BioSpectrum the business of Bio & Health Sciences

Edesa biotech receives approval to proceed with its clinical investigation

20 June 2019 | News

EB01 employs a novel mechanism of action against a common inflammation pathway.

Edesa Biotech, a clinical-stage biopharmaceutical company has reported that the U.S. Food and Drug Administration has notified the company that it may proceed with its clinical investigation of EB01, a novel sPLA2 inhibitor, which Edesa is developing as a potential treatment for chronic allergic contact dermatitis.

The FDA "safe to proceed" letter formally approves the company's Phase 2b clinical protocol and authorizes the company to begin its clinical investigation. Edesa expects the first patient to be enrolled in the coming quarter following the manufacturing of its drug candidate.

EB01 employs a novel mechanism of action against a common inflammation pathway. Unlike steroids and other anti-inflammatory drugs, like ibuprofen, the topical treatment being developed by Edesa is intended to inhibit the inflammatory process at its inception rather than after inflammation has occurred. In two previous clinical studies, EB01 has demonstrated significant improvement of multiple symptoms in contact dermatitis patients.

"There are limited options for ACD patients and we have been pleased with the level of interest from physicians in the U.S.," said Dr. Par Nijhawan, Chief Executive Officer of Edesa. "The company is committed to rapidly advancing our clinical plans and remains on track to initiate our clinical study for EB01."

In addition to its lead product candidate, Dr. Nijhawan noted that the company plans to selectively target additional indications

within the areas of dermatology and gastroenterology. The company also plans to expand its portfolio with assets that can drive long-term growth opportunities.

"This is an active and exciting time for Edesa and we look forward to providing clinical and business updates over the coming quarter," said Dr. Nijhawan.

Clinical Protocol for Phase 2b Trial of EB01

The protocol evaluates EB01 in a randomized, double-blind, vehicle-controlled, sample size adaptive design. ACD patients in this study will be treated for 28 days with various strengths of EB01 cream. Primary outcome measures will evaluate safety and efficacy. Secondary and exploratory measures will evaluate symptom reduction, quality of life and dose-relationships among various strengths of EB01 cream. The company plans to complete an interim analysis following the enrollment of the first cohort to determine the total sample size in the second part of the study; up to 166 total patients may be enrolled.