



Transition Therapeutics Announces Results from ELND005 Clinical Study in Adults with Down Syndrome

TORONTO, ON, November 20th, 2014 – Transition Therapeutics Inc. (“Transition” or the “Company”) (NASDAQ: TTHI, TSX: TTH) today announced the results of a clinical study of neuropsychiatric drug candidate ELND005 in young adults with Down syndrome. Transition’s wholly-owned subsidiary, Transition Therapeutics Ireland Limited (“TTIL”) completed this first study in Down syndrome subjects without dementia to allow optimal dose selection for future larger studies.

The study enrolled 23 Down syndrome subjects in three study arms over a four-week treatment period: placebo (n=6), 250mg once daily (QD) (n=5), and 250mg twice daily (BID) (n=12). ELND005, at the doses evaluated, was determined to have an acceptable safety and tolerability profile and there were no serious adverse events reported in the study. Treatment emergent adverse events were reported in seven of the subjects receiving ELND005 and all were deemed to be mild in severity. The two ELND005 doses achieved the plasma levels expected in pharmacokinetic modeling and will inform the selection of a higher dose in a future clinical study.

An exploratory endpoint of the study was the effect of ELND005 on behavior using the Cumming’s NPI (“Neuropsychiatric Inventory”) which assesses the severity of 12 neuropsychiatric symptoms. Subjects enrolled in the study had no major affective disorder, but were allowed to be on stable doses of psychotropic drugs. The most common neuropsychiatric symptoms at baseline in the study were agitation and aggression followed by aberrant motor behavior, disinhibition and irritability. Of the 15 subjects who had neuropsychiatric symptoms at baseline, numerical improvements (decreased NPI-total score) was observed at 4 weeks as follows: in 1 of 3 placebo subjects, in 0 of 4 subjects receiving 250mg QD of ELND005, and in 7 of 8 subjects receiving 250mg BID of ELND005.

“Although in small numbers of study subjects, we continue to be encouraged by the consistent trend of improvement in neuropsychiatric measures seen in the earlier Bipolar study and now in the Down syndrome study. The safety and pharmacokinetic data in this study supports the escalation of ELND005 to a dose higher than 250mg BID to evaluate both neuropsychiatric/behavioral and cognitive outcomes in a larger trial in young adults with Down Syndrome. TTIL will be engaging our Down Syndrome experts and investigators to set a course for future clinical development with ELND005 in Down syndrome”, said Dr. Tony Cruz, Chairman and Chief Executive Officer of Transition.

About Down Syndrome

Down syndrome (DS, Trisomy 21), caused by an extra copy of chromosome 21, is the most common genetic form of intellectual disability with a prevalence of approximately 1 in 830 live births in the US. Children with DS exhibit developmental delay and various degrees of intellectual disability, while adults are at increased risk of Alzheimer's dementia. There are currently no drugs approved for the treatment of cognitive or behavioral dysfunction in DS.

Excess activity of genes on chromosome 21, such as amyloid precursor protein (APP) and sodium-myoinositol active transporter (SMIT), are thought to play a role in the cognitive dysfunction of DS. Life-long exposure to increased amyloid and myo-inositol levels in the brain are thought to lead to synaptic dysfunction and cognitive disability. ELND005 may have the potential to improve cognition in persons with DS by decreasing amyloid levels and regulating myo-inositol-dependent neuronal signalling.

About ELND005

ELND005 is an orally bioavailable small molecule that is being investigated for multiple neuropsychiatric indications on the basis of its proposed dual mechanism of action, which includes β -amyloid anti-aggregation and regulation of brain myo-inositol levels. An extensive clinical program of Phase 1 and Phase 2 studies has been completed with ELND005 to support clinical development, including the published Phase 2 study ELND005-AD201 in AD. ELND005 is also being studied as a potential treatment of agitation and aggression in Alzheimer's disease (Study ELND005-AG201).

In July 2013, the ELND005 program received fast track status designation from the US FDA for the treatment of Neuropsychiatric Symptoms in AD.

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 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.

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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.

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