# Emerald Health Pharmaceuticals Starts Activities for Initiation of Phase 2 Clinical Study in Multiple Sclerosis

EHP-101, a novel product candidate with a unique multi-modal mechanism of action, has demonstrated disease-modifying potential in validated preclinical models of multiple sclerosis

SAN DIEGO, CA, March 08, 2021 (GLOBE NEWSWIRE)-- Emerald Health Pharmaceuticals Inc. (EHP or the Company), a clinical-stage biotechnology company developing a new class of medicines to treat neurodegenerative, autoimmune and other diseases with unmet medical needs, has initiated activities for a Phase 2 international clinical study for the treatment of patients with multiple sclerosis (MS).

“The initiation of this MS Phase 2 study is another important milestone for our lead product candidate, EHP-101,” said Joachim Schupp, M.D., Dr. med., EHP’s Chief Medical Officer. “We have finalized the trial design with our MS Clinical Advisory Board members, who are globally-recognized key clinical opinion leaders in the treatment of MS. We will soon be seeking regulatory approvals to begin the study and look forward to starting clinical site initiations and enrolling multiple sclerosis patients later this year.”

The MS Phase 2 study is an open label study to evaluate the safety, tolerability, pharmacokinetics and preliminary efficacy of the company’s lead product candidate, EHP-101, an oral formulation of a patented new synthetic molecule, in patients with relapsing forms of multiple sclerosis (RMS). The study is planned to enroll approximately 50 patients who suffer from RMS (relapsing-remitting and relapsing secondary progressive MS) in approximately 20 study centers in the United States and Australia. Escalating doses administered once or twice daily are planned to be evaluated over a treatment duration of 24 weeks. The dose levels were established based on previous successful 6 and 9-month animal toxicity studies and a Phase 1 human study in 104 healthy subjects, all showing a good safety and tolerability profile.

Along with assessments of safety and tolerability, efficacy endpoints in the Phase 2 MS study will include the changes from baseline in brain lesion activity as measured by MRI; disease progression and disability status, as well as the proportion of relapse-free patients, patient-reported outcomes, and assessments of several biomarkers such as changes in the neurofilament light chain (NfL) levels in the blood, which is a promising diagnostic, prognostic and monitoring biomarker used in assessing neurological diseases.

In 2020, the company presented promising remyelination (restoration of the protective myelin sheath around the nerves) data in animal models of MS at the Americas Committee for Treatment in Multiple Sclerosis (ACTRIMS) conference.

Jim DeMesa, M.D., M.B.A., EHP’s President and CEO added, “This MS clinical study is the second Phase 2 study we are conducting with EHP-101. Our other Phase 2 study is in systemic sclerosis, a severe form of scleroderma, which is enrolling patients in the United States, Australia and New Zealand. These two Phase 2 studies provide us the opportunity for significant clinical milestones in 2022 and beyond.”

EHP is also continuing preclinical development of its second compound, EHP-102, with an initial focus on Huntington’s disease and Parkinson’s disease.

**About Multiple Sclerosis and EHP-101**

Multiple sclerosis is an inflammatory and demyelinating disorder of the central nervous system affecting an estimated 2.3 million people worldwide. Myelin is a sheath around nerves that aids in conducting nerve impulses. Demyelination is a breakdown of this sheath and in people with MS it is not reversible naturally or through existing therapies. As MS progresses, it affects muscles, nerves, and joints, causing significant pain, as well as spasms, stiffness, difficulty chewing, swallowing, and speaking. Currently, approved MS drugs are all primarily intended to relieve symptoms and reduce the rate of relapses, but none are curative.

**About Emerald Health Pharmaceuticals Inc.**

Emerald Health Pharmaceuticals is developing proprietary product candidates to treat CNS, autoimmune, and other diseases. The Company’s technology platform consists of two families of patented new chemical entities derived from synthetic cannabidiol (CBD) and cannabigerol (CBG), two of the non-psychoactive cannabinoids, chemically modified through rational drug design to create new molecules that affect validated receptors and pathways in the body which are pertinent to targeted diseases. EHP-101 is in Phase 2 clinical development for the treatment of systemic sclerosis, a severe form of scleroderma, and multiple sclerosis. It has received Orphan Drug designation in the US and EU and Fast Track status in the US for systemic sclerosis. EHP-102 is in preclinical development and focused on treating Parkinson’s disease and Huntington’s disease. It has received Orphan Drug designation in the US and EU for Huntington’s disease. For more information, go to http://www.emeraldpharma.life or contact EHP via email at 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