

BirchBioMed Receives Health Canada Green Light to Start the Last Stage of its Groundbreaking Clinical Program of FS2 to Minimize Scarring from Burns

Canadian-based clinical stage biopharmaceutical company pioneers in offering one of the first natural health products for burn patients

Guelph, October 22, 2024: BirchBioMed, a leading biopharmaceutical company expert in the development of products for scarring and other fibrosis-related disorders, announced the authorization from Health Canada to conduct its Phase II/III randomized clinical trial of a naturally based compound, FS2, at multiple centres of expertise throughout Canada.

FS2, a kynurenic acid product to be used as a topical cream, was first identified by investigators at the University of British Columbia as a potential drug candidate for clinical research. In preclinical trials, FS2 demonstrated the prevention of scars as well as the breakdown and reduction of existing scars that occurred after injury, surgery, or disease, both externally and internally. FS2 targets scarring on the molecular level, making it unique in its therapeutic category.

“Health Canada’s approval of our phase II/III randomized clinical trial is an outstanding achievement that validates BirchBioMed’s vision to bring innovative, effective and safe therapeutic options to many millions of people suffering from disfiguring and often life-threatening scars every year,” said Mark Miller, BirchBioMed’s Chairman and Chief Executive Officer. “In this process, BirchBioMed selected SGS Nutrasource as our Contract Research Organization. An innovative leader in the biopharmaceutical world, SGS Nutrasource provides BirchBioMed with extensive commercial, clinical and regulatory expertise at this strategic pivotal point in our development.”

SGS Nutrasource will run the Phase II/III randomized study involving up to 10 clinical sites in Canada.

“We are delighted to have been chosen by sponsor BirchBioMed as their CRO partner,” says William Rowe, President and CEO at SGS Nutrasource. “We have been working together scaling this and other programs and are excited to support a Canadian company as it advances in this highly novel area of human healthcare.”

There is considerable anticipation for FS2 as this promising product signifies a potential breakthrough for burn patients.

About SGS Nutrasource

SGS Nutrasource is a leading nutraceutical and pharmaceutical life sciences company focused on helping clients commercialize health and wellness products. In addition to a unique offering of clinical trial management, strategic and regulatory support services along with a state-of-the-art clinical trial site, SGS Nutrasource offers a series of third-party natural ingredient product certification programs (NutraStrong™, IFOS™, IKOS™, IAOS™, IGEN™, IPRO™, and Radioactivity Tested & Certified™.)

Learn more at <https://www.nutrasource.ca/>

About BirchBioMed

BirchBioMed is a pioneering clinical stage biopharmaceutical company focused on developing novel, breakthrough treatments for organ fibrosis, scarring, skin disorders, and autoimmune diseases, including Type 1 Diabetes. It holds exclusive, worldwide, pharmaceutical licenses from the University of British Columbia (“UBC”) for two scientific, novel technologies, FS1 (kynurenine)/FS2 (kynurenic acid) and AI-001 (kynurenic acid in combination with antigen-presenting cell therapy). Following preclinical and early/mid-stage clinical trials, BirchBioMed’s technologies have shown paramount potential for future medical breakthrough treatments addressing multiple life-threatening diseases and severe debilitating conditions.

Learn more at <https://www.birchbiomed.com>