



InMed Pharmaceuticals Announces Commencement of Phase 2 Clinical Trial Investigating Cannabinol (CBN), a Rare Cannabinoid, in the Treatment of Epidermolysis Bullosa

September 30, 2021

VANCOUVER, British Columbia, Sept. 30, 2021 (GLOBE NEWSWIRE) -- InMed Pharmaceuticals Inc. ("InMed" or the "Company") (Nasdaq: INM), a leader in the manufacturing and clinical development of rare cannabinoids, today announced that it has commenced its Phase 2 clinical trial of INM-755 (cannabinol) cream in the treatment of Epidermolysis Bullosa ("EB"). This marks the first time cannabinol has advanced to a Phase 2 Clinical trial to be studied as a therapeutic option to treat a disease.

This study will be taking place at eleven sites across seven countries including Austria, Germany, Greece, France, Italy, Israel and Serbia. Clinical Trial Applications ("CTAs") have been filed in all participating countries with regulatory authority and ethics committee approvals currently in place in four countries (Austria, France, Greece, Israel). The first site initiation visit was completed at a clinical site in Austria, where screening for eligible patients will begin shortly.

"The start of this Phase 2 clinical trial represents a very important step forward to test the efficacy of INM-755 (cannabinol) cream in treating epidermolysis bullosa, a disease that has very few treatment options," stated Alexandra Mancini, Senior Vice President of Clinical and Regulatory Affairs at InMed. "Based on our earlier studies, we are hopeful that our cannabinol cream will prove to be a safe and effective treatment for people living with this severe genetic skin disease."

"The achievement of this important milestone along the continuum of pharmaceutical drug development in EB supports our belief that this class of compounds hold broad therapeutic potential," said Eric A. Adams, President and CEO of InMed. "This study further demonstrates InMed's leadership in the development of rare cannabinoids as therapeutic products. In addition, we look forward to achieving key milestones of our second CBN drug candidate for the treatment of glaucoma in the year ahead."

INM-755 is a cannabinol (CBN) cream intended as a topical therapy to treat EB and potentially other dermatological diseases. Preclinical data demonstrate that INM-755 (cannabinol) cream may help relieve hallmark EB symptoms, such as inflammation and pain, as well potentially restore the integrity of the skin in a subset of EB Simplex patients. Phase 1 data in healthy volunteers demonstrated INM-755 (cannabinol) cream to be well-tolerated on both normal, intact skin as well as on open wounds and caused no delay in wound healing.

The 755-201-EB study is designed to enroll up to 20 patients, conservatively within 12 months. All four subtypes of inherited EB, being EB Simplex, Dystrophic EB, Junctional EB, and Kindler Syndrome, are eligible for this study in which InMed will evaluate the safety of INM-755 (cannabinol) cream and its preliminary efficacy in treating symptoms and healing wounds over a 28-day period. The study will use a within-patient, double-blind design whereby matched index areas will be randomized to INM-755 (cannabinol) cream or vehicle cream as a control.

About InMed: InMed Pharmaceuticals is a clinical-stage company developing a pipeline of cannabinoid-based pharmaceutical drug candidates, initially focused on the therapeutic benefits of cannabinol ("CBN"), and is developing IntegraSyn™ to produce pharmaceutical-grade cannabinoids. The Company is dedicated to delivering new therapeutic alternatives to patients that may benefit from cannabinoid-based pharmaceutical drugs. For more information, visit www.inmedpharma.com.

About Epidermolysis Bullosa (EB): EB is the collective name of a group of genetic disorders of characterized by fragile skin and mucous membranes that are easily damaged, leading to extensive blistering and wounding. The blisters may appear in response to minor injury, even from heat, rubbing, scratching or adhesive tape. The disease has no approved cure and most current treatments are directed towards symptomatic relief.

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Cautionary Note Regarding Forward-Looking Information:

This news release contains "forward-looking information" and "forward-looking statements" (collectively, "forward-looking information") within the

meaning of applicable securities laws. Forward-looking statements are frequently, but not always, identified by words such as “expects”, “anticipates”, “believes”, “intends”, “potential”, “possible”, “would” and similar expressions. Such statements, based as they are on current expectations of management, inherently involve numerous risks, uncertainties and assumptions, known and unknown, many of which are beyond our control. Forward-looking information is based on management’s current expectations and beliefs and is subject to a number of risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. Forward-looking information in this news release includes statements about: being a leader in the manufacturing and clinical development of rare cannabinoids; the Phase 2 Clinical trial taking place at eleven sites across seven countries with screening for eligible patients beginning shortly and enrolling up to 20 patients within 12 months; being able to demonstrate that cannabinoil cream is a safe and effective treatment for epidermolysis bullosa; the cannabinoid class of compounds potentially holding broad therapeutic potential; achieving key milestones for the glaucoma program in the year ahead; cannabinoil (CBN) cream potentially treating epidermolysis bullosa (EB) and potentially other dermatological diseases; and developing a pipeline of cannabinoid-based pharmaceutical drug candidates and IntegraSyn™ to produce pharmaceutical-grade cannabinoids.

With respect to the forward-looking information contained in this news release, InMed has made numerous assumptions regarding, among other things: While InMed considers these assumptions to be reasonable, these assumptions are inherently subject to significant business, economic, competitive, market and social uncertainties and contingencies.

Additionally, there are known and unknown risk factors which could cause InMed’s actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking information contained herein. Known risk factors include, among others: regulatory filings may not be filed or approved on a timely basis, or at all; the outbreak and impact of COVID-19 may worsen; further results may not support continued development of INM-755 in the EB program; demand or interest for InMed’s products may decrease or cease; and economic and market conditions may become unstable or unfavorable. A more complete discussion of the risks and uncertainties facing InMed’s stand-alone business is disclosed in InMed’s 10-K filed with the Security and Exchange Commission.

All forward-looking information herein is qualified in its entirety by this cautionary statement, and InMed disclaims any obligation to revise or update any such forward-looking information or to publicly announce the result of any revisions to any of the forward-looking information contained herein to reflect future results, events or developments, except as required by law.