



Tilray® Announces Support of Two New Clinical Research Studies in Australia and Canada

April 1, 2019

Tilray cannabis products will be used to support the Murdoch Children's Research Institute led pilot study to evaluate the feasibility and acceptability of a randomized placebo-controlled trial of the efficacy of cannabidiol (CBD) oral solution in reducing Severe Behavioral Problems in children with Intellectual Disabilities

Tilray CBD and THC capsules will be used in a study examining the safety, tolerability and effectiveness of medical cannabis on immune activation in people living with HIV being conducted by the McGill University Health Centre

Tilray's support of numerous studies conducted by leading research institutions and hospitals around the world reflects the need for more clinical data in the medical cannabis field and the Company's commitment to advancing cannabinoid-based science to further understand the benefits it can offer to critical patient populations

NANAIMO, British Columbia--(BUSINESS WIRE)--Apr. 1, 2019-- Tilray, Inc. (NASDAQ:TLRY), a global leader in cannabis research and production, today announced its support of two new clinical studies: a pilot study led by Murdoch Children's Research Institute (MCRI) in Melbourne, to evaluate the feasibility and acceptability of a larger randomized placebo-controlled trial of cannabis extract as a form of treatment for reducing Severe Behavioral Problems (SBP) in pediatric patients with Intellectual Disabilities (ID); and a study with McGill University Health Centre's Division of Infectious Diseases and Chronic Viral Illness, to examine the effectiveness of medical cannabis on immune activation in People Living with HIV.

"Tilray is at the forefront of clinical research in the medical cannabis field and we're very proud to support two groundbreaking studies that have potential to identify more indications in which medical cannabis can benefit patients in-need," says Philippe Lucas, VP of Global Patient Research and Access, Tilray. "We are committed to advancing cannabinoid-based science to further understand the potential benefits of medical cannabis as a treatment option among these critical patient populations. There is a serious need for more clinical data in our field, and we are proud to support research like this around the world."

Murdoch Children's Research Institute in Australia:

Over 50,000 youth in Australia today have Intellectual Disability with Severe Behavioral Problems such as irritability, aggression, and self-injury. Anti-psychotic and other psychotropic medications are prescribed for half of these patients in Australia, despite limited evidence for their efficacy and a high risk of serious side-effects, including weight gain, metabolic syndrome and extrapyramidal movement disorders. Polypharmacy and off-label prescribing are common in these patients, and drugs are sometimes added to treat side effects. Novel interventions are urgently needed for this highly vulnerable patient group.

The American Academy of Pediatrics and the Royal Australasian College of Physicians have highlighted the need for further research into the therapeutic uses of cannabinoids in youth. There is intense interest from parents and physicians in medical cannabis as a treatment for SBP in youth with ID. Research to date suggests that CBD and other cannabis extracts, have had fewer reported side-effects than anti-psychotic medications; however, there is currently insufficient evidence to inform its use in treating SBP. MCRI is among the first institutions to conduct research specifically testing the effectiveness of CBD on patients with intellectual disabilities to reduce severe behavioral problems.

"We are committed to increasing the scientific understanding of cannabinoid-based medicine as treatment for pediatric patients with intellectual disability and associated severe behavioral problems through this study." says Associate Professor Daryl Efron, senior researcher at MCRI and pediatrician.

The single site, double-blind, parallel group, randomized, placebo-controlled pilot study of 10 participants, compares CBD with a placebo in reducing Severe Behavioral Problems in pediatric patients aged eight to 16 years of age with Intellectual Disability. Participants are randomized 1:1 to receive either Tilray C100 oral solution or the placebo.

Tilray supplied the medical cannabis products used for this trial, which were successfully exported from Tilray's Good Manufacturing Practices (GMP) certified facility in Nanaimo, British Columbia, Canada to Australia in early 2019, with the trial commencing shortly thereafter.

The results from this trial are expected to be published by 2020.

McGill University Health Centre's Division of Infectious Diseases and Chronic Viral Illness:

Despite antiretroviral therapy (ART), persistent immune activation is associated with increased risk of non-opportunistic complications in people living with HIV, such as cardiovascular, pulmonary, renal and hepatic events. Research has suggested that medical cannabis may hold many potential therapeutic benefits for PLWH due to its promising anti-inflammatory and anti-fibrotic effects.

The use of medical cannabis to potentially benefit people living with HIV has been largely unexplored due to regulatory restrictions which impeded its thorough evaluation in the past decade. The changing regulatory environment and access to high-quality pharmaceutical-grade cannabis products has allowed researchers to begin generating critical data in support of this patient population, living with a number of difficult-to-treat conditions. The trial led by McGill University Health Centre's Division of Infectious Diseases and Chronic Viral Illness will contribute to a growing body of evidence in support of medical cannabis as treatment option for People Living with HIV, and provide important data on the anti-inflammatory effects of cannabinoids.

"There is a critical need for more data on methods to reduce chronic immune activation in People Living with HIV," says Dr. Cecilia T. Costiniuk, MD, MSc, Assistant Professor at McGill University, Division of Infectious Diseases, and Lead Investigator on the study. "We hope can demonstrate that THC and CBD capsules consumed orally are safe and well-tolerated in PLWH and can contribute to improving the quality of the patient's life."

The randomized open-label interventional study will measure the safety, tolerability and effectiveness of Tilray oral capsules: a THC and CBD balanced low dose capsule and a low THC and mid/high CBD concentration capsule, on immune activation in People Living with HIV. The first phase of the trial will call for 26 participants aged 18 years or older living with diagnosed HIV, separated into two groups, who will undergo medical cannabis treatment for 12 weeks.

The trial is expected to begin in the second half of 2019. More information about the trial will be shared in the coming months.

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 twelve 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 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, including statements in respect to Tilray's medical cannabis products. Forward-looking statements are not a guarantee of future performance 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 Annual Report on Form 10-K, which was filed with the Securities and Exchange Commission and Canadian securities regulators on March 25, 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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