September 13, 2022

Fresh Tracks Therapeutics Initiates Multiple Ascending Dose Portion of Phase 1 Study of DYRK1A Inhibitor FRTX-02

FRTX-02 has been well tolerated in completed SAD cohorts; dosing of remaining SAD cohorts to continue in parallel with MAD cohorts dosing

On track to report SAD and MAD topline results from FRTX-02 Phase 1 study by early 2023

BOULDER, Colo., Sept. 13, 2022 (GLOBE NEWSWIRE) -- Fresh Tracks Therapeutics, Inc. ("FRTX" or the "Company") (Nasdaq: FRTX), a clinical-stage pharmaceutical company striving to transform patient lives by developing innovative and groundbreaking prescription therapeutics for the treatment of autoimmune, inflammatory, and other debilitating diseases, today announced that it has initiated the multiple ascending dose ("MAD") portion of the ongoing Phase 1 clinical trial in Canada evaluating FRTX-02, the Company's lead drug candidate, in healthy adult subjects. FRTX-02 is a potent, highly selective, and orally bioavailable potential first-in-class DYRK1A inhibitor that aims to restore immune balance by modulating both adaptive and innate immune responses in patients with autoimmune and inflammatory diseases.

"We are excited with the progress we are making in the first-in-human study of FRTX-02, particularly as we enter the MAD part of the trial on schedule and complete the SAD cohorts," commented Dr. Monica Luchi, Chief Medical Officer of Fresh Tracks Therapeutics. "We are encouraged that FRTX-02 has been safe and well tolerated thus far and remain on track to report Phase 1 SAD and MAD topline results by early 2023."

The first-in-human Phase 1 trial of FRTX-02 is a randomized, double-blind, placebo-controlled study designed to evaluate the safety, tolerability, pharmacokinetics ("PK"), and pharmacodynamics ("PD") of FRTX-02 capsules in both healthy adult subjects and patients with atopic dermatitis ("AD"). Part 1A of the study is a single ascending dose ("SAD") assessment, which will enroll a total of 56 healthy volunteers in one of seven cohorts, each of which includes six subjects receiving a single dose of FRTX-02 and two subjects receiving a placebo. Part 1B of the study is a MAD assessment of FRTX-02 or placebo in healthy adult subjects. In the MAD assessment, 33 healthy volunteers will be enrolled in one of three cohorts made up of 11 subjects each, and the cohorts will include nine subjects who will receive FRTX-02 and two subjects who will receive a placebo, in each case once-daily for 14 days. After completing Part 1, the Company intends to initiate Part 2 of the study, which will compare FRTX-02 to placebo in patients with moderate-to-severe AD over 28 days of treatment and will also include a preliminary assessment of efficacy. The ongoing Phase 1 study of FRTX-02 marks the first time a DYRK1A inhibitor intended for patients with autoimmune diseases has been administered in humans. Additional information on this clinical trial can be found on www.clinicaltrials.gov under identifier NCT05382819.

About FRTX-02

FRTX-02 is a potent, highly selective, and orally bioavailable potential first-in-class dual specificity tyrosine-phosphorylation-regulated kinase 1A (DYRK1A) inhibitor that is currently being evaluated in a Phase 1 clinical trial and has shown promising results in various preclinical models, including of atopic dermatitis and rheumatoid arthritis. In these preclinical models, decreases in disease severity and reduction of pro-inflammatory cytokines were reported compared to certain current standard-of-care agents, such as Janus kinase (JAK) inhibitors and anti-tumor necrosis factor (TNF) biologics. Notably, many current therapies for autoimmune disorders are broadly immunosuppressant, which may lead to severe side effects, such as increased infection risk. Preclinical data suggest that FRTX-02 may drive regulatory T cell differentiation while dampening pro-inflammatory T helper cells and myeloid differentiation primary response 88 ("MyD88")/IRAK4-related signaling pathways. Regulatory T cells serve to maintain tolerance and keep the autoreactive, pro-inflammatory T cells in check, thus decreasing the likelihood of autoimmune disease and limiting chronic inflammation. The MyD88 protein is normally spliced into a long form and a short form. The long form of MyD88 drives inflammation via pathways related to IRAK4, a protein kinase involved in signaling immune responses from toll-like receptors, while the short form of MyD88 limits IRAK4 phosphorylation and its respective downstream signaling pathway. DYRK1A inhibition shifts the balance to produce more MyD88 short form, which leads to deactivation of the downstream release of certain pro-inflammatory cytokines. Based on current understanding, inhibition of this release of excess cytokines can be achieved by re-establishing the role of MyD88 short form as a negative regulator of this pathway. Unlike many existing therapies for autoimmune diseases, as well as the majority of those currently being investigated, FRTX-02 may have the ability to target both the adaptive and innate immune imbalance simultaneously, potentially resulting in, or substantially achieving, restoration of immune homeostasis that, if proven, would represent a paradigm shift in the treatment of certain autoimmune and inflammatory diseases.

About Fresh Tracks Therapeutics

Fresh Tracks Therapeutics, Inc., formerly Brickell Biotech, Inc., is a clinical-stage pharmaceutical company striving to transform patient lives through the development of innovative and differentiated prescription therapeutics. The Company's pipeline aims to disrupt existing treatment paradigms and features several new molecular entities that inhibit novel targets with first-in-class potential for autoimmune, inflammatory, and other debilitating diseases. Fresh Track Therapeutics' executive management team and board of directors have a proven track record of leadership across early-stage research, product development, and global commercialization, having served in leadership roles at large global pharmaceutical and biotech companies that successfully developed and/or launched first-in-class products that achieved iconic status, including Cialis®, Taltz®, Gemzar®, Prozac®, Cymbalta®, Juvederm®, Pluvicto®, and Sofpironium Bromide. The Company's strategy is to align this experience and clear vision to explore beyond the limitations of current therapies by identifying, pursuing, and developing next-generation therapeutics that can be groundbreaking in their ability to help millions of people struggling with autoimmune, inflammatory, and other debilitating diseases. For more information, visit https://www.frtx.com/.

Cautionary Note Regarding Forward-Looking Statements

Any statements made in this press release relating to future financial, business, and/or research and investigational, preclinical or clinical performance, conditions, plans, prospects, trends, or strategies and other such matters, including without limitation, FRTX's strategy; future operations; future potential; future financial position; future liquidity; future revenue; territorial focus; projected expenses; results of operations; the anticipated timing, scope, design, progress, results, possible impact of, and/or reporting of data of ongoing and future non-clinical and clinical trials; intellectual property rights, including the acquisition, validity, term, and enforceability of such; the expected timing and/or results of regulatory submissions and approvals; and prospects for commercializing (and competing with) any product candidates of FRTX or third parties, or research and/or licensing collaborations with, or actions of, its partners, including in the United States, Japan, South Korea, or any other country, are forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. In addition, when or if used in this press release, the words "may," "could," "should," "might," "change," "announce," "establish," "anticipate," "reflect," "believe," "estimate," "expect," "intend," "plan," "predict," "potential," "will," evaluate," "advance," "excited," "aim," "strive," "help," "progress," "select," "initiate," "look forward," "promise," "provide," "commit," "best-in-class," "first-in-class," "broad potential," "encouraging," and similar expressions and their variants, as they relate to FRTX or any of FRTX's investigational products, partners or third parties, may identify forward-looking statements. FRTX cautions that these forward-looking statements are subject to numerous assumptions, risks, and uncertainties, which change over time, often quickly, and in unanticipated ways. Important factors that may cause actual results to differ materially from the results discussed in the forward-looking statements or historical experience include risks and uncertainties, including without limitation, research results and data that do not meet targets, expectations or regulatory approval requirements; ability to obtain adequate financing for product development, regulatory submissions, and any commercialization; ability to acquire, maintain, and enforce intellectual property rights; potential delays or alterations in product development, trials of any type, and regulatory submission and reviews; changes in law or policy; litigation, regulatory agency actions, feedback, or requests; supply chain disruptions; unanticipated demands on cash resources; disruptions and negative effects related to the COVID-19 pandemic and the conflict in Ukraine; interruptions, disruption, or inability by FRTX, its partners or third parties to obtain or supply research material, raw materials, and/or product anywhere, or secure essential services, in the world; efforts to obtain and retain adequate pricing and adequate reimbursement and other insurance coverage for FRTX's future products; the outcome of and reaction to FRTX's current and planned preclinical and clinical trials across its portfolio of assets; the inability of third parties to achieve the regulatory and sales-based events under FRTX's agreements with them, or their lack of funds, resulting in FRTX not receiving additional or full payments due from them; and other risks associated with developing and obtaining regulatory approval for, and commercializing, any product candidates.

Further information on the factors and risks that could cause actual results to differ from any forward-looking statements are contained in FRTX's filings with the United States Securities and Exchange Commission, which are available at https://www.sec.gov (or at https://www.frtx.com/). The forward-looking statements represent the estimates of FRTX as of the date hereof only. FRTX specifically disclaims any duty or obligation to update forward-looking statements.

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Source: Fresh Tracks Therapeutics, Inc.