Therapix Biosciences filed an application with the FDA to approve an "orphan" designation for the drug developed based on the entourage technology for treating Tourette's syndrome

- **The application was filed after completion of the pre-clinical phase and proof-of-concept of the entourage technology and further to the Company's preparations towards clinical trials in humans**

- **The Company estimates that an initial clinical trial will begin in H2/2016, subject to receipt of an applicable FDA approval**

Tel Aviv, Israel. Therapix Biosciences, (OTCQB: THXBY) (TASE: THXBY.TA) the pharma company specializing in the development and commercialization of cannabinoid-based drugs, announced that it filed an application with the U.S. Food and Drug Administration to approve an orphan drug designation for a drug (THX-RS01) developed based on the entourage technology, which combines cannabinoid substances in treating Tourette syndrome.

The application was filed after the completion of the pre-clinical phase and proof-of-concept of the entourage technology and further to the Company's preparations towards the development of a drug based on the technology in the context of clinical trials in humans.

The Orphan Drug Act of 1983 was promulgated to set forth the rights of patients suffering from rare medical conditions, and for such purpose, determined several incentives to encourage pharmaceutical companies to invest in research and development in such fields. The Act defines an "orphan drug" as a chemical or biological agent, used in treating rare diseases that affect less than 200,000 patients in the United States. Among the incentives provided by the Act, are a seven-year market exclusivity commencing on the drug's date of approval; tax benefits; participation in development costs; assistance in regulatory proceedings – fast-track registrations; and a full exemption from the FDA's drug registration fees.

The entourage technology is based on the combination of cannabinoid substances or cannabinoid analogs with existing drugs. The technology enables improving the treatment of various medical indications by reducing the standard dosages of the drug, while increasing its efficacy and improving its safety profile.

Dr. Elran Haber, Therapix Biosciences' CEO, stated that "the filing of the application for an orphan drug designation is an additional step towards the fulfillment of the Company's business and clinical objectives. The orphan designation route, if approved, will enable an accelerated regulatory process that will shorten time-to-market and facilitate the drug's market accessibility. The Company is simultaneously acting to initiate clinical trials that will begin in H2/2016, subject to receipt of the required approvals, including FDA approval for the commencement of trials in THX-TS".

Several days ago, the Company announced the joining of internationally renowned experts, from Israel and the world, to the scientific board and the Company's team of consultants, including **Prof. James Leckman**, a child psychiatrist, psychiatrist and physician at Yale University, **Prof. Kirsten Müller-Vahl**, Professor of Psychiatry at the Department of Psychiatry, Socialpsychiatry and Psychotherapy of the Hannover Medical School, Germany, **Prof. Michael Davidson**, Professor of Psychiatry and Chairman of the Stuckinski Centre for Alzheimer's Disease Research in Ramat Gan, **Prof. Avi Weizman**, Professor of Psychiatry at Tel Aviv University and Director of the Center and Head of Geha Mental Health Center's Research Unit, and **Dr. Michael Bloch**, a Yale University School of Medicine graduate.

The new experts will join Prof. Raphael Mechoulam, who identified the active compound in cannabis, THC, on the advisory board, and Dr. Yafit Stark, a vice president at Teva serving on the Company's Board of Directors.

About Therapix Biosciences

Therapix Biosciences is an Israeli pharma company specializing in the development and commercialization of approved drugs that are based on cannabinoid molecules. The Company is listed on the Tel Aviv Stock Exchange and is also traded over-the counter (OTC) in the United States. The Company is engaged in the development of a drug based on cannabinoids and the entourage technology for treating Tourette syndrome, and is preparing for the development of a cannabinoid-based drug for treating impairments in cognitive functioning (including preliminary stages of Alzheimer's disease). The Company's Chairman is Dr. Ascher Shmulewitz and Dr. Elran Haber is its CEO.

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