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BirchBioMed Inc. Announces Positive Topline Data from Phase 2 Study of FS2 for Treatment of Keloid Scars

Topical FS2 shows statistically significant improvement versus the market leader

VANCOUVER, BC - January 21, 2021 – BirchBioMed Inc., a clinical-stage immunology company focused on the prevention and reduction of immunological fibrotic conditions and defects in the immune system, has announced statistically significant, positive results of a double-blind study into the safety and efficacy of topical FS2 in the treatment of keloid scars. FS2, the active ingredient in BirchBioMed's FS2 cream, has been shown to inhibit the formation of collagen, which is the major component of scars.

"The study definitively shows that FS2 has significant efficacy on mature keloid scars as compared not only to the vehicle control but to an active scar treatment (Mederma)," said Dr. Mark Nestor, M.D., Ph.D., the study's principal investigator and director of the Center for Clinical and Cosmetic Research in Aventura, Florida. "Showing significant benefit on mature keloid scars points to significant efficacy for the treatment of hypertrophic scars as well as cosmetic benefit to all post-surgical scars."

The prospective randomized double-blind trial compared the safety and efficacy of topical FS2 versus the market leading scar cream (Mederma) and a vehicle (placebo cream) in the treatment of mature keloids in 75 subjects. Trial participants were evaluated using both the Vancouver Scar Scale (VSS) and the Patient and Observer Scar Assessment Scale (POSAS).

The percentage change in VSS scores for FS2 showed a statistically significant improvement when compared to Mederma ($p<0.001$) and versus vehicle ($p<0.05$) at the conclusion of the 180-day trial.

Secondary data analysis using POSAS showed dramatic patient satisfaction with FS2 patients scoring a 51% improvement with FS2 versus Mederma's 28% ($p<0.05$) and vehicle 20% ($p<0.01$). Neither Mederma nor vehicle showed statistically significant improvement according to the subjects' evaluations.

“Subjects using FS2 graded the improvement in their scar greater than Mederma and vehicle at every time point culminating in highly significant differences at 180 days,” said Dr. Nestor. “This signifies that it wasn’t only the appearance of the keloid scar that changed over time with FS2 but more fundamentally the way the subject globally felt about the improvement. Furthermore, there were no safety concerns noted and no significant local skin reactions observed.”

As BirchBioMed’s lead antifibrotic platform therapy, FS2 acts at the molecular level by reducing production of two primary extracellular scar-forming proteins (collagen and fibronectin) and by increasing the production of key scar-degrading enzymes (MMP-1 and MMP-3) to stop the formation of scars and promote the breakdown of existing scars.

“We are delighted with the results of FS2 in providing a safe and effective treatment for disfiguring scars that often profoundly affect a patient’s quality of life,” said Mark S. Miller, chief executive officer of BirchBioMed. “Scarring poses a chronic and growing therapeutic challenge for millions of patients each year. The global cost of treating scars is expected to reach $41.8 billion in 2022, compared with $21.4 billion just three years ago. Moreover, the U.S. National Institutes of Health estimates that 11 million Americans suffer from keloid scars, making it all the more critical that we develop cost-effective and successful treatments.”

About BirchBioMed

BirchBioMed Inc. is a clinical-stage immunology company focused on the prevention and reduction of immunological fibrotic conditions and reversing defects in the immune system. As a University of British Columbia (UBC) spinoff, BirchBioMed holds the exclusive, worldwide pharmaceutical license from UBC for two breakthrough medical technologies in the treatment of scarring and certain autoimmune diseases.

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