Therapix Biosciences Announces Completion of Enrollment of Phase IIa Study at Yale University for Tourette Syndrome Program

- Top-Line Results Currently Anticipated in Early 2018 -

TEL AVIV, Israel, Dec. 4, 2017 /PRNewswire/ -- Therapix Biosciences Ltd. (Nasdaq: TRPX), a specialty clinical-stage pharmaceutical company specializing in the development of cannabinoid-based therapies, announces the completion of enrollment in its investigator-initiated Phase IIa study at Yale University evaluating its investigational compound THX-110, a therapeutic compound consisting of FDA-approved dronabinol (synthetic Δ-9-tetrahydracannabinol) and palmitoylethanolamide (PEA) , for Tourette syndrome. Sixteen patients have been enrolled in the study. Top-line results are currently anticipated in the first half of 2018.

"The completion of enrollment for this study is a significant milestone for Therapix," said Dr. Adi Zuloff-Shani, Chief Technology Officer at Therapix. "We're optimistic that this study will support earlier clinical research documenting the therapeutic benefits of cannabinoid-based therapies and may suggest that the combination of dronabinol and PEA, which we are developing as our investigatory compound THX-110, will demonstrate a safe and efficacious treatment for this highly debilitating disease with high unmet medical need. In addition, enrollment was completed on time and on budget."

The study is sponsored by Therapix and led by Michael H. Bloch, M.D., Associate Professor at the Yale University Child Study Center, and James F. Leckman, M.D., Ph.D., Neison Harris Professor in the Child Study Center and Professor of Child Psychiatry at Yale University.

Dr. Bloch added, "As there are many adult patients with Tourette syndrome who do not respond to antipsychotic medications and other treatments currently approved to treat tic symptoms, we are hopeful that a new treatment with a novel mechanism of action will be safe, well-tolerated and efficacious and that it can advance to a large, double-blind, placebo-controlled study."

The Yale study is a single-arm, open-label study, in which subjects receive once-daily oral treatment of the investigational drug for 12 weeks. The objective of the clinical study is to prove the safety, tolerability and efficacy of the combination of dronabinol and PEA in adult patients with Tourette syndrome. The primary efficacy endpoint is the change from baseline to the end of the 12-week treatment in the Yale Global Tic Severity Scale Total Tic Score (YGTSS-TTS), which is a clinical measure designed to provide an evaluation of tic severity. Secondary efficacy endpoints include demonstrating the safety and tolerability of the dronabinol and PEA combination and to evaluate its benefit on premonitory urges, quality of life, disease severity and comorbidities including ADHD, OCD, depression and anxiety. More information about the study is available on clinicaltrials.gov.

About Therapix Biosciences Ltd.:

Therapix Biosciences Ltd. is a specialty clinical-stage pharmaceutical company led by an experienced team

of senior executives and scientists. Our focus is creating and enhancing a portfolio of technologies and assets based on cannabinoid pharmaceuticals. With this focus, the Company is currently engaged in the following drug development programs based on repurposing an FDA approved synthetic cannabinoid (dronabinol): THX-110 for the treatment of Tourette syndrome (TS) and Obstructive Sleep Apnea (OSA); THX-130 for the treatment of Mild Cognitive Impairment (MCI) and Traumatic Brain Injury (TBI); and THX-150 for the treatment of infectious diseases. Please visit our website for more information at www.therapixbio.com

About TXH-110:

THX-110 is a combination drug candidate for the treatment of Tourette syndrome and Obstructive Sleep Apnea. It is based on two components: (1) dronabinol (an FDA approved synthetic analog of Δ9-tetrahydracannabinol, or "THC"), which is the psychoactive molecule in the cannabis plant, and (2) palmitoylethanolamide ("PEA"), which is an endogenous fatty acid amide that belongs to the class of nuclear factor agonists, which are proteins that regulate the expression of genes. The combination of THC and PEA may induce a reaction known as the "entourage effect." The basic tenet of the entourage effect is that cannabinoids work together, or possess synergy, and affect the body in a mechanism similar to the body's own endocannabinoid system, which is a group of molecules and receptors in the brain that mediates the psychoactive effects of cannabis. This entourage effect may account for the pharmacological actions of PEA. Based on an activity enhancement of other physiological compounds, PEA may indirectly stimulate the cannabinoid receptors by potentiating their affinity for a receptor or by inhibiting their metabolic degradation, and by doing so, may increase the uptake of cannabinoid compounds, such as THC. Thus, it is speculated that the presence of the PEA molecule could increase the efficacy of orally administered THC, while reducing the required dosage and decreasing associated deleterious adverse events.

Forward-Looking Statements:

This press release contains forward-looking statements about the Company's expectations, beliefs, and intentions. Forward-looking statements can be identified by the use of forward-looking words such as "believe", "expect", "intend", "plan", "may", "should", "could", "might", "seek", "target", "will", "project", "forecast", "continue" or "anticipate" or their negatives or variations of these words or other comparable words or by the fact that these statements do not relate strictly to historical matters. Such forward-looking statements used in this press release include, among other things, references to the clinical and commercial potential of THX-TS01 for the treatment of Tourette syndrome. Actual results could differ from those projected in any forward-looking statements due to numerous factors. Such factors include, among others, our ability to raise the additional funding needed to continue to pursue our business and product development plans, the inherent uncertainties associated with developing new products or technologies, our ability to obtain regulatory approval for our product candidates, our ability to commercialize our product candidates, competition in the industry in which we operate and overall market conditions. Any forward-looking statement in this press release speaks only as of the date of this press release. The Company undertakes no obligation to publicly update or review any forward-looking statement, whether as a result of new information, future developments or otherwise, except as may be required by any applicable securities laws. More detailed information about the risks and uncertainties affecting the Company is contained under the heading "Risk Factors" in Therapix Biosciences Ltd.'s annual report on Form 20-F dated May 1, 2017 filed with the SEC, which is available on the SEC's website, www.sec.gov.

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Additional assets available online:

http://therapix.investorroom.com/2017-12-04-Therapix-Biosciences-Announces-Completion-of-Enrollment-of-Phase-IIa-Study-at-Yale-University-for-Tourette-Syndrome-Program