematologic malignancies such as CLL and MCL, ROR1 acts as a receptor for the tumor growth factor Wnt5a. Researchers at the UC San Diego School of Medicine discovered that targeting a critical epitope on ROR1 was the key to specifically targeting ROR1 expressing tumors, and this finding led to the discovery of the potent and highly selective antitumor activity of cirmtuzumab observed in preclinical studies. ROR1 activates pathways that lead to increased cancer cell proliferation, invasiveness and drug resistance.

Oncternal believes ROR1 is an attractive target for cancer therapy because it is an oncofetal antigen – a protein not normally expressed in adults, and confers a survival and fitness advantage when reactivated and expressed by tumor cells. Overexpression of ROR1 in tumors results in cancer cells becoming less differentiated, increasing their ability to self-renew and metastasize by increasing cell migration and the ability to initiate new tumors. Patients with tumors that overexpress ROR1 have poor prognoses, consistent with the increased cell migration, tumor initiation, and chemotherapy resistance observed in preclinical models. Preclinical data indicate that when cirmtuzumab binds to ROR1, it blocks Wnt5a signaling, induces differentiation of the tumor cells, and inhibits tumor cell proliferation, migration and survival. Cirmtuzumab has not been approved by the U.S. Food and Drug Administration for any indication.

About Oncternal Therapeutics

Oncternal Therapeutics is a clinical-stage biopharmaceutical company focused on developing a diverse pipeline of product candidates for the treatment of cancers with critical unmet medical need. Oncternal focuses drug development on promising yet untapped biological pathways implicated in cancer progression. The pipeline includes cirmtuzumab, a monoclonal antibody that is designed to inhibit the ROR1 receptor that is being evaluated in a Phase 1/2 clinical trial in combination with ibrutinib for the treatment of CLL and MCL, and TK-216, a small-molecule that is designed to inhibit ETS-family oncoproteins, which is being evaluated in a Phase 1 clinical trial alone and in combination with vincristine as a treatment for Ewing sarcoma, a rare pediatric cancer. In addition, Oncternal has a CAR-T product candidate that targets ROR1, which is currently in preclinical development as a potential treatment for hematologic cancers and solid tumors. More information is available at www.oncternal.com.

Merger with GTx, Inc.

Oncternal has entered into an Agreement and Plan of Merger and Reorganization (the Merger Agreement) with GTx, Inc., a Delaware corporation (GTx), and a wholly-owned subsidiary of GTx incorporated in Delaware (Merger Sub). Upon the terms and subject to the satisfaction of the conditions described in the Merger Agreement, Merger Sub will be merged with and into Oncternal (the Merger), with Oncternal surviving the Merger as a wholly-owned subsidiary of GTx.

Immediately after the Merger, Oncternal's stockholders as of immediately prior to the Merger are expected to own approximately 77.5% of the outstanding capital stock of GTx, with GTx's stockholders as of immediately prior to the Merger owning approximately 22.5% of the outstanding capital stock of GTx. These estimates are subject to adjustment prior to closing of the Merger. After completion of the Merger, GTx will be renamed Oncternal Therapeutics, Inc., and expects to trade on Nasdaq under the symbol "ONCT."

Additional Information about the Proposed Merger and Where to Find It

In connection with the proposed Merger, GTx has filed relevant materials with the SEC, including a Registration Statement on Form S-4 containing the Joint Proxy Statement that was first mailed to GTx's and Oncternal's stockholders on or about May 10, 2019 and filed with the SEC on May 8, 2019. Investors and security holders of GTx and Oncternal are urged to read

the Joint Proxy Statement and other materials filed or that will be filed with the SEC because they contain or will contain important information about GTx, Oncternal and the Merger. The Joint Proxy Statement and other relevant materials (when they become available), and any other documents filed by GTx with the SEC, may be obtained free of charge at the SEC web site at www.sec.gov. In addition, investors and security holders may obtain free copies of the documents filed with the SEC by GTx by directing a written request to: GTx, Inc., 17 W Pontotoc Ave., Suite 100, Memphis TN 38103, Attention: Corporate Secretary. Investors and security holders are urged to read the Joint Proxy Statement and other relevant materials when they become available before making any voting or investment decision with respect to the Merger.

This communication shall not constitute an offer to sell or the solicitation of an offer to sell or the solicitation of an offer to buy any securities, nor shall there be any sale of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction. No offering of securities shall be made except by means of a prospectus meeting the requirements of Section 10 of the Securities Act of 1933, as amended.

Participants in the Solicitation

GTx and its directors and executive officers and Oncternal and its directors and executive officers may be deemed to be participants in the solicitation of proxies from the stockholders of GTx in connection with the proposed Merger. Information regarding the special interests of these directors and executive officers in the Merger is contained in the Joint Proxy Statement referred to above. These documents are available free of charge at the SEC web site (www.sec.gov) and from the Corporate Secretary of GTx at the address above.

Forward-Looking Information

Oncternal cautions you that statements included in this press release that are not a description of historical facts are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “contemplates,” “believes,” “estimates,” “predicts,” “potential” or “continue” or the negatives of these terms or other similar expressions. These statements are based on the Company’s current beliefs and expectations. Forward looking statements include statements regarding Oncternal’s beliefs, goals, intentions and expectations, and include Oncternal’s belief that the ROR1-Wnt5a signaling pathway remains active in ibrutinib-treated CLL and MCL and is an attractive target for cancer therapy, that inhibition of BTK in CLL cells increases dependence on ROR1 signaling, and that a ROR1 inhibitor such as cirmtuzumab may be an effective treatment for ROR1-expressing lymphoid malignancies such as CLL and MCL; Oncternal’s estimates regarding enrollment of patients in the Phase 1/2 clinical trial of cirmtuzumab in combination with ibrutinib; and the timing for publicly presenting additional clinical data regarding cirmtuzumab. Forward looking statements are subject to risks and uncertainties, which include, but are not limited to: uncertainties associated with the clinical development and process for obtaining regulatory approval of cirmtuzumab and Oncternal’s other product candidates, including potential delays in the commencement, enrollment and completion of clinical trials; the risk that interim results of a clinical trial do not necessarily predict final results and that one or more of the clinical outcomes may materially change as patient enrollment continues, following more comprehensive reviews of the data, and as more patient data become available; the risk that unforeseen adverse reactions or side effects may occur in the course of developing and testing product candidates such as cirmtuzumab and Oncternal’s other product candidates; and risks related to the inability of Oncternal to obtain sufficient additional capital to continue to advance the development of cirmtuzumab and its other product candidates. All forward-looking statements in this press release are current only

as of the date hereof and, except as required by applicable law, Oncternal undertakes no obligation to revise or update any forward-looking statement, or to make any other forward-looking statements, whether as a result of new information, future events or otherwise. All forward-looking statements are qualified in their entirety by this cautionary statement. This caution is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

Oncternal Contacts:

Investors
Richard Vincent
858-434-1113
rvincent@oncternal.com

Media
Jason Spark
619-849-6005
jason@canalecomm.com