

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, DC 20549**

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**FORM 8-K**

**CURRENT REPORT**

**Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

Date of report (Date of earliest event reported) **October 24, 2013**

**GTx, Inc.**

(Exact Name of Registrant as Specified in Charter)

**Delaware**  
(State or Other Jurisdiction  
of Incorporation)

**000-50549**  
(Commission File  
Number)

**62-1715807**  
(IRS Employer Identification No.)

**175 Toyota Plaza**  
**7<sup>th</sup> Floor**  
**Memphis, Tennessee**  
(Address of Principal Executive Offices)

**38103**  
(Zip Code)

Registrant's telephone number, including area code: **(901) 523-9700**

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communication pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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ITEM 8.01 Other Events.

On October 24, 2013, GTx, Inc. (the "Company") issued a press release announcing that results from the Company's enobosarm Phase 3 clinical studies for the prevention and treatment of muscle wasting in patients with non-small cell lung cancer will be presented during the 15th World Conference on Lung Cancer being held by the International Association for the Study of Lung Cancer in Sydney, Australia, October 27-30, 2013.

A copy of the press release is furnished as Exhibit 99.1 to this Current Report.

ITEM 9.01 Financial Statements and Exhibits.

(d) Exhibits.

**Exhibit  
Number**  
99.1

**Description**  
Press Release issued by GTx, Inc. dated October 24, 2013

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**SIGNATURE**

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: October 24, 2013

GTx, Inc.

By: /s/ Henry P. Doggrell

Name: Henry P. Doggrell

Title: Vice President, Chief Legal Officer and Secretary

## GTx Presents Results from Enobosarm POWER Trials for the Prevention and Treatment of Muscle Wasting in Patients with Non-Small Cell Lung Cancer at 15<sup>th</sup> World Conference on Lung Cancer

*Enobosarm had a significant effect on Lean Body Mass (LBM) and stair climb power (SCP) through Day 84 and 147 in POWER1 trial (platinum plus taxane) using a longitudinal continuous variable analysis*

*Enobosarm had a significant effect on Lean Body Mass (LBM) through Day 84 and 147 in POWER2 trial (platinum plus non-taxane) using a longitudinal continuous variable analysis*

*Patients who had a  $\geq 1$ kg increase in LBM demonstrated a significant advantage in Stair Climb Power (SCP)*

*Findings from both trials show that maintenance or improvement in LBM improves survival by landmark analysis*

MEMPHIS, Tenn.—(BUSINESS WIRE)—October 24, 2013— GTx, Inc. (Nasdaq: GTXI) announced today that a poster presentation, entitled *Results from two Phase 3 randomized trials of enobosarm, a selective androgen receptor modulator (SARM), for the prevention and treatment of muscle wasting in patients with non-small cell lung cancer (NSCLC) receiving chemotherapy*, will be given by Jeffrey Crawford, M.D., Chief, Division of Medical Oncology at Duke University School of Medicine, and principal investigator for the POWER1 (platinum plus taxane) and POWER2 (platinum plus non-taxane) trials, which were chemotherapy add-on placebo controlled studies.

Top line results from the POWER trials showed that enobosarm 3 mg once daily had a significant effect on LBM through Day 84 and 147 in both trials, compared to placebo (taxane:  $p=0.0003$  and  $<0.0001$ , respectively; non-taxane:  $p=0.0227$  and  $0.0036$ , respectively, using a continuous variable analyses). By the responder analysis, a larger proportion of patients receiving enobosarm maintained or increased LBM at Day 84 and 147 in both clinical trials (taxane:  $p=0.036$  and  $0.026$ ; non-taxane:  $p=0.113$  and  $0.013$ ), as compared to placebo. Additionally, the POWER1 clinical study met the pre-specified endpoints for the European regulatory agency, using the longitudinal continuous variable analysis. As compared with placebo, enobosarm treated patients in POWER1 achieved the primary endpoint in SCP through Day 84 ( $p=0.0185$ ) and the secondary endpoint of SCP through Day 147 ( $p=0.0486$ ).

In a post-hoc analysis, regardless of treatment, patients with a  $\geq 1$ kg increase in LBM were more likely to demonstrate at least a 10% increase in SCP compared to patients who did not have a  $\geq 1$ kg increase in LBM (taxane: 43.7% vs 29.3%,  $p=0.0250$ ; and non-taxane: 40.5% vs 26.5%,  $p=0.0321$ ). Importantly, a larger proportion of enobosarm treated patients, with 1kg or greater increases in LBM, demonstrated at least a 10% increase in SCP (taxane:  $p=0.0698$ ,  $\geq 1$ kg 46.4%,  $<1$ kg 29.6%; and non-taxane:  $p=0.0335$ ,  $\geq 1$ kg 39.6%,  $<1$ kg 20.4%), while this same trend was not observed in placebo treated patients (taxane:  $p=0.3149$ ,  $\geq 1$ kg 38.7%,  $<1$ kg 29.0%; and non-taxane:  $p=0.2852$ ,  $\geq 1$ kg 41.5%,  $<1$ kg 31.3%). This observation suggests that SCP improvements, in both trials, may be related to enobosarm increases in LBM.

Post-hoc landmark survival analyses at Day 84 suggest improved survival in patients who maintained or increased LBM in both clinical trials, regardless of treatment. As required by the study protocols, the final survival analysis will be completed after 450 deaths have been observed among patients in the studies.

Enobosarm was very well tolerated in both clinical trials. Although only minor differences in adverse events were observed between the groups treated with enobosarm 3 mg and placebo in the POWER1 and POWER2 trials, there were notable differences in the adverse event profile between studies with anemia and other hematologic toxicities more prevalent in the POWER2 (platinum plus non-taxane) clinical trial.

Abstract ID: 2266: Results from two phase 3 randomized trials of enobosarm, selective androgen receptor modulator (SARM), for the prevention and treatment of muscle wasting in NSCLC. NSCLC Novel Therapies Poster Session 3 (P3.11-026), Wednesday, October 30, 2013, from 9:30 AM -2:30 PM AEDT in the Exhibit Hall, Ground Level at the 15<sup>th</sup> World Conference on Lung Cancer being held by the International Association for the Study of Lung Cancer in Sydney, Australia.

### About The POWER Trials

A 3 mg dose of enobosarm was studied in two Phase 3 clinical trials to prevent and treat muscle wasting in patients with NSCLC. In each of these placebo controlled, double blind, add-on clinical trials, approximately 325 patients with stage III or IV NSCLC were randomized to oral daily doses of placebo or enobosarm 3 mg at the time they began first-line standard platinum doublet chemotherapy. The POWER trials were designed to assess the effect of enobosarm versus placebo on

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maintenance or improvement of total LBM (muscle) assessed by Dual-energy X-ray Absorptiometry (DXA) and improvement in physical function measured by SCP. Durability of enobosarm treatment was assessed at five months. Secondary endpoints included an assessment of whether enobosarm-treated patients had an improved quality of life and reduced healthcare resource utilization compared to placebo. Overall survival is being assessed as an additional safety endpoint. GTx announced early this year that the FDA has designated enobosarm for the prevention and treatment of muscle wasting in patients with NSCLC as a *Fast Track* development program.

### About Cancer-Induced Muscle Wasting

Cancer-induced muscle wasting begins early in the disease process, resulting in decreased physical function and other detrimental consequences, such as fatigue and weight loss, which can contribute to disability, reduced quality of life and shorter overall survival, compared with patients without muscle loss. There are currently no drugs approved for the prevention and treatment of muscle wasting in patients with cancer.

### About Non-Small Cell Lung Cancer

The American Cancer Society estimates about 228,190 new cases of lung cancer will be diagnosed in the United States in 2013, and approximately 85 to 90 percent of these are non-small cell lung cancer. Approximately 159,480 Americans are expected to die from lung cancer this year.

### 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 cancer, cancer supportive care, and other serious medical conditions.

**Forward-Looking Information is Subject to Risk and Uncertainty**

*This press release contains forward-looking statements based upon GTx's current expectations. Forward-looking statements involve risks and uncertainties, and include, but are not limited to, statements relating to GTx's clinical trials for enobosarm (also known as Ostarine® or GTx-024). GTx's 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, the risks (i) that GTx will not be able to commercialize its product candidates if clinical trials do not demonstrate safety and efficacy in humans; (ii) that GTx may not be able to obtain required regulatory approvals to commercialize its product candidates in a timely manner or at all; (iii) that clinical trials being conducted by GTx may not be completed on schedule, or at all, or may otherwise be suspended or terminated; or (iv) that GTx could utilize its available cash resources sooner than it currently expects and may be unable to raise capital when needed, which would force GTx to delay, reduce or eliminate its product candidate development programs or commercialization efforts. You should not place undue reliance on these forward-looking statements, which apply only as of the date of this press release. GTx's quarterly report on Form 10-Q filed with the Securities and Exchange Commission on July 22, 2013 contains under the heading, "Risk Factors", a more comprehensive description of these and other risks to which GTx is subject. 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.*

Source:  
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