

# GTx and Oncternal Therapeutics Enter into Definitive Merger Agreement to Create Nasdaq-Listed Clinical-Stage Company Developing a Diverse Pipeline of Novel Cancer Therapies

March 7, 2019

- -- Merger will combine Oncternal's clinical stage oncology pipeline and expertise with GTx's preclinical Selective Androgen Receptor Degrader (SARD) program for castration-resistant prostate cancer --
- -- Conference call to be held today at 8:30 a.m. Eastern Time/5:30 a.m. Pacific Time --

MEMPHIS, Tenn. & SAN DIEGO--(BUSINESS WIRE)--Mar. 7, 2019-- GTx, Inc. (Nasdaq: GTXI) and Oncternal Therapeutics, Inc., a privately held clinical-stage biotechnology company developing potential first-in-class therapeutic candidates for cancers with critical unmet medical need, today jointly announced that they have entered into a definitive merger agreement under which the stockholders of Oncternal would become the majority owners of GTx's outstanding common stock. The proposed merger will create a publicly-traded, clinical-stage oncology company.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20190307005220/en/

The combined company will be named Oncternal Therapeutics, Inc. and plans to change its ticker symbol on the Nasdaq Capital Market to ONCT upon closing of the transaction.

The combined company will have a strong balance sheet and deep pipeline of promising oncology drug programs advancing in development:

- Oncternal's lead program, cirmtuzumab, is an investigational, potential 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 chronic lymphocytic leukemia (CLL) and mantle cell lymphoma (MCL). 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 the University of California San Diego (UC San Diego).
- TK216, an investigational, potential first-in-class small molecule designed to inhibit the biological activity of ETS-family transcription factor oncoproteins, is being evaluated alone and in combination with vincristine in a Phase 1 clinical trial in patients with relapsed or refractory Ewing sarcoma.
- A ROR-1 targeted chimeric antigen receptor T-cell (CAR-T) program is in preclinical development at UC San Diego for hematologic and solid tumors.
- A Selective Androgen Receptor Degrader (SARD) program, an investigational, potential first-in-class preclinical program
  designed for oral administration to treat castration-resistant prostate cancer in men who are non-responsive to current
  androgen targeted therapies.

Cash, cash equivalents and short-term investments for the combined company are expected to be approximately \$26 million, if the merger closes by the end of the second quarter of 2019. These funds are expected to be sufficient to advance Oncternal's programs into the second quarter of 2020, including the Phase 2 study of cirmtuzumab and ibrutinib, and will fund the planned SARD preclinical studies to support the submission of an investigational new drug application with the U.S. Food and Drug Administration.

James Breitmeyer, MD, PhD, cofounder, president and CEO of Oncternal and a 30-year veteran of the pharmaceutical industry, will continue as president and CEO of the combined company. David Hale, cofounder of Oncternal and a 35-year veteran of numerous successful private and public biotech companies, will continue as Chairman of the Board of the combined company.

"This merger introduces Oncternal and its promising oncology pipeline to the public market and provides additional capital resources to advance our programs to potential value inflection points," said Dr. Breitmeyer. "In addition to clinical data expected from our cirmtuzumab and TK216 programs later this year and during the first half of 2020, we also plan to have preclinical results that get us ready for clinical testing of our ROR1 CAR-T program. The addition of GTx's SARD technology strengthens our pipeline and augments our entire oncology franchise, which includes a range of therapeutic approaches for a variety of difficult to treat cancers."

"This transaction with Oncternal reflects the continued commitment of our management team and Board of Directors to deliver value to stockholders and make a difference in patients' lives," said Robert J. Wills, PhD, Executive Chairman of GTx. "Following a thorough review of strategic alternatives, we have determined that a reverse merger with Oncternal will enable GTx investors to participate in Oncternal's broader pipeline of oncology opportunities, including product candidates designed to address rare disease indications, and enable the continued development of our first-in-class SARD technology by a company whose leadership has deep experience in developing oncology medicines."

#### **About the Proposed Merger**

The merger is structured as a stock-for-stock transaction whereby all of Oncternal's outstanding shares of common stock and securities convertible into or exercisable for Oncternal's common stock will be converted into GTx common stock and securities convertible into or exercisable for GTx common stock. Immediately following the closing of the transaction, the former stockholders of Oncternal will hold approximately 75% of the outstanding shares of common stock of the combined company. In addition to retaining an ownership interest representing approximately 25% of the outstanding shares of common stock of the combined company, the GTx stockholders of record as of immediately prior to the effective time of the

merger will receive non-transferable contingent value rights ("CVR") entitling the holders to receive in the aggregate 50% of any net proceeds derived from the grant, sale or transfer of rights to SARD or selective androgen receptor modulator (SARM) technology during the term of the CVR and, if applicable, to receive royalties on the sale of any SARD products by the combined company during the term of the CVR. Under certain circumstances further described in the merger agreement, the exchange ratio of the outstanding shares of common stock of the combined company may be adjusted upward or downward based on cash levels of each of the companies at closing.

Upon closing of the transaction, GTx will be renamed Oncternal Therapeutics, Inc. and will be headquartered in San Diego, California under the leadership of Oncternal's current management team. Although no GTx employee is expected to remain an employee of the combined company, the merger agreement provides that the Board of Directors of the combined company will be comprised of nine members, including seven designated Oncternal directors as well as Robert J. Wills, PhD and Michael G. Carter, MD, from GTx's current Board. The combined company is expected to trade on The Nasdaq Capital Market under a new ticker symbol, ONCT. The merger agreement has been unanimously approved by the Board of Directors of each company. The transaction is expected to close in the second quarter of 2019, subject to approvals by stockholders of each company and other customary closing conditions.

Aquilo Partners, L.P. is acting as exclusive financial advisor to GTx on the proposed transaction and Cooley LLP serves as legal counsel to GTx. Piper Jaffray is acting as exclusive financial advisor to Oncternal on the proposed transaction and Latham & Watkins, LLP serves as legal counsel to Oncternal.

#### **Conference Call Information**

Dr. Wills and Dr. Breitmeyer will co-host a conference call to discuss the proposed merger on March 7, 2019, at 5:30 A.M. Pacific Time at Oncternal's headquarters in San Diego.

To access the live conference call, please dial 1.877.407.2991 from the U.S. and Canada or 1.201.389.0925 internationally. A playback of the call will be available from approximately 12:00 P.M. Pacific Time today through May 7, 2019 and may be accessed by dialing 877.660.6853 from the U.S. and Canada or 201.612.7415 internationally, and using conference ID 13688553. The conference call information will also be available on the Investor section of the GTx website at <a href="https://www.gtxinc.com">www.gtxinc.com</a>.

#### **About GTx**

GTx, Inc., headquartered in Memphis, Tenn., is a biopharmaceutical company dedicated to the discovery, development and commercialization of small molecules for the treatment of muscle-related diseases and other serious medical conditions.

#### **About Oncternal Therapeutics**

Oncternal Therapeutics is a clinical-stage oncology company developing novel, potential first-in-class therapeutic candidates for cancers with critical unmet medical need. The company is leveraging its scientific and development expertise, as well as academic collaborations, to rapidly advance its pipeline.

## **About Cirmtuzumab**

Cirmtuzumab is an investigational, potential first-in-class humanized monoclonal antibody that is designed to bind with high affinity to a biologically important epitope on ROR1 (Receptor-tyrosine kinase-like Orphan Receptor 1). Cirmtuzumab has been developed in collaboration with UC San Diego, and with the California Institute for Regenerative Medicine (CIRM), which funded both previous preclinical development work, as well as previous and ongoing clinical trials. ROR1 is a type 1 transmembrane protein expressed on the plasma membrane with an extracellular domain that is essential for ligand binding and signal transduction. In preclinical studies, it has been observed to bind to many different types of cancer cells, but not to most normal human tissues. Tumor cells that express ROR1 have tumor-initiating features that are associated with a de-differentiated oncogenic state. When expressed by hematologic malignancies such as mantle cell lymphoma (MCL), chronic lymphocytic leukemia (CLL), and small lymphocytic leukemia (SLL), ROR1 has been observed to act as a receptor for the tumor growth factor Wnt5a. Cirmtuzumab is designed to bind to ROR1 in such a manner that it blocks Wnt5a activation and inhibits tumor-cell proliferation, migration and survival and induces differentiation. Early clinical data suggests that cirmtuzumab may synergize with ibrutinib, and Oncternal is evaluating this pairing as a potential combination treatment for CLL and MCL.

## **About TK216**

TK216 is an investigational, potential first-in-class small molecule that is designed to inhibit the biological activity of ETS-family transcription factor oncoproteins in a variety of tumor types, in an effort to inhibit cancer cell growth and tumor formation. In Ewing sarcoma, it is designed to target the well-characterized fusion proteins that cause the disease. TK216 is being developed collaboratively by Georgetown University and Oncternal. Oncternal is also planning clinical studies of TK216 in leukemia and performing preclinical studies in prostate cancer.

### Additional Information about the Proposed Merger and Where to Find It

In connection with the proposed merger, GTx and Oncternal intend to file relevant materials with the Securities and Exchange Commission, or the SEC, including a registration statement on Form S-4 that will contain a prospectus, a proxy statement and an information statement. *Investors and security holders of GTx and Oncternal are urged to read these materials when they become available because they will contain important information about GTx, Oncternal and the merger.* The proxy statement, prospectus, information 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 <a href="https://www.sec.gov">www.sec.gov</a>. 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., 175 Toyota Plaza, 7<sup>th</sup> Floor, Memphis, Tennessee 38103, Attention: Corporate Secretary. Investors and security holders are urged to read the proxy statement, prospectus, information 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 transaction. Information regarding the special interests of these directors and executive officers in the merger will be included in the proxy statement/ prospectus/information statement referred to above. Additional information regarding the directors and executive officers of GTx is also included in GTx's definitive proxy statement in connection with its 2018 Annual Meeting of Stockholders filed with the SEC on March 23, 2018. These documents are available free of charge at the SEC web site (<a href="www.sec.gov">www.sec.gov</a>) and from the Corporate Secretary of GTx at the address above.

# GTx Forward-Looking Information is Subject to Risks and Uncertainty

This press release contains forward-looking statements based upon GTx's and Oncternal's current expectations. Forward-looking statements involve risks and uncertainties, and include, but are not limited to, statements about the structure, timing and completion of the proposed merger; the combined company's listing on Nasdaq after closing of the proposed merger; the timing and results of planned preclinical studies or clinical trials of cirmtuzumab, TK216 or Oncternal's ROR-1 targeted CAR-T product candidates; the possibility that any grant, sale or transfer of rights to SARD or SARM technology or the sale of any SARD or SARM products will occur during the term of the CVR and that the conditions to payment under the CVRs will be met: expectations regarding the ownership structure of the combined company; the combined company's expected cash position at the closing of the proposed merger; the future operations of the combined company, including with respect to the continued development of GTx's SARD technology; the nature, strategy and focus of the combined company; the development and commercial potential and potential benefits of any product candidates of the combined company; the executive and board structure of the combined company; the location of the combined company's corporate headquarters; anticipated preclinical and clinical drug development activities and related timelines, including the expected timing for data and other clinical and preclinical results; Oncternal having sufficient resources to advance its pipeline; and other statements that are not historical fact. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation: (i) the risk that the conditions to the closing of the proposed merger are not satisfied, including the failure to timely obtain stockholder approval for the transaction, if at all; (ii) uncertainties as to the timing of the consummation of the proposed merger and the ability of each of GTx and Oncternal to consummate the proposed merger; (iii) risks related to GTx's ability to manage its operating expenses and its expenses associated with the proposed merger pending closing; (iv) risks related to the failure or delay in obtaining required approvals from any governmental or quasi-governmental entity necessary to consummate the proposed merger; (v) the risk that as a result of adjustments to the exchange ratio, GTx stockholders and Oncternal stockholders could own more or less of the combined company than is currently anticipated; (vi) risks related to the market price of GTx's common stock relative to the exchange ratio; (vii) unexpected costs, charges or expenses resulting from the transaction; (viii) potential adverse reactions or changes to business relationships resulting from the announcement or completion of the proposed merger; (ix) the uncertainties associated with the clinical development and regulatory approval of product candidates such as cirmtuzumab and TK216, including potential delays in the commencement, enrollment and completion of clinical trials; (x) risks related to the inability of the combined company to obtain sufficient additional capital to continue to advance these product candidates and its preclinical programs, including GTx's SARD program and Oncternal's CAR-T program; (xi) uncertainties in obtaining successful clinical results for product candidates and unexpected costs that may result therefrom; (xii) risks related to the failure to realize any value from product candidates and preclinical programs being developed and anticipated to be developed in light of inherent risks and difficulties involved in successfully bringing product candidates to market; (xiii) the risk that the conditions to payment under the CVRs will be not be met and that the CVRs may otherwise never deliver any value to GTx stockholders; and (xiv) risks associated with the possible failure to realize certain anticipated benefits of the proposed merger, including with respect to future financial and operating results. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties. These and other risks and uncertainties are more fully described in periodic filings with the SEC, including the factors described in the section entitled "Risk Factors" in GTx's Quarterly Report on Form 10-Q for the quarter ended September 30, 2018 filed with the SEC, and in other filings that GTx makes and will make with the SEC in connection with the proposed transactions, including the proxy statement/prospectus described above under "Additional Information about the Proposed Merger and Where to Find It." You should not place undue reliance on these forward-looking statements, which apply only as of the date of this press release. GTx expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in its expectations with regard thereto or any change in events, conditions or circumstances on which any such statements are based.

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