



## **Emerald Health Pharmaceuticals Initiates Phase I Clinical Study on its Oral Drug Candidate Derived from Cannabidiol**

*The First Cannabidiol Derivative in Clinical Development Affecting the Known Targets Involved in Multiple Sclerosis and Scleroderma*

SAN DIEGO, CA, September 27, 2018 – Emerald Health Pharmaceuticals Inc. (EHP), a company developing medicines based on cannabinoid science, today announced the initiation of enrollment of its Phase I clinical trial of EHP-101, an oral formulation of a patented, synthetic new chemical entity (NCE) derived from cannabidiol (CBD) and chemically modified to affect other validated targets. The primary objectives of the study are to evaluate the safety and tolerability of EHP-101 in healthy volunteers. Secondary objectives are to assess the pharmacokinetic profile, food effects, and pharmacodynamic effects of EHP-101, as well as to evaluate various biomarkers related to the drug product mechanism of action and its potential for efficacy.

“Our research and development team has demonstrated the unique mechanism of action of EHP-101 in preclinical studies, indicating the potential to treat deadly diseases which currently have no cure”, said Jim DeMesa, MD, Chief Executive Officer of EHP. “We believe our novel, proprietary oral treatment represents a significant advancement in the treatment of patients with multiple sclerosis (MS) and scleroderma. The initiation of human studies is a major accomplishment as we continue to advance cannabinoid science and deliver on another important development milestone. Based on our recent pre-IND meeting with the U.S. FDA, we believe the results from this Phase I study are likely to support Phase II studies in both MS and scleroderma.”

This Phase I trial, being conducted in Australia, is a randomized, double-blind, placebo-controlled study and will be completed in two parts: a single-ascending dose phase (Part 1) and a multiple-ascending dose phase (Part 2). In Part 1, up to 64 eligible subjects will receive EHP-101 or matching placebo in single ascending oral doses. In Part 2, up to 40 eligible subjects will receive EHP-101 or matching placebo in multiple ascending oral doses daily (as determined on the basis of results in Part 1). The Company expects to report top-line results in mid-2019. For more information on the study, please contact EHP at [info@emeraldpharma.life](mailto:info@emeraldpharma.life).

### **About EHP-101**

EHP-101 is an oral drug product candidate based on a proprietary aminoquinone NCE derived from CBD. It has been designed to enhance the therapeutic benefits of CBD by increasing peroxisome proliferator-activated receptor-gamma (PPAR $\gamma$ ) and cannabinoid receptor type 2 (CB $_2$ ) agonist activity, and also by stimulating the hypoxia inducible factor (HIF) pathway. Multiple scientific publications indicate that PPAR $\gamma$  and CB $_2$  receptor activation and modulation of the HIF pathway can positively affect neuroinflammation and myelination in the central nervous system, and fibrogenesis throughout the body. EHP holds issued patents on EHP-101 and other new chemical entities in this class of synthetic CBD-derived molecules. EHP-101 has been granted Orphan Drug Designation for the scleroderma indication by the U.S. FDA and the European Medicines Agency.



## **About Multiple Sclerosis**

MS is one of the most common acquired neurological diseases in young adults. The National Multiple Sclerosis Society estimates that more than 2.3 million people are affected by multiple sclerosis worldwide. Disease progression is considered the result of two related processes, namely myelin destruction (demyelination) with failure to remyelinate and progressive axonal damage, with little capacity for recovery. Exacerbated innate and adaptive immune responses contribute to the pathophysiology of the disease and the majority of current therapies for MS are directed towards modulation of the immune response. Novel therapies to enable axonal remyelination are urgently needed. HIF-1 $\alpha$  activation may exert anti-inflammatory properties and may be also linked to neuroprotection and remyelination.

Natural CBD has been shown to have anti-inflammatory, neuroprotective, and anti-oxidant effects that may act on neurodegenerative diseases such as MS, and EHP-101 builds on the effect of this natural cannabinoid. It is a synthetic aminoquinone derivative of CBD endowed with dual PPAR $\gamma$  and CB $_2$  activity, which also targets the HIF pathway, which are all validated therapeutic targets for MS.

## **About Scleroderma**

Systemic scleroderma (or systemic sclerosis) is a rare and chronic autoimmune disease, causing fibrosis of skin and internal organs and can also affect blood vessels, muscles, and joints. The tissues of involved organs become hard and fibrous, causing them to function less efficiently. While the symptoms of systemic scleroderma vary for each person, it can be life-threatening, depending on which parts of the body are affected and the extent of disease. The disease is more common in adults. Currently, there are no approved treatments specific to systemic scleroderma. Current therapies for scleroderma are limited in efficacy and may present toxicities. New treatments and early diagnosis will be critical to help reduce the symptoms of systemic scleroderma and prevent further damage to the body. EHP-101 is expected to target fibrosis and inflammation without suppressing the immune system and has the potential for positive vascular effects.

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

Emerald Health Pharmaceuticals is developing product candidates derived from cannabinoids for the treatment of CNS, autoimmune, and other diseases. The Company currently has two families of NCEs, derived from CBD and cannabigerol that it has modified through rational drug design to affect validated receptors pertinent to targeted diseases. Its first drug candidate, EHP-101, is focused on treating MS and scleroderma. Its second, EHP-102, is focused on treating Huntington's disease and Parkinson's disease. For more information, visit [www.emeraldpharma.life](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 these presentations 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.*