

Tilray® Imports GMP-Certified CBD into the U.S. for Two Clinical Trials Led by NYU School of Medicine

NYU School of Medicine will lead trials testing CBD treatment for patients with Alcohol Use Disorder and Post-Traumatic Stress Disorder with Alcohol Use Disorder

NANAIMO, British Columbia--(BUSINESS WIRE)--August 8, 2019--Tilray, Inc. (NASDAQ:TLRY), a global pioneer in cannabis research, cultivation, production, and distribution, today announced it has received approval from the U.S. government and successfully imported an initial shipment of medical cannabinoids into the U.S. to support two clinical trials led by NYU School of Medicine.

The two studies will test the efficacy of cannabidiol, or CBD, to treat patients suffering from Alcohol Use Disorder (AUD) and patients suffering from AUD comorbid with Post-Traumatic Stress Disorder (PTSD). Tilray has provided a Good Manufacturing Practices (GMP)-certified CBD formulation in capsule form for the studies.

Michael Bogenschutz, M.D., Professor in the Department of Psychiatry at NYU School of Medicine, will lead one trial focused on testing CBD in patients with AUD, and Charles R. Marmar, M.D., the Lucius Littauer Professor and Chair of the Department of Psychiatry at NYU School of Medicine, will lead another trial testing CBD in patients with AUD comorbid with PTSD. Both trials are expected to begin recruitment in the summer of 2019 and will take place at NYU School of Medicine.

The first NYU led clinical trial is a double-blind, randomized study designed to assess CBD treatment in patients with AUD. NYU will evaluate the safety and tolerability of a daily CBD treatment regimen in an AUD population and assess the impact of CBD on neuropsychological and neurophysiological domains implicated in AUD.

The second clinical trial is a double-blind, randomized study designed to assess the safety, tolerability, efficacy, and effect size of CBD in reducing alcohol use and PTSD symptoms for those suffering from AUD comorbid with PTSD.

Quotes:

- “We’re proud to support these two clinical trials led by NYU School of Medicine,” says Philippe Lucas, Tilray’s VP of Global Patient Research and Access. “Tilray is committed to supporting research that can provide further evidence for the safety and efficacy of medical cannabis and, ultimately, data to support the treatment of more patients in need around the world.”

- “NYU School of Medicine enjoys an outstanding reputation in advancing the study of CBD for its use in treating several illnesses, most notably various forms of epilepsy,” says Dr. Marmar of NYU School of Medicine. “We are now coupling that experience with our past and ongoing efforts to better understand and treat PTSD and AUD. We are confident that our studies will lead to benefits. Our returning veterans, in particular, who suffer from PTSD resulting from their military service, deserve our best efforts.”
- “Preclinical work and limited human experience suggest that CBD may have anti-addictive effects that may be useful in the treatment of alcohol use disorder and other substance use disorders,” says Dr. Bogenschutz of NYU School of Medicine. “Our study is the first to investigate the effects of CBD in the treatment of alcohol use disorder, and will provide important new information on its mechanisms of action and clinical benefits.”

About Tilray®

Tilray is a global pioneer in the research, cultivation, production and distribution of cannabis and cannabinoids currently serving tens of thousands of patients and consumers in 13 countries spanning five continents.

Cautionary note regarding forward-looking statements:

This press release contains “forward-looking statements” within the meaning of the U.S. Private Securities Litigation Reform Act of 1995 and “forward-looking information” within the meaning of Canadian securities laws, or collectively, forward-looking statements. Forward-looking statements or forward-looking-information in this press release may be identified by the use of words such as, “may”, “would”, “could”, “will”, “likely”, “expect”, “anticipate”, “believe”, “intend”, “plan”, “forecast”, “project”, “estimate”, “outlook” and other similar expressions. Forward-looking statements are not a guarantee of future performance, future action or any particular result to clinical trials and are based upon a number of estimates and assumptions of management in light of management’s experience and perception of trends, current conditions and expected developments, as well as other factors that management believes to be relevant and reasonable in the circumstances, including assumptions in respect of current and future market conditions, the current and future regulatory environment and future approvals and permits. Actual results, performance or achievement could differ materially from that expressed in, or implied by, any forward-looking statements in this press release, and, accordingly, you should not place undue reliance on any such forward-looking statements and they are not guarantees of future results. Please see the heading “Risk Factors” in Tilray’s Quarterly Report on Form 10-Q, which was filed with the Securities and Exchange Commission and Canadian securities regulators on May 15, 2019, assumptions, uncertainties and other factors that may cause actual future results or anticipated events to differ materially from those expressed or implied in any forward-looking statements. Tilray does not undertake and specifically declines any obligation to update any forward-looking statements that are included herein, except in accordance with applicable securities laws.

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