Emerald Health Pharmaceuticals Provides Phase 2 Systemic Sclerosis Clinical Trial Update

Enrollment open in systemic sclerosis study of novel lead product candidate

SAN DIEGO, CA, May 28, 2020 – Emerald Health Pharmaceuticals Inc. (EHP), a clinical-stage biotechnology company developing a new class of medicines to treat diseases with unmet medical needs, continues to advance its Phase 2a clinical study of EHP-101, an oral formulation of a patented new chemical entity derived from cannabidiol (CBD) being developed for the treatment of systemic sclerosis (SSc), a severe, debilitating and life-threatening form of scleroderma, and multiple sclerosis (MS).

During the COVID-19 pandemic, site qualification and initiation activities have continued remotely for the SSc Phase 2a study, and important drug manufacturing and other related activities continued as planned to keep the EHP-101 development program on track and in line with corporate goals. Enrollment is now open at sites in Australia and the United States (US), with sites in New Zealand expected to be open soon. The study will enroll approximately 36 patients who suffer from systemic sclerosis in approximately 30 study centers in these three countries.

“The process of site selection, qualification and initiation is lengthy, involving evaluations of each site for the appropriate patient population, staff experience and ability to perform the required procedures. As such, we are pleased with the progress our team has made in daily remote interactions to ensure the clinical advancement of our lead product candidate during these unprecedented times,” said Dr. Joachim Schupp, EHP’s Chief Medical Officer. “Based on current expectations for increased ability for in-person encounters, we are optimistic that patients needing a new treatment option for SSc will soon be able to enroll safely into our Phase 2 study.”

The SSc Phase 2a study is a double-blind, randomized, intracohort, placebo-controlled, multicenter study to evaluate the safety, tolerability, pharmacokinetics and preliminary efficacy of EHP-101 in patients with diffuse cutaneous systemic sclerosis (dcSSc).

With Fast Track designation in hand from the US FDA and progress continuing toward initiating enrollment of patients into the study, EHP remains on track to receive preliminary results from its Phase 2a study in SSc during the beginning of 2021, with anticipated study completion in mid-2021.

About Systemic Sclerosis and EHP-101

Systemic sclerosis (SSc), a severe form of scleroderma, is a rare and chronic autoimmune disease, causing fibrosis of the skin and internal organs, including small blood vessel damage in the skin and multiple other organs in the body such as lung, heart, kidneys, musculoskeletal system and the gastrointestinal tract. The tissues of involved organs become hard and fibrous, causing them to function less efficiently. While the symptoms of SSc vary for each person, it can be life-threatening depending on which parts of the body are affected and the extent of the disease. SSc is subclassified into diffuse cutaneous SSc (dcSSc) or limited cutaneous SSc (lcSSc) based on the extent of skin involvement. Patients with the diffuse form have more skin areas and organs involved and are the target population for clinical trials of disease-modifying interventions in SSc.
The disease is more common in adults, with approximately 80,000-100,000 people affected in the US. Currently, there are no approved treatments specific to SSc. Current therapies for this disease include mainly drugs that suppress the immune system, are limited in efficacy and may present toxicities. New treatments will be critical to help reduce the symptoms of SSc and prevent further damage to the body.

EHP is developing drug product candidates from its portfolio of patented cannabinoid derivatives, one derived from cannabidiol (CBD) for multiple sclerosis and systemic sclerosis (EHP-101). EHP-101 is an oral formulation of a synthetic aminoquinone derivative of CBD endowed with dual peroxisome proliferator-activated receptor gamma (PPARγ) and cannabinoid receptor type 2 (CB2) agonist activity. Both receptors are therapeutic targets for SSc. EHP-101 also affects the hypoxia inducible factor (HIF) pathway, another related target, expanding the rationale for the development of EHP-101 as a novel SSc drug. EHP has received Orphan Drug Designation for EHP-101 in SSc in both the US and EU and the active pharmaceutical ingredient in EHP-101 has been deemed to not be a controlled substance in the US, Canada and the United Kingdom.

About Emerald Health Pharmaceuticals Inc.

Emerald Health Pharmaceuticals is developing product candidates derived from cannabinoids for the treatment of central nervous system (CNS), autoimmune, fibrotic and other diseases. The Company has two families of new chemical entities, derived from synthetic cannabidiol (CBD) and cannabigerol (CBG), that it has chemically modified through rational drug design to affect validated receptors and pathways pertinent to targeted diseases. Its first drug product candidate, EHP-101, has completed a Phase 1 clinical study and is entering Phase 2 studies focused on treating systemic sclerosis and multiple sclerosis. Its second product candidate, EHP-102, is in preclinical development and is focused on treating Huntington’s disease and Parkinson’s disease. For more information, visit www.emeraldpharma.life or contact: 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.