First Patient Enrolled in BirchBioMed's Study Investigating FS2 for the Treatment of Scars

VANCOUVER, BC (February 28, 2019) – BirchBioMed Inc., a clinical-stage biomedical company focused on the clinical evaluation, development and commercialization of anti-scarring drugs, autoimmune therapeutics and novel strategies for transplantation, announces that the first subjects have been enrolled in its study with FS2 for the reduction of keloid scars. FS2 is the company's anti-fibrotic platform therapy that acts on a molecular level to prevent the excess buildup of a protein and promote the breakdown of scars.

Mark S. Nestor, M.D., Ph.D., director of the Center for Clinical and Cosmetic Research in Aventura, Fla., is the principal investigator of this clinical study, which is investigating a twice-daily application of FS2-formulated moisturizer on keloid scars for 120 days. The first part of the double-blind, placebo-controlled and comparative trial randomizes 75 patients across three treatment arms: active market comparator, base moisturizer, and FS2-formulated moisturizer. Scars will be assessed using both the Patient and Observer Scar Assessment Scale (POSAS) and Vancouver Scar Scale (VSS) at each patient visit, with a final assessment at six months.

"We are delighted to begin this proof-of-concept study with FS2 and are optimistic it will demonstrate that FS2 ameliorates disfiguring scars," said Mark S. Miller, chief executive officer of BirchBioMed. "The global market for scar treatments is extremely large and growing, with expectations it will reach $41.8 billion in 2022, compared with $21.4 billion in 2017. In addition, the National Institutes of Health estimates that 11 million people in the U.S. suffer from keloid scars, which oftentimes have a profoundly negative impact on patient quality of life. We are looking forward to providing a safe and effective treatment for these conditions."

Ryan Hartwell, Ph.D., BirchBioMed's chief science officer, said, "Prior studies demonstrated clinical safety and tolerability of the FS2-cream product. Preclinical research evidence strongly supports the benefit our FS2-product has for scar care, contributing to a reduction in scar elevation index and the primary defining elements of a scar. We are looking forward to confirming these results in humans."

About the FS2 Study in Scar Reduction

The FS2 study is divided into two parts. The first part will randomize 75 subjects across a total of three treatment arms, investigating an FS2-formulated cream, a vehicle cream-base, and leading market comparator. Randomized patients will apply product twice a day for 120 days and be assessed over 180 days using both Patient and Observer Scar Assessment Scale (POSAS) and Vancouver Scar Scale (VSS).

About BirchBioMed

BirchBioMed Inc. is a biomedical company focused on the commercialization, clinical evaluation and development of proprietary anti-scarring drugs, autoimmune therapeutics/therapies and novel strategies for transplantation. As a University of British Columbia (UBC) spinoff, BirchBioMed holds the exclusive, worldwide pharmaceutical license for two medical therapeutic technologies from UBC, which the university considers to be significant medical breakthroughs in the treatment of scarring and certain autoimmune diseases.

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