CANNSUN RECEIVES REGULATORY APPROVAL FOR THE FIRST WOMEN'S FOCUSED PHASE II PSILOCYBIN TRIAL ON THE AFRICAN CONTINENT

CAPE TOWN, SOUTH AFRICA, April 14, 2022 /EINPresswire.com/ -- Cannsun Group PLC ("Cannsun"), a bio-pharmaceutical company focused on developing and commercializing new medicines to optimize human potential with operations in South Africa & Thailand, announces the receipt of approval from the South African Health Products Regulatory Authority (SAHPRA) to commence an in-human women's specific clinical trial to evaluate a safety and efficacy of psilocybin in 30 HIV positive study participants suffering from Major Depressive Disorder.

The trial is a Double-Blind, Randomized, Phase 2 Feasibility Study of Psilocybin-Assisted Brief Supportive Psychotherapy in HIV Positive Females with Major Depressive Disorder.

Mental health disorders are one of the leading causes of disease burden in the world, according to a 30-year global systematic analysis published in Lancet Psychiatry. As MDD is one of the more prevalent co-morbidities in HIV and in women, where an estimated 7.7 million people are living with HIV in South Africa, the trial will to be conducted in an all-female HIV positive group. Women have previously been underrepresented in clinical trials related to mental health, trials where women were included, the published results were not gender specific.

"It is vitally important to have a deeper understanding of how woman respond to medical treatment for major depression versus men in order to develop psychedelic therapies and treatment protocols for women that have clinically significant outcomes that are safe and effective. This research to be conducted in South Africa follows a globally renewed interest in

psychedelics aimed at exploring the treatment benefits of these previously misunderstood compounds." Donaghue Woodman, Head of Research & Development at Cannsun Group PLC.

Cannsun Medicinals has contracted TASK, a South African based clinical research institute to conduct the clinical trial.

TASK is a multinational clinical research institute which conducts clinical trials to determine the treatment effects of novelties in healthcare and offers services in conducting complex clinical trials in a wide variety of therapeutic areas.

Established in 2005, TASK is a renowned research specialist organization in infectious diseases, most notably in tuberculosis, COVID-19 treatment and vaccines and has been published and mentioned in several leading journals, notably in the New England Journal of Medicine. Similarly, TASK's founder Professor Andreas Diacon has been celebrated by the Bill and Melinda Gate's Foundation as a 'hero in the field' for his contribution to TB drug development.

"The TASK team are proud to have been selected by the Cannsun group to conduct this ground-breaking trial, first in our unique African population. We look forward to making progress in the treatment of mental health disorders and to the influence this trial may have in generating further investment in psychiatric research with innovative compounds." Duncan McDonald, Head of Business Development at TASK.

TASK will work in conjunction with Soraya Seedat, a distinguished Professor of Psychiatry and Executive Head of the Department of Psychiatry at Stellenbosch University. She has more than 20 years of clinical, epidemiological and basic neuroscience research experience as a psychiatrist.

She has also been the recipient of several awards including the World Federation of the Society of Biological Psychiatry Fellowship, the Lundbeck Institute Fellowship Award in Psychiatry, an MRC mid-career award, research fellowship from the University of California San Diego, the Anxiety Disorders Association of America Career Development Award, the Humboldt Research Award in memory of Neville Alexander, the Chancellor's Award for Research from Stellenbosch University and an MRC Gold Merit Award.

"Mental health is a global pursuit, and we are hopeful this research may bring advancement of treatment of depression and anxiety illness. Our research will be conducted in South Africa where women's heath in a clinical setting is underrepresented, 25% of the adult women population between ages 15-49 are HIV positive. Our R&D team at Cannsun aim to further advance medical treatments in South Africa utilizing emerging medicines." David Parry, Chief Executive Officer at Cannsun Group PLC.

All clinical trials conducted by TASK are reviewed and approved by the South African Health Products Regulatory Authority (SAHPRA) and an independent ethics committee prior to trial

commencement and follow Good Clinical Practice (GCP) standards and guidelines. Study participation is in line with GCP and is completely voluntary.

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