fresh tracks THERAPEUTICS

NASDAQ: FRTX

FRTX-02: Phase 1 SAD/MAD Topline Results

Making Fresh Tracks in Medicine®

March 2023

Forward-Looking Statements

- Any statements made in this presentation relating to future financial, business, and/or research and development, investigational, preclinical or clinical performance and potential, conditions, plans, prospects, impacts, shifts, trends, progress, or strategies and other such matters, including without limitation, Fresh Tracks Therapeutics Inc.'s ("FRTX") strategy; future operations; future potential; future financial position; future liquidity; future revenue; territorial focus; projected expenses; results of operations; the anticipated timing, scope, design, 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 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 presentation, the words "may," "could," "should," "might," "show," "topline," "positive," "announce," "anticipate," "advance," "reflect," "believe," "estimate," "expect," "intend," "plan," "predict," "potential," "will," evaluate," "advance," "excited," "aim," "strive," "help," "progress," "meet," "support," "select," "initiate," "look forward," "promise," "provide," "commit," "best-in-class," "first-in-class," "standard-of-care," "on track," "opportunity," "disrupt," "reduce," "restore," "demonstrate," "suggest," "attenuate," "reinforce," "imply," "induce," "attain," "regulate," "dampen," "inhibit," "target," "shift," 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; study limitations, including small sample sizes and the enrollment of only healthy patients; data variability; expectations or regulatory approval requirements; ability to obtain adequate financing for (i) product development, (ii) clinical trials, (iii) regulatory submission(s), and (iv) any future commercialization; ability to acquire, maintain, and enforce global intellectual property rights; potential delays or alterations in (i) product development, (ii) trials of any type, and (iii) regulatory submission and reviews; changes in law or policy; litigation; regulatory agency actions; feedback, or requests; supply chain disruptions; unanticipated demands on cash resources; interruptions, disruption, or inability by FRTX, its partners, or third parties to obtain or supply (i) research material, (ii) raw materials, and/or (iii) product anywhere, or secure essential services, in the world; the outcome of and reaction to FRTX's current and planned preclinical and clinical trials across its portfolio of assets and for the SAD/MAD portion of this Phase 1 study on FRTX-02; 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, especially related to the sale and assignment of FRTX's ownership of sofpironium bromide; 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 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.

Potential First-in-Class Oral DYRK1A Inhibitor

FRTX-02 is a potent, highly selective, and orally bioavailable potential first-in-class DYRK1A inhibitor with strong preclinical validation and broad potential to treat debilitating autoimmune and inflammatory diseases

Novel Autoimmunity Target

- **Dual mechanism potentially restoring immune homeostasis** through enhanced regulatory T-cell differentiation and concomitant inhibition of pro-inflammatory pathways
- **Emerging field** with recent significant investor & pharma interest

Strong Preclinical Validation

- **Proof-of-mechanism established** by thorough characterization
- **Preclinical proof-of-concept in 10+ animal models** of autoimmune disorders
- **Promising efficacy profile** vs. established therapies

Significant Market Opportunity

- **Robust potential** across multiple different autoimmune diseases
- Oral & topical formulations under development
- **Strong IP position (CoM)** in U.S. & other key countries **through 2038+**

Phase 1 Trial Ongoing

- **Reported positive SAD/MAD topline results from FRTX-02 Phase 1 study in March 2023**
- **Results support advancement of FRTX-02 as potential first-in-class treatment for autoimmune diseases**
- FRTX-02 is first oral DYRK1A inhibitor tested in the clinic for autoimmune diseases

DYRK1A = Dual-specificity tyrosine phosphorylation regulated kinase 1A; CoM= composition of matter

FRTX-02-101

Key Highlights from Part 1 (SAD/MAD)

Topline results from Part 1 (SAD/MAD) of the Phase 1 study support the continued development of FRTX-02 as a potential first-in-class, once-daily oral treatment for atopic dermatitis and/or other autoimmune diseases

- FRTX-02 was generally safe and well tolerated within the potential therapeutic dose range
- Plasma concentrations within the potential therapeutic dose range were consistent with efficacious exposure levels established in nonclinical disease models
- Pharmacokinetic (PK) data support once-daily oral dosing with FRTX-02 and steady state concentrations were attained before Day 14
- Reduction in disease-relevant cytokines was observed in exploratory *ex-vivo* lipopolysaccharide (LPS)-stimulated whole blood pharmacodynamic (PD) assays

FRTX-02-101

Phase 1 Clinical Study Design Overview

FRTX-02-101 is a two-part, randomized, double-blinded, placebo-controlled study evaluating the safety, tolerability, PK and PD of oral FRTX-02 in healthy adult subjects (Part 1) and atopic dermatitis patients (Part 2)

PART 1: SINGLE ASCENDING DOSE (SAD) PHASE

56 healthy subjects (8 per cohort) randomized 6:2 to once daily doses of FRTX-02 or placebo

Endpoints: safety, tolerability, PK

COHORT 1 10 mg → COHORT 2 30 mg → COHORT 3 75 mg → COHORT 4 150 mg → COHORT 5 300 mg → COHORT 6 450 mg → COHORT 7 600 mg

COHORT 4 (FED) 150 mg

PART 1: MULTIPLE ASCENDING DOSE (MAD) PHASE

33 healthy subjects (11 per cohort) randomized 9:2 to either 14 once-daily doses of FRTX-02 or placebo

Endpoints: safety, tolerability, PK, exploratory PD

COHORT 8 150 mg QD → COHORT 9 300 mg QD → COHORT 10* 75 mg QD

PART 2: ATOPIC DERMATITIS

30-40 patients receiving 28 once-daily doses of FRTX-02 or placebo

Endpoints: safety, tolerability, PK, PD, exploratory efficacy

*75 mg QD dose was selected for Cohort 10 based on 150 mg QD (Cohort 8) PK exposures exceeding FRTX-02 concentrations at the mouse efficacious dose (30 mg/kg BID) and safety findings from 300 mg QD (Cohort 9).

fresh tracks THERAPEUTICS

SAD: Blinded Safety Summary

FRTX-02 was generally safe and well tolerated in all seven SAD cohorts (10 mg - 600 mg)

- No Serious Adverse Events (SAEs) and no discontinuations due to Treatment-Emergent Adverse Events (TEAEs)
- No dose-dependent trend in frequency or severity of TEAEs was observed
- All but one TEAE were mild (single count of moderate back pain unlikely related to treatment in 450 mg cohort)
- Most TEAEs were not related or unlikely related to study treatment
- No ECG or lab findings of clinical relevance

POSSIBLY RELATED TREATMENT-EMERGENT AEs* (>1 SUBJECT)

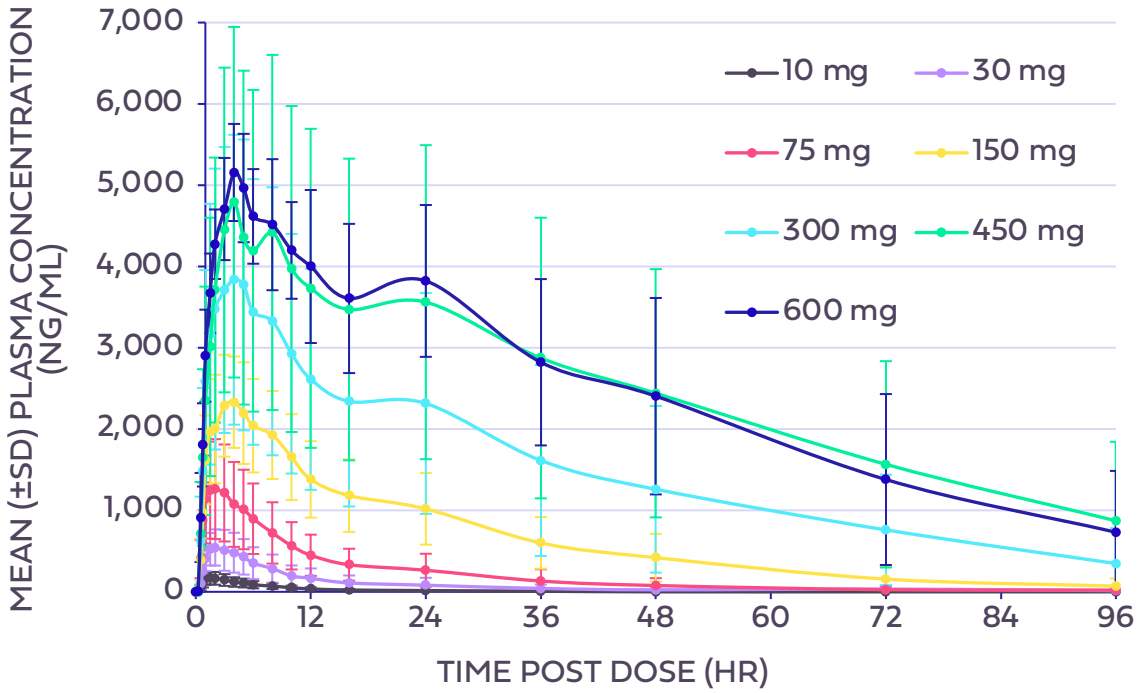
AE TERM	# SUBJECTS	SEVERITY	COHORT
HEADACHE	5	Mild (x5)	75 mg, 150 mg (FAST & FED), 600 mg
NAUSEA	2	Mild (x2)	75 mg, 600 mg

* Per investigator assessment.

SAD: FRTX-02 PK Summary

FRTX-02 was well absorbed for all SAD doses and reached peak plasma concentrations between 2 to 4.5 hours post dose

FRTX-02 MEAN PLASMA CONCENTRATIONS OVER TIME



SAD PK PARAMETERS*

PK PARAMETER	10 MG (N=6)	30 MG (N=6)	75 MG (N=6)	150 MG (N=6)	300 MG (N=6)	450 MG (N=6)	600 MG (N=6)
C_{MAX} (NG/ML)	156.54 (44.1)	530.98 (40.9)	928.27 (47.6)	2145.52 (48.1)	3052.29 (46.0)	4089.87 (43.7)	5137.33 (11.7)
AUC_{0-24} (H*NG/ML)	1176.69 (49.3)	4618.56 (55.7)	9895.73 (51.2)	35194.37 (47.7)	45059.69 (50.8)	65041.61 (50.0)	93518.36 (18.2)
T_{MAX} (HR)	1.82 (34.7)	2.62 (53.7)	2.50 (25.7)	6.26 (31.9)	3.80 (31.6)	3.81 (50.0)	4.31 (11.9)
$T_{1/2}$ (HR)	6.98 (33.6)	10.11 (55.2)	15.00 (65.0)	15.56 (33.7)	16.79 (47.9)	30.18 (49.9)	21.99 (52.6)

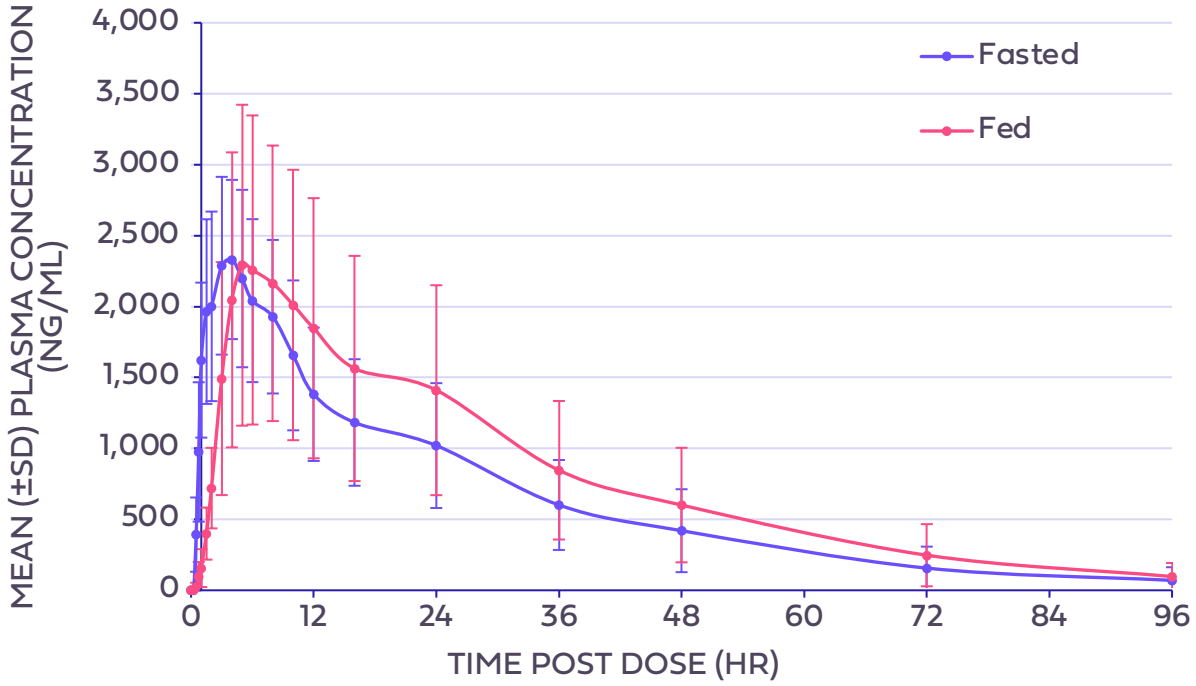
*Geometric Mean (%CV) reported for all parameters.

fresh tracks THERAPEUTICS

SAD: Minimal FRTX-02 Food Effect

Minimal effect of food was observed on PK of a single 150 mg oral dose of FRTX-02

150 MG FRTX-02 MEAN PLASMA CONCENTRATIONS OVER TIME



SAD PK PARAMETERS*

PK PARAMETER	150 MG FAST (N=6)	150 MG FED (N=6)
C_{MAX} (NG/ML)	2145.52 (48.1)	2316.81 (25.5)
AUC_{0-24} (H*NG/ML)	35194.37 (47.7)	33867.79 (30.8)
T_{MAX} (HR)	6.26 (31.9)	3.36 (30.0)
$T_{1/2}$ (HR)	15.56 (33.7)	14.96 (39.0)

*Geometric Mean (%CV) reported for all parameters.

FRTX-02-101

MAD: Blinded Safety Summary

FRTX-02 was safe and generally well tolerated at 75 mg and 150 mg over 14 days of oral QD dosing

- No SAEs
- Majority of TEAEs were mild (single count of moderate headache possibly related to treatment in 300 mg cohort)
- No dose-dependent trend in TEAE frequency or severity observed
- No lab findings of clinical relevance
- QTc prolongation observed in two subjects in 300 mg cohort
  - Both subjects were asymptomatic, their QTc intervals returned to baseline levels and remained in the normal range after dosing cessation, and all study assessments were completed
  - Exposures where QTc prolongation was observed are 2 to 4-fold above exposures within the potential therapeutic dose range (75 mg – 150 mg)

POSSIBLY RELATED TREATMENT-EMERGENT AEs* (>1 SUBJECT)

AE TERM	# SUBJECTS	SEVERITY	COHORT
CONSTIPATION	3	Mild (x3)	75 mg, 150 mg, 300 mg
HEADACHE	3	Mild (x2)	75 mg, 300 mg
		Moderate (x1)	300 mg
NAUSEA	2	Mild (x2)	75 mg, 300 mg
ECG QT PROLONGED	2	Mild (x2)	300 mg

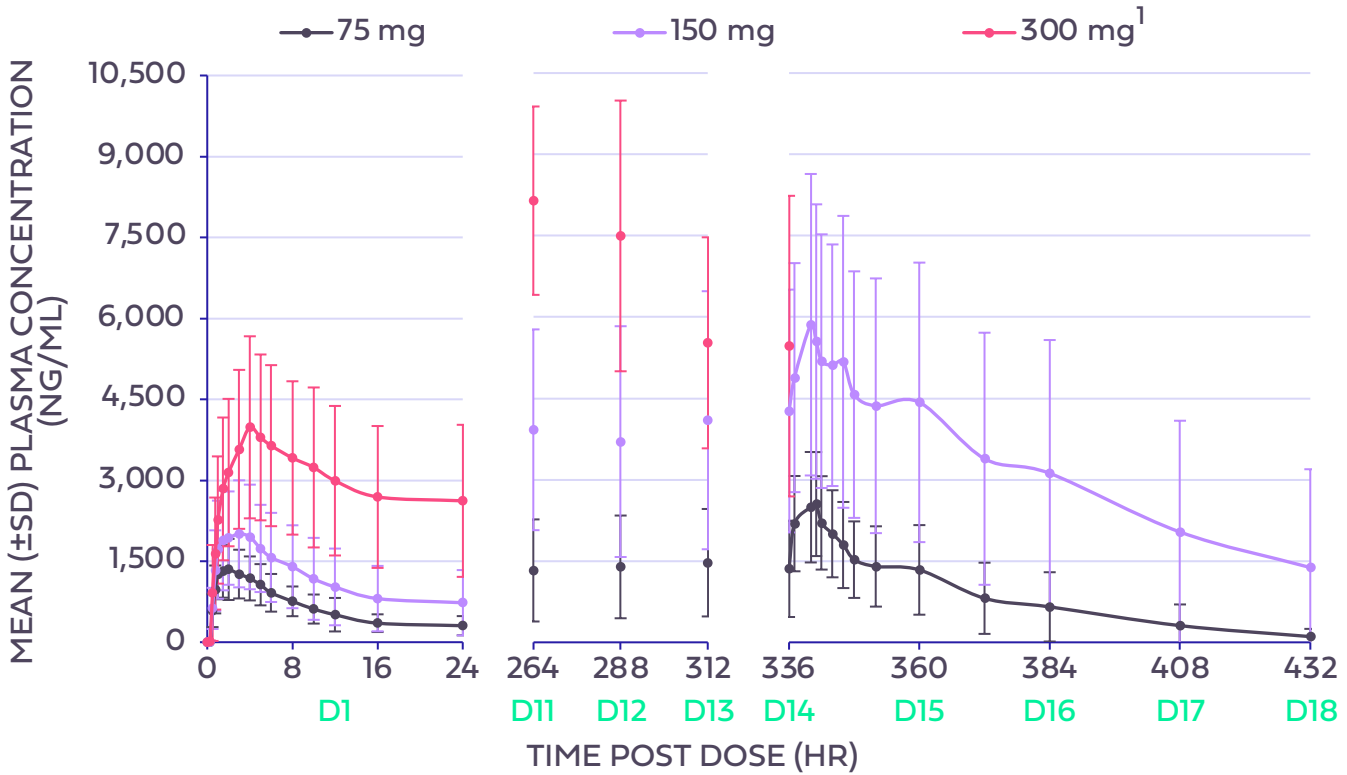
* Per investigator assessment.

fresh tracks THERAPEUTICS

MAD: FRTX-02 PK Summary

MAD PK data support once-daily dosing with FRTX-02 and steady state was attained before Day 14

FRTX-02 MEAN PLASMA CONCENTRATIONS OVER TIME



MAD (DAY 14) PK PARAMETERS*

PK PARAMETER	75 MG QD (N=9)	150 MG QD (N=9)
C_{MAX} (NG/ML)	2450.68 (37.3)	5417.64 (46.6)
AUC_{0-24} (H*NG/ML)	37898.58 (46.2)	102394.70 (50.3)
T_{MAX} (HR)	2.68 (49.4)	3.25 (32.8)
$T_{1/2}$ (HR)	15.97 (37.6)	28.26 (82.46)
C_{TROUGH} (NG/ML)	1355.53 (888.22)	4266.56 (2239.21)
DAY 14/1 $RATIO_{CMAX}$	1.85	2.85
DAY 14/1 $RATIO_{AUC}$	2.80	4.20

*Geometric Mean (%CV) reported for all parameters, except for C_{trough} where Mean (±SD) concentration is reported.

[1] 1 subject received 8, 1 subject received 9, and the remaining 7 subjects received 10 daily doses of FRTX-02; Dosing was halted (as per pre-defined protocol stopping rules) due to QTc prolongation observed in two subjects

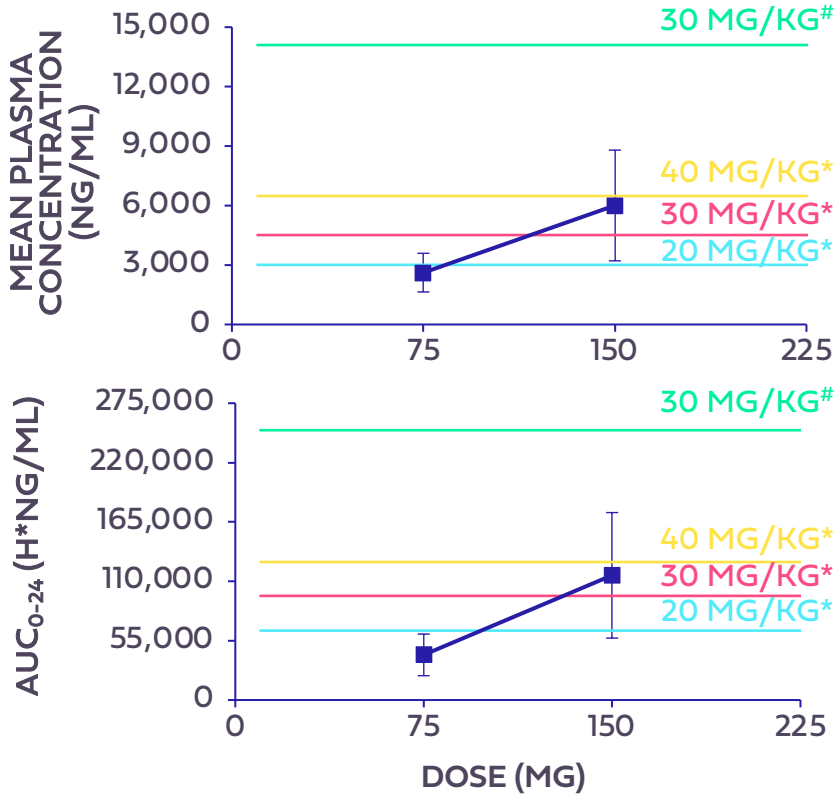
fresh tracks THERAPEUTICS

MAD: Therapeutic Dose Summary

Plasma concentrations within the potential FRTX-02 therapeutic dose range (75 mg and 150 mg) were consistent with efficacious exposure levels established in nonclinical disease models

- After once-daily dosing with 150 mg FRTX-02 over 14 days:
  - C_{max} and AUC_{0-24} concentrations are above estimated exposures at mouse efficacious dose of 30 mg/kg BID
- After once-daily dosing with 75 mg FRTX-02 over 14 days:
  - C_{max} and AUC_{0-24} concentrations are consistent with estimated exposures at mouse dose of 20 mg/kg BID
- If mouse PD effects translate to a human autoimmune patient population (next clinical study), the FRTX-02 therapeutic dose range is expected to be between 75 mg and 150 mg

FRTX-02 C_{MAX} & AUC_{0-24} (DAY 14)



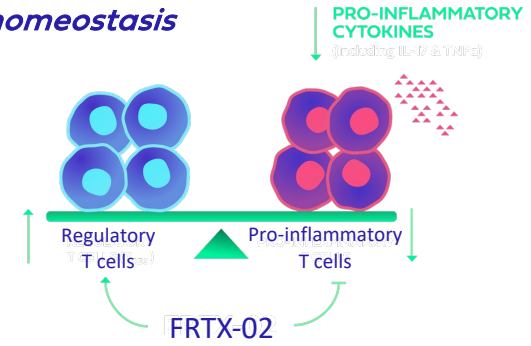
*Mouse BID Day 28 Estimates; #Dog BID Day 28 Estimates.

fresh tracks THERAPEUTICS

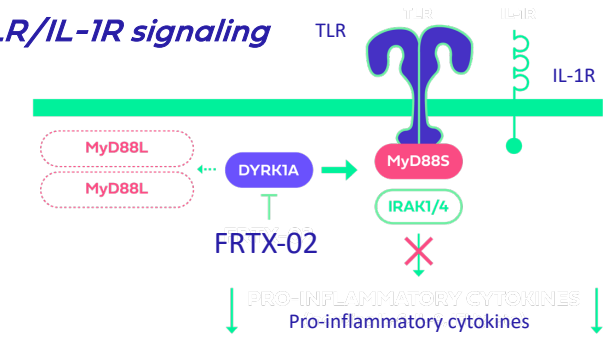
MAD: PD Biomarker Sampling Methodology

Dual Mode of Action

T cell homeostasis

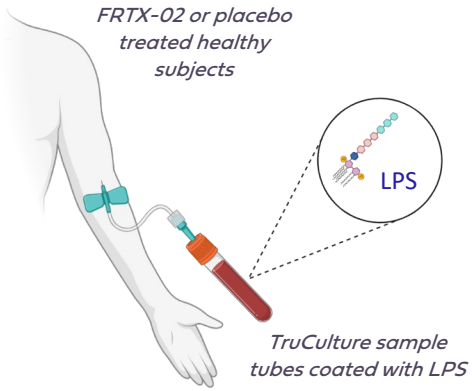


TLR/IL-1R signaling



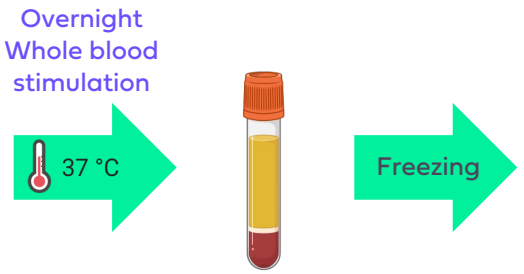
PD biomarker assay in stimulated PBMCs from healthy subjects

PBMC COLLECTION & STIMULATION



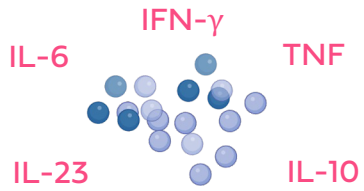
Patient blood was drawn into TruCulture® tubes coated with LPS to stimulate cytokine release

SAMPLE PROCESSING



Plasma was separated from blood cells within the TruCulture® tube

CYTOKINE MEASUREMENTS



Cytokines in supernatant were measured by a multiplex assay

Images generated by Fresh Tracks Therapeutics and in Biorender

MAD: FRTX-02 PD Summary

Reduction in disease-relevant cytokines was observed in exploratory *ex-vivo* LPS-stimulated whole blood pharmacodynamic assays

- Exploratory PD activity was measured by impact on cytokine secretion following *ex vivo* LPS stimulation of peripheral blood mononuclear cells (PBMCs) derived from the MAD cohorts
- Cytokines were selected for assessment based on those observed to be reduced by FRTX-02 in various nonclinical disease models
- FRTX-02 demonstrated a reduction in disease-relevant proinflammatory cytokines, suggesting initial support for the FRTX-02 mechanism of action
- Mean percent cytokine reduction from baseline after 14 days of once-daily 75 mg or 150 mg FRTX-02 treatment versus placebo were in the range of approximately 66% to 20% for IFNγ, IL-23, IL-10, IL-6, and TNFα
- Maximum individual subject cytokine reductions from baseline were shown to be >90% for IFNγ, >50% for IL-23, IL-10 and TNFα, and approximately 40% for IL-6

fresh tracks THERAPEUTICS

NASDAQ: FRTX

Thank You!

Making Fresh Tracks in Medicine®

ir@frtx.com

March 2023