



Transition Therapeutics Announces Top Line Phase 2 Clinical Study Results of Diabetes Drug Candidate TT401

TORONTO, ON, February 1, 2016 – Transition Therapeutics Inc. (“Transition” or the “Company”) (NASDAQ: TTHI, TSX: TTH) today announced the results of a Phase 2 clinical study of drug candidate TT401 (LY2944876) for the treatment of type 2 diabetes. TT401 is a once-weekly administered oxyntomodulin analog with dual GLP-1 and glucagon agonist activity. TT401 development collaborator Eli Lilly and Company performed the Phase 2 study enrolling 420 type 2 diabetes subjects into a 24 week study consisting of a 12-week randomized blinded stage followed by a 12-week open-label stage. The study included four once-weekly dose arms of TT401 (10mg, 15mg, 30mg, 50mg), a placebo arm, and an active comparator arm (exenatide extended release – 2mg).

TT401 demonstrated HbA1c improvements of up to -1.43% (similar to the exenatide arm). All TT401 dose arms and the exenatide arm were statistically significant relative to the placebo arm at Weeks 12 and 24.

TT401 also produced dose dependent weight loss (up to -3.3 kg). The weight loss observed in the highest dose arm (50mg of TT401) was statistically significant relative to both the placebo and exenatide arms at weeks 12 and 24.

In the study, TT401 appeared to have an acceptable safety and tolerability profile. There were a similar number of study discontinuations and serious adverse events between the TT401 dose arms and the exenatide arm. The most frequently observed adverse events were gastrointestinal; these were generally classified as mild to moderate and diminished over time.

The Phase 2 study data will be submitted for presentation at a future medical meeting.

Should Lilly continue TT401 development, Transition would be eligible to receive a milestone payment as well as future milestone payments and royalties. Otherwise, Transition may elect to assume development and commercialization rights to TT401. This option allows Transition to pursue TT401 development on its own or with a third party, subject to future royalty payments to Lilly.

About the TT401 (LY2944876) Phase 2 Study

The randomized, double-blind, placebo-controlled study included six study arms, four doses of TT401, a placebo arm and a once-weekly exenatide arm. There were 420 type 2 diabetes subjects enrolled in the study with a mean baseline Hb1Ac of 8.2% and a mean baseline weight of 92kg. Over 90% of subjects were on a stable dose of metformin at baseline. The study comprised a 12-week blinded treatment period, where neither the participant nor the investigator knew which treatment each individual was assigned. Thereafter followed a 12-week period (weeks 13-24) where participants and the investigator were aware



Transition Therapeutics Announces Top Line Phase 2 Clinical Study Results of Diabetes Drug Candidate TT401

of which treatment they were assigned to. Participants on TT401 and on once-weekly exenatide continued treatment through weeks 13-24, and those who received placebo were followed without treatment. The main efficacy outcome measures were the change in HbA1c (a measure of blood-glucose levels) at week 12 and 24 and change in body weight over the course of the study.

About TT401 (LY2944876)

TT401 is being developed to treat type 2 diabetes. The TT401 (LY2944876) drug candidate is an oxyntomodulin analog that has dual agonist activity of the GLP-1 (Glucagon-Like Peptide-1) and glucagon receptors. In March 2010, Transition licensed a series of pre-clinical compounds from Lilly, including TT401. In June 2013, Lilly exercised its option to assume all development and commercialization rights of TT401.

About Transition

Transition is a biopharmaceutical development company, advancing novel therapeutics for CNS and metabolic disease indications. The Company's wholly-owned subsidiary, Transition Therapeutics Ireland Limited is developing CNS drug candidate ELND005 for the treatment of Alzheimer's disease and Down syndrome. Transition's lead metabolic drug candidate is TT401 (LY2944876) for the treatment of type 2 diabetes and accompanying obesity. The Company's shares are listed on the NASDAQ under the symbol "TTHI" and the Toronto Stock Exchange under the symbol "TTH". For additional information about the Company, please visit www.transitiontherapeutics.com.

Notice to Readers: Information contained in our press releases should be considered accurate only as of the date of the release and may be superseded by more recent information we have disclosed in later press releases, filings with the OSC, SEC or otherwise. Except for historical information, this press release may contain forward-looking statements, relating to expectations, plans or prospects for Transition, including conducting clinical trials and potential efficacy of its products. These statements are based upon the current expectations and beliefs of Transition's management and are subject to certain risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. These risks and uncertainties include factors beyond Transition's control and the risk factors and other cautionary statements discussed in Transition's quarterly and annual filings with the Canadian commissions.

For further information on Transition, visit www.transitiontherapeutics.com or contact:

Dr. Tony Cruz
Chief Executive Officer
Transition Therapeutics Inc.
Phone: 416-260-7770 x 223
tcruz@transitiontherapeutics.com

Patrick McKillop
Director - Investor Relations
Transition Therapeutics Inc.
Phone: 339-788-4962
pmckillop@transitiontherapeutics.com