

## **Emerald Health Pharmaceuticals Completes First-In-Human Clinical Study of Novel Oral Treatment for Multiple Sclerosis and Systemic Scleroderma**

**Phase I study of CBD-derived drug candidate demonstrates safety and tolerability in over 100 subjects**

**Phase II studies planned to start before year-end**

SAN DIEGO, CA, August 26, 2019 – Emerald Health Pharmaceuticals Inc. (EHP), a clinical-stage company developing medicines based on cannabinoid science, announced today the successful completion of its first-in-human Phase I clinical trial evaluating the safety, pharmacokinetics, pharmacodynamics and exploratory biomarkers of its lead product candidate, EHP-101, an oral formulation of a patented new chemical entity (NCE) derived from cannabidiol (CBD). This Phase I clinical trial was designed to enable Phase II clinical trials assessing the safety and efficacy of EHP-101 in the treatment of multiple sclerosis (MS) and systemic scleroderma (SSc) patients. Start-up activities are underway for the initiation of Phase II clinical studies of EHP-101 in MS and SSc patients, with initiation of the first Phase II study expected before the end of 2019.

The Phase I clinical trial was conducted in 104 healthy volunteers as a randomized, double-blind, placebo-controlled study consisting of two regimens: 8 single ascending dose (SAD) groups and 4 multiple ascending dose (MAD) groups, with the dosage increasing with each group. In the SAD part of the study, each group received EHP-101 or placebo in single oral doses, increasing from 0.9 milligrams (mg) in the lowest dose group to 185 mg in the highest dose group. In the MAD part of the study, each group received EHP-101 or placebo in multiple oral doses (once or twice per day for seven days), increasing from 20 mg per day for seven days in the lowest dose group to 100 mg per day for seven days in the highest dose group. At all doses administered in the study, EHP-101 was well tolerated, with only mild to moderate adverse events observed with increasing dose levels. The highest doses tested are well above the expected therapeutic dose for MS and SSc. These results provide EHP with flexibility in setting the dosing of patients in the upcoming Phase II clinical trials.

"The safety and tolerability profile of EHP-101 in our large first-in-human study allows us to define an appropriate dosing regimen and proceed with our planned Phase II studies in multiple sclerosis and systemic scleroderma patients," said Joachim Schupp, MD, Chief Medical Officer of EHP. "On behalf of our entire EHP team, I thank the investigators, volunteers and all study team members for contributing to the understanding of EHP-101 in humans as we work to develop treatments for diseases with significant unmet medical need."

"Based on the novel mechanism of action of our product candidates, our preclinical proof-of-concept, these positive first-in-human clinical results, and our experienced team, we are now well positioned to advance our lead product candidate through clinical development," said Jim DeMesa, MD, Chief Executive Officer of EHP.

The Company plans to announce top-line results from the Phase I study before year-end, once the data are fully analyzed, and will be submitting the study results for presentation at upcoming international conferences.

## **About EHP-101**

EHP-101 is an oral formulation of a synthetic aminoquinone derivative of CBD, developed through rational drug design with a multi-pronged mechanism of action, including a dual peroxisome proliferator-activated receptor gamma and cannabinoid receptor type 2 agonist activity. Both of these receptors are validated therapeutic targets for MS and SSc. In addition, EHP-101 also targets the hypoxia inducible factor (HIF) pathway, expanding the rationale for its development as a novel drug since the HIF pathway has effects on myelination, which is instrumental to nerve function and integral to autoimmune diseases such as MS, and neovascularization, the formation of new blood vessels, which can be important in the treatment of many diseases, including SSc. EHP has received Orphan Drug Designation for EHP-101 in SSc from both the US FDA and EMA.

## **About Emerald Health Pharmaceuticals Inc.**

Emerald Health Pharmaceuticals is developing drug product candidates derived from cannabinoids for the treatment of central nervous system, autoimmune, and other diseases. The Company has two families of new chemical entities, derived from synthetic CBD and cannabigerol, that it has modified through rational drug design to affect validated receptors and pathways pertinent to targeted diseases. Its first drug candidate, EHP-101, has completed a Phase I clinical study and is being developed for the treatment of multiple sclerosis and systemic scleroderma. Its second, EHP-102, is in preclinical development and is focused on treating Huntington's disease and Parkinson's disease. For more information, visit <http://www.emeraldpharma.life> or contact: [info@emeraldpharma.life](mailto:info@emeraldpharma.life).

*To the extent statements contained in this news release are not descriptions of historical facts regarding Emerald Health Pharmaceuticals Inc. they should be considered "forward-looking statements," as described in the private securities litigation reform act of 1995, that reflect management's current beliefs and expectations. You can identify forward-looking statements by words such as "anticipate," "believe," "could," "estimate," "expect," "forecast," "goal," "hope," "hypothesis," "intend," "may," "plan," "potential," "predict," "project," "should," "strategy," "will," "would," or the negative of those terms, and similar expressions that convey uncertainty of future events or outcomes. Forward-looking statements contained in this news release include, but are not limited to, statements regarding: (i) the success and timing of our product development activities and clinical trials; (ii) our ability to develop our product candidates; (iii) our plans to research, discover, evaluate and develop additional potential product, technology and business candidates and opportunities; (iv) the anticipated timing of clinical data availability; (v) our ability to meet our milestones; and (vi) our expectations regarding our ability to obtain and maintain intellectual property protection. Forward-looking statements are subject to known and unknown factors, risks and uncertainties that may cause actual results to differ materially from those expressed or implied by such forward-looking statements. Undue reliance should not be placed on forward-looking statements. We undertake no obligation to update any forward-looking statements. Emerald Health Pharmaceuticals' investigational drug products have not been approved or cleared by the FDA.*