

Stero Biotechs Announces First Patient in Phase 2A Clinical Trial for CBD Effects on Chronic Spontaneous Urticaria

A placebo-controlled, single-center study conducted to evaluate tolerability, safety, efficacy, and steroid-sparing effect of CBD in CSU patients.

TEL AVIV, ISRAEL, August 5, 2020 /EINPresswire.com/ -- <u>Stero Biotechs Ltd.</u>, an Israel-based, clinical-stage company focused on research and development of Cannabidiol (CBD) based treatments, announces the entrance of the first patient into its ongoing, Phase 2A, clinical trial in Chronic Spontaneous Urticaria (CSU).

Chronic Spontaneous Urticaria (CSU) is a skin condition that causes red, swollen, itchy, and sometimes painful hives. Urticaria is defined as 'chronic' when the symptoms spontaneously recur at least 3 times per week for 6 or more weeks. The condition is described as 'spontaneous' when symptoms are not triggered by an identifiable external factor. Women are twice as likely to be diagnosed with the disease and most people first develop symptoms between the ages of 20 and 40. CSU substantially affects the quality of life and has a considerable cost burden. Patients require continuous treatments and steroids are occasionally used as part of the medication arsenal.

The purpose of the ongoing study is to evaluate the tolerability, safety, efficacy, and steroid-sparing effect of CBD in CSU patients. The study is a placebo-controlled, single-center study projected to last 6 months. The trial is conducted in the Allergy and Clinical Immunology Unit, at Meir Medical Center, Kfar Saba, Israel and led by Prof. Ronit Confino-Cohen, Head of Drug Allergy Service, and Head of the Allergy and Clinical Immunology. Approximately 20 participants with CSU are currently being recruited.

Results from a previous Phase 2 clinical trial showed CBD administration enhanced the therapeutic effect of steroids or reduced the steroid dosage while maintaining or improving the steroid's original therapeutic effect. The earlier study was conducted by a company established and sold by Stero founders.

This is the second clinical trial (in addition to the ongoing multi-center phase 2A Crohn's Disease clinical trial) in the groundbreaking partnership between Stero and its strategic shareholder, MOR Research Applications, the tech transfer company of Clalit Health Services. Clalit is the second-largest HMO in the world, with over 4.5 million members. Clalit operates 14 full-scale hospitals specializing in all fields of medicine, as well as over 2,000 community clinics with over

9,000 physicians. The partnership with MOR allows deep support of Stero's clinical trials and creates tailor-made research connections to best available hospitals, Key Opinion Leaders (KOLs), advisors, and physicians at reduced cost costs and higher efficiency than most trials. About Stero Biotechs, Ltd.

Stero Biotechs Ltd., founded in 2017 and headquartered in Israel, is a clinical-stage company committed to the research and development of novel Cannabidiol (CBD) based treatment solutions that will potentially benefit millions of patients by reducing the side effects and need for steroid therapy. Stero was issued a U.S. patent on over 130 potential indications and is planning to commence more clinical trials in 2020.

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