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Fresh Tracks Therapeutics Announces Publication of Preclinical Data for FRTX-02, a Potential First-in-Class Oral DYRK1A Inhibitor, in the Peer-Reviewed Journal of Translational Autoimmunity

Topline results from SAD and MAD parts of FRTX-02 Phase 1 study expected in Q1 2023

BOULDER, Colo., Jan. 11, 2023 (GLOBE NEWSWIRE) -- Fresh Tracks Therapeutics, Inc. ("Fresh Tracks" or the "Company") (Nasdaq: FRTX), a clinical-stage pharmaceutical company aiming to disrupt existing treatment paradigms by developing innovative and differentiated prescription therapeutics for the treatment of autoimmune, inflammatory, and other debilitating diseases, today announced publication of data from preclinical studies of FRTX-02, a potential first-in-class, orally bioavailable DYRK1A inhibitor, in the *Journal of Translational Autoimmunity*. The paper shows FRTX-02 to be a potent and selective inhibitor of DYRK1A with the potential to restore immune homeostasis by regulating adaptive and innate immune system responses in models of various autoimmune and inflammatory diseases.

"We are excited to publish the results from several preclinical studies of FRTX-02 in animal models of psoriasis and atopic dermatitis," commented Monica Luchi, M.D., Chief Medical Officer of Fresh Tracks. "These data provide preclinical characterization of FRTX-02 and evidence supporting its role in modulating chronic inflammatory and autoimmune responses, which helped pave the way for this drug candidate to enter a Phase 1 clinical trial in 2022. FRTX-02, to our knowledge, is the first and only clinical-stage, oral DYRK1A inhibitor being developed for patients with autoimmune diseases, and we look forward to reporting topline results from Part 1 (SAD and MAD) of the current Phase 1 study with FRTX-02 by the end of this quarter."

Key preclinical findings as published in *Journal of Translational Autoimmunity* suggest the novel FRTX-02:

- Attenuates inflammation in mouse models of atopic dermatitis and psoriasis, implying potential as a treatment for various autoimmune and inflammatory diseases;
- Restores the adaptive immune system through promotion of Treg differentiation and suppression of pro-inflammatory Th17 and Th1 differentiation;
- Induces alternative splicing of myeloid differentiation primary response 88 (MyD88), thereby regulating the innate immune system by blocking Interleukin-1 receptor-associated kinase 4 (IRAK4) phosphorylation; *and*

- Has the potential to restore immune homeostasis, presenting a novel approach to regulating adaptive and innate inflammatory immune responses.

A link to the publication titled, “**FRTX-02, a selective and potent inhibitor of DYRK1A, modulates inflammatory pathways in mouse models of psoriasis and atopic dermatitis**” may be found online [here](#).

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 first-in-human Phase 1 clinical trial (topline results expected in the first quarter of 2023) 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 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 several 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 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 chemical entities that inhibit novel targets with first-in-class potential for autoimmune, inflammatory, and other debilitating diseases. Fresh Tracks’ 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, some of which have achieved iconic status, including Cialis[®], Taltz[®], Gemzar[®], Prozac[®], Cymbalta[®], Juvederm[®], Pluvicto[®], and

sofipironium 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 development, investigational, preclinical, or clinical performance and potential, conditions, plans, prospects, impacts, shifts, trends, or strategies and other such matters, including without limitation, Fresh Tracks' 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 nonclinical and clinical trials involving FRTX-02 and any other products; 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 treatment of patients and commercializing (and competing with) any product candidates for any disease by Fresh Tracks 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," "announce," "anticipate," "advancing," "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," "standard-of-care," "on track," "opportunity," "disrupt," "restore," "suggest," "attenuate," "imply," "induce," "regulates," "dampens," "targets," "shift," and similar expressions and their variants, as they relate to Fresh Tracks or any of Fresh Tracks' investigational products, partners, or third parties, may identify forward-looking statements. Fresh Tracks 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 Fresh Tracks, 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 Fresh Tracks' future products; the outcome of and reaction to Fresh Tracks' 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 Fresh Tracks' agreements with them, or their lack of funds, resulting in Fresh

Tracks not receiving additional or full payments due from them; and other risks associated with (i) developing and obtaining regulatory approval for, and commercializing, product candidates, (ii) raising additional capital, and (iii) maintaining compliance with Nasdaq listing requirements.

Further information on the factors and risks that could cause actual results to differ from any forward-looking statements are contained in Fresh Tracks' 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 Fresh Tracks as of the date hereof only. Fresh Tracks specifically disclaims any duty or obligation to update forward-looking statements.

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