



Corporate Investor Presentation

April 2024

Safe Harbor Statement

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This document contains forward-looking statements concerning TFF Pharmaceuticals, Inc. (“TFF”, “TFF Pharmaceuticals”, the “Company,” “we,” “us,” and “our”). The words “believe,” “may,” “will,” “potentially,” “estimate,” “continue,” “anticipate,” “intend,” “could,” “would,” “project,” “plan,” “expect” and similar expressions that convey uncertainty of future events or outcomes are intended to identify forward-looking statements. These forward-looking statements include, but are not limited to, statements concerning the following:

- the benefits of our TFF platform;
- advancement of TFF TAC and TFF VORI into potentially registration-enabling studies;
- TFF TAC’s and TFF VORI’s substantial market opportunity;
- the expectation that the further data from the ongoing Phase 2 clinical trial for TFF TAC and TFF VORI will be consistent with the data readouts for each product candidate to date; and
- our exploration of strategic alternatives for TFF VORI, including partnering opportunities, collaborations, and government-based funding sources.

Those forward-looking statements involve known and unknown risks, uncertainties and other factors that could cause actual results to differ materially. Among those factors are: (i) the risk that the further data from the ongoing Phase 2 clinical trials for TFF TAC and TFF VORI will not be favorably consistent with the initial data readouts, (ii) the risk that we may not be able to advance to registration-enabling studies for TFF TAC, (iii) the risk we may not be successful in our pursuit of strategic alternatives for TFF VORI; (iv) success in early phases of pre-clinical and clinicals trials do not ensure later clinical trials will be successful; (v) no drug product incorporating the TFF platform has received FDA pre-market approval or otherwise been incorporated into a commercial drug product, (vi) the Company has no current agreements or understandings with any large pharmaceutical companies for the development of a drug product incorporating the TFF platform, (vii) the risk that the Company may not be able to obtain additional working capital with which to continue the Phase 2 clinical trials and or advance to the initiation of registration-enabling studies, for TFF TAC as and when needed and (viii) those other risks disclosed in the section “Risk Factors” included in the Company’s Annual Report on Form 10-K filed with the SEC on March 28, 2024 and subsequently filed reports. TFF Pharmaceuticals cautions readers not to place undue reliance on any forward-looking statements. TFF Pharmaceuticals does not undertake, and specifically disclaims, any obligation to update or revise such statements to reflect new circumstances or unanticipated events as they occur, except as required by law.

This document contains only basic information concerning TFF. Because it is a summary it does not contain all of the information you should consider before investing. Please refer to our reports and registration statements on file with the SEC for more comprehensive information concerning TFF Pharmaceuticals.

Investment Highlights

Thin Film Freezing (TFF)

- Unique technology for generation of dry powder formulations optimized for inhalational delivery
 - Driving efficacy and minimizing systemic toxicities
- Over 170 patents issued or pending

Strong Internal Pipeline

- TFF TAC (Tacrolimus Inhalation Powder) for lung transplantation with >\$2 billion annual peak sales potential
- TFF VORI (Voriconazole Inhalation Powder) for serious pulmonary fungal infections with >\$1 billion annual peak sales potential

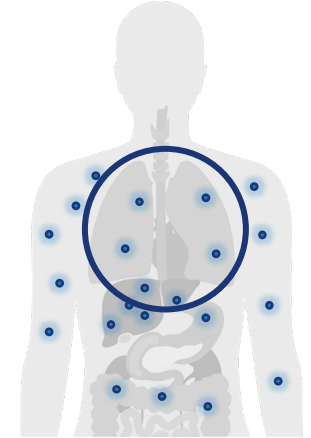
Positive Initial Clinical Data

- Recent data supports Company moving into registration enabling trials
- Favorable efficacy, safety and tolerability in both programs
- Both programs qualify for 505(b)2 pathway

Broadly Applicable Platform

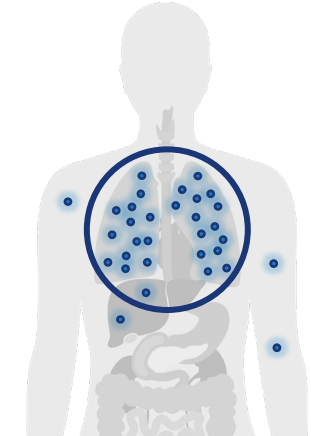
- Created dry powder formulations for a variety of small and large molecules
- Significant number of collaborations in place

Oral



Lower efficacy, Higher adverse events

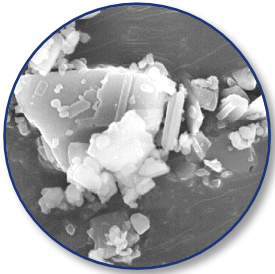
Inhaled



Higher efficacy, Lower adverse events

Thin Film Freezing Process

Bulk drug material



Proprietary freezing process

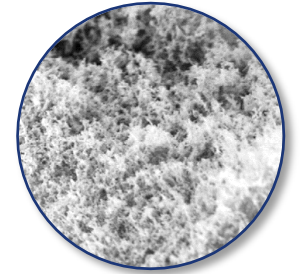


- ✓ Use proprietary combination of freezing rate and liquid surface to volume ratio
- ✓ Confers advantages in engineering particles for various routes of administration
- ✓ Stabilizes biologics not achievable with other process technologies

Drying and lyophilization



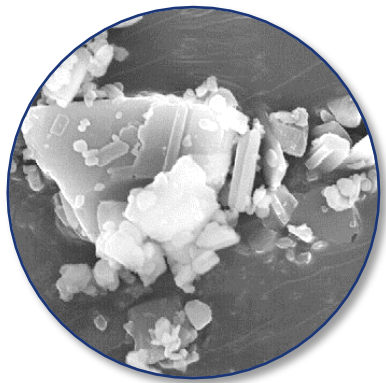
Brittle matrix powder



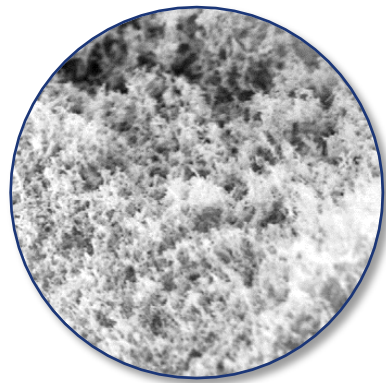
TFF technology enables the generation of dry powder formulations optimized for inhalational delivery via an easy-to-use dry powder inhaler

Inhalation Device for Lung Deposition

Bulk drug material



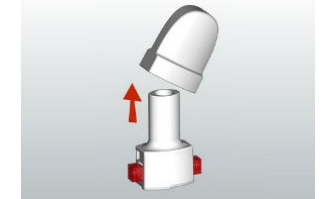
Brittle matrix powder



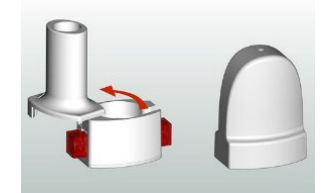
Commercial dry powder inhaler



Removal of protective cap



Open mouthpiece to access capsule housing



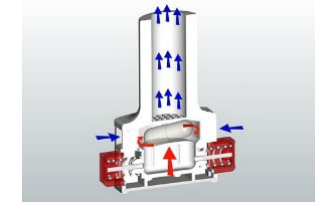
Insert capsule into housing





Close mouthpiece



Actuate pushbuttons to pierce the capsule and inhale



Delivering Value with an Internal Pipeline

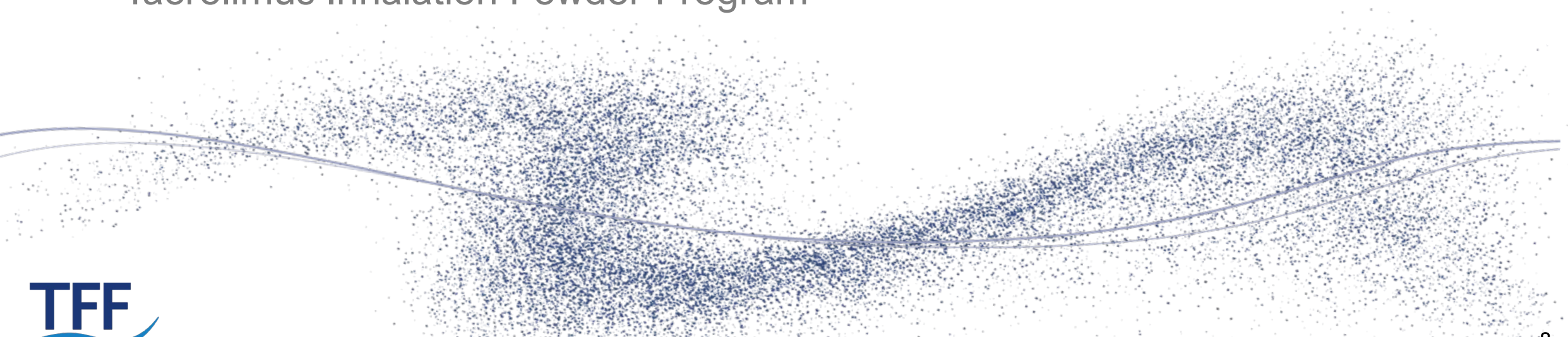
ASSET	PLATFORM	INDICATION	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3	ACHIEVED MILESTONES
TFF TAC	Tacrolimus inhalation powder	Prophylaxis of organ rejection in lung transplant					<ul style="list-style-type: none"> • Positive initial P2 data reported Dec 2023 • Additional P2 data reported in March 2024
TFF VORI	Voriconazole inhalation powder	Serious pulmonary fungal infections					<ul style="list-style-type: none"> • Positive initial P2 data reported Dec 2023 • Additional P2 data reported in March 2024

- ≥\$2 billion market opportunity for TFF TAC¹
- ≥\$1 billion market opportunity for TFF VORI¹
- >70 granted U.S. and ex-U.S. patents and patent applications for TFF TAC and TFF VORI with patent term extending to 2043

1. Internal estimates

TFF TAC Clinical Development

Tacrolimus Inhalation Powder Program



TFF TAC: Addressing Significant Unmet Need in Lung Transplant Rejection

TFF TAC is in Phase 2 development for prevention of rejection in lung transplant recipients

- Tacrolimus is first-line calcineurin inhibitor for prevention of rejection in lung transplant
- Significant toxicities associated with oral tacrolimus
- TFF TAC delivers tacrolimus directly to the lung to drive efficacy through immune suppression locally in the lung, where inflammation leads to rejection and allograft failure, while limiting systemic exposure thus systemic toxicities
- High unmet medical need with **~50% mortality in 5 years¹** due to narrow therapeutic index:
 - Too little immune suppression leads to acute rejection or chronic rejection leading to chronic lung allograft dysfunction (CLAD)
 - Too much immune suppression leads to infections, chronic kidney disease, and post transplant lymphoproliferative disease

~40,000 new and existing patients worldwide²

≥\$2 billion peak TFF TAC global gross sales forecast³

TFF TAC is intended to increase lung delivery to drive efficacy while minimizing systemic exposures and toxicities

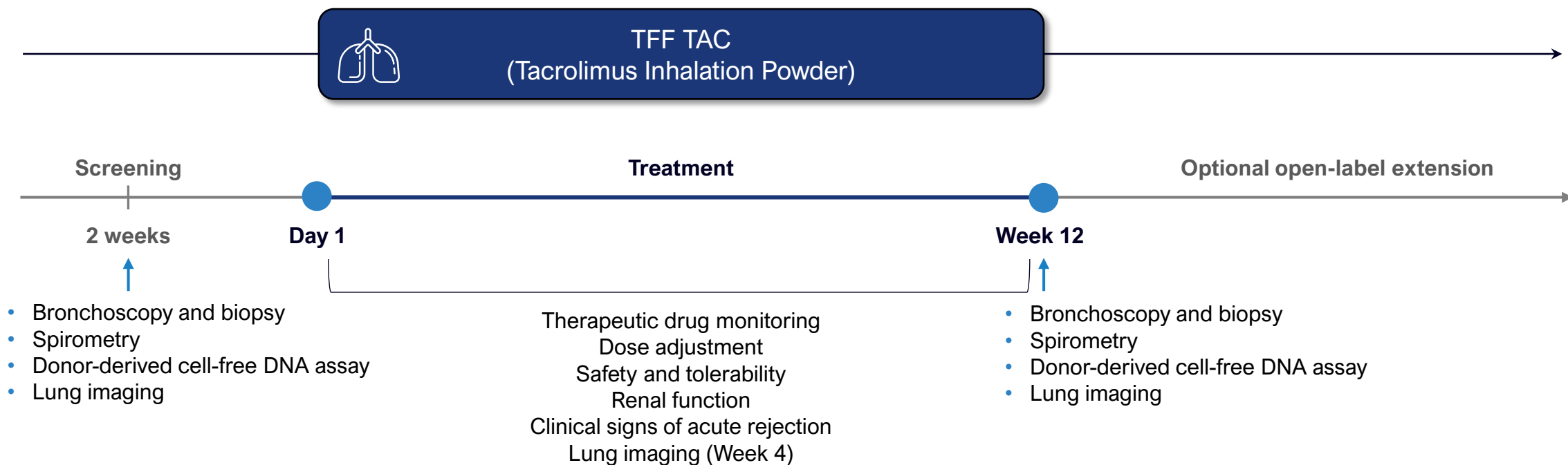
1. [Costa, Benvenuto, and Sonett, Best Practice & Research Clinical Anesthesiology, 2017.](#)

2. UpToDate; OPTN, UNOS, and Transplant Literature

3. Internal estimates

TFF TAC: Phase 2 Australia Trial Design in Lung Transplant Patients

- **Design:** Open label study of TFF TAC in lung transplant patients who require reduced tacrolimus blood levels due to kidney toxicity
- **Duration:** Part A: 12 weeks; Part B: optional safety extension
- **Endpoints:** Safety and tolerability, kidney function, acute allograft rejection



TFF TAC: Baseline Characteristics and Demographics

Patient	Age (years)	Sex	Race	Years since transplant	CLAD	Years with kidney disease	Time on TFF Tac (weeks)	Disposition
Pt 1	73	M	W	9	No	5	49.0	Chose to proceed to Part B
Pt 2	73	F	W	8	No	6	40.0	Chose to proceed to Part B
Pt 3	68	M	W	5	No	4	33.0	Chose to proceed to Part B
Pt 4	67	F	W	3	No	2.5	20.0	Chose to proceed to Part B
Pt 5	64	M	W	3	No	2.5	11.9	Still in Part A
Pt 6	52	F	W	23	No	7	9.0	Still in Part A
Pt 7	41	F	W	0.75	No	N/A	5.9	Still in Part A
Pt 8	56	M	NH	1.25	No	N/A	5.0	Still in Part A

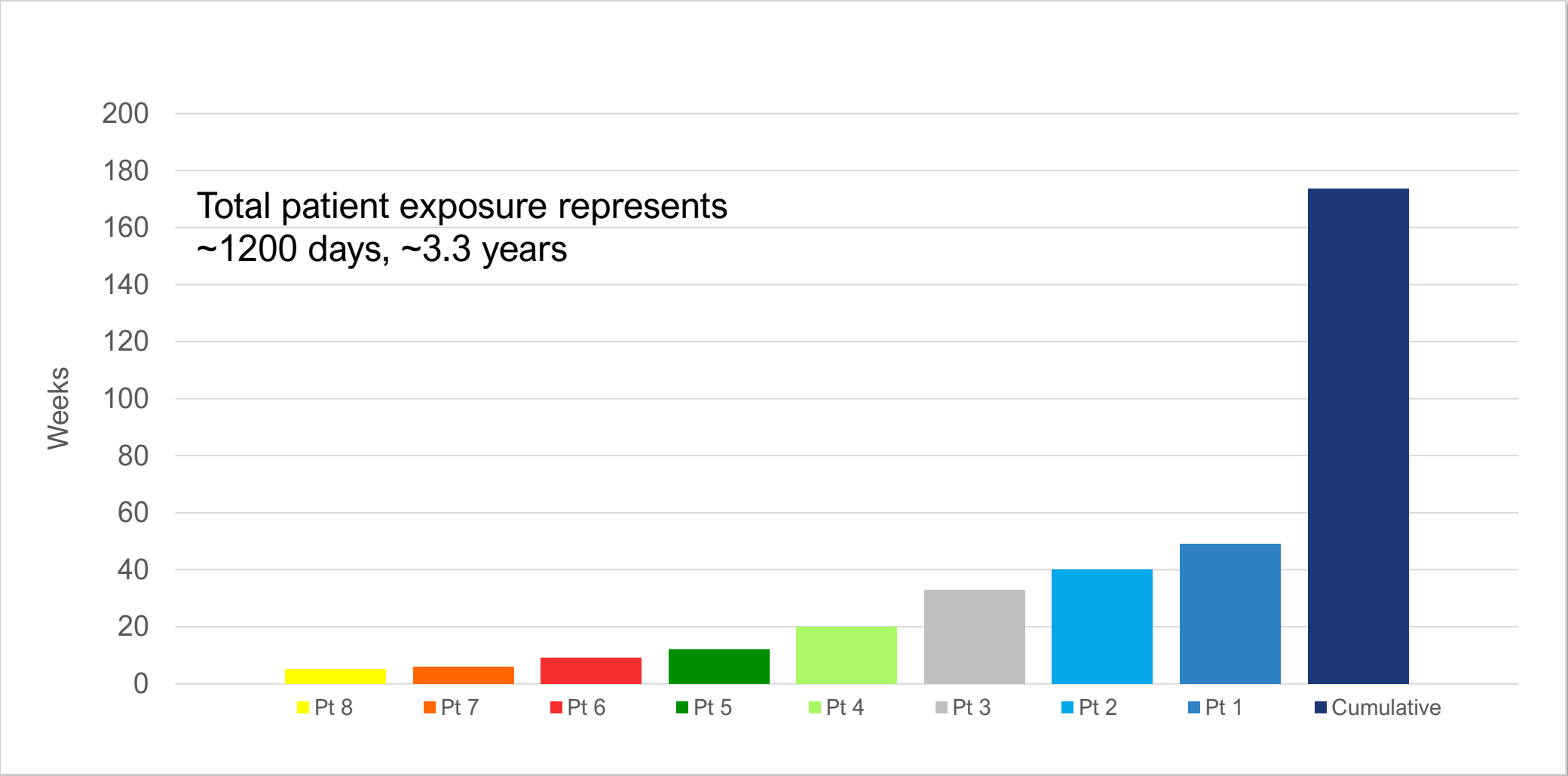
CLAD: chronic lung allograft dysfunction

W: white ; F: female; M: male; NH: Native Hawaiian

N/A: not available

Data is from TFF-T2-001 pre-database lock; Data cut off date: 3/25/24

TFF TAC: Total Patient Exposure



Data is from TFF-T2-001 pre-database lock; Data cut off date: 3/25/24

TFF TAC: Data suggest TFF TAC prevents rejection at reduced systemic exposure

Efficacy

- Successful transition of 8/8 patients from oral Tacrolimus to TFF TAC
- No evidence of acute rejection
 - No signs and symptoms suggestive of acute rejection
 - No use of pulse corticosteroids for treatment of rejection
 - No spirometry deterioration suggestive of acute rejection
 - No chest x-ray findings suggestive of acute rejection
 - Biomarker data to be disclosed in late April 2024
- **4/4 patients who completed Part A chose to remain on TFF TAC and proceeded to Part B**

Safety

- No mortality
- No TFF TAC discontinuation due to an AE
- Majority of TEAEs were Grade 2 or lower in severity
- Maintenance of kidney function

Key Takeaways

- Interim clinical data suggest:
 - Lower doses of TFF TAC compared to oral Tacrolimus are sufficient to prevent rejection.
 - TFF TAC prevents rejection at reduced systemic Tacrolimus blood levels, thus lowering the risk of systemic toxicity.

Mean Stable TFF TAC Dose / Mean Stable oral Tacrolimus Dose	Stable Trough Tacrolimus Blood Levels: TFF TAC / Oral Tacrolimus
~1/6 (~17%)	~2/3 (~66%)

n=8

Data is from TFF-T2-001 pre-database lock; Data cut off date: 3/8/24



TFF VORI Clinical Development

Voriconazole Inhalation Powder Program

TFF VORI: Addressing Significant Unmet Need in Pulmonary Fungal Infections

TFF VORI is in Phase 2 development for the treatment of pulmonary fungal infections including invasive pulmonary aspergillosis (IPA)

- IPA primarily impacts immune compromised patients (hematologic malignancies, solid organ, and stem cell transplant recipients)
- Oral and intravenous voriconazole is first-line therapy for the treatment of IPA
- Narrow therapeutic window associated with oral and IV voriconazole
 - Significant toxicities
 - Liver toxicity, arrhythmias and QT prolongation, infusion related reactions, visual disturbances, severe cutaneous adverse reactions, photosensitivity and renal toxicity¹
 - Drug-drug interactions
- High unmet medical need with **~30% mortality in 12 weeks²** due to high rate of toxicity and drug-drug interactions limiting systemic dosing and overall efficacy

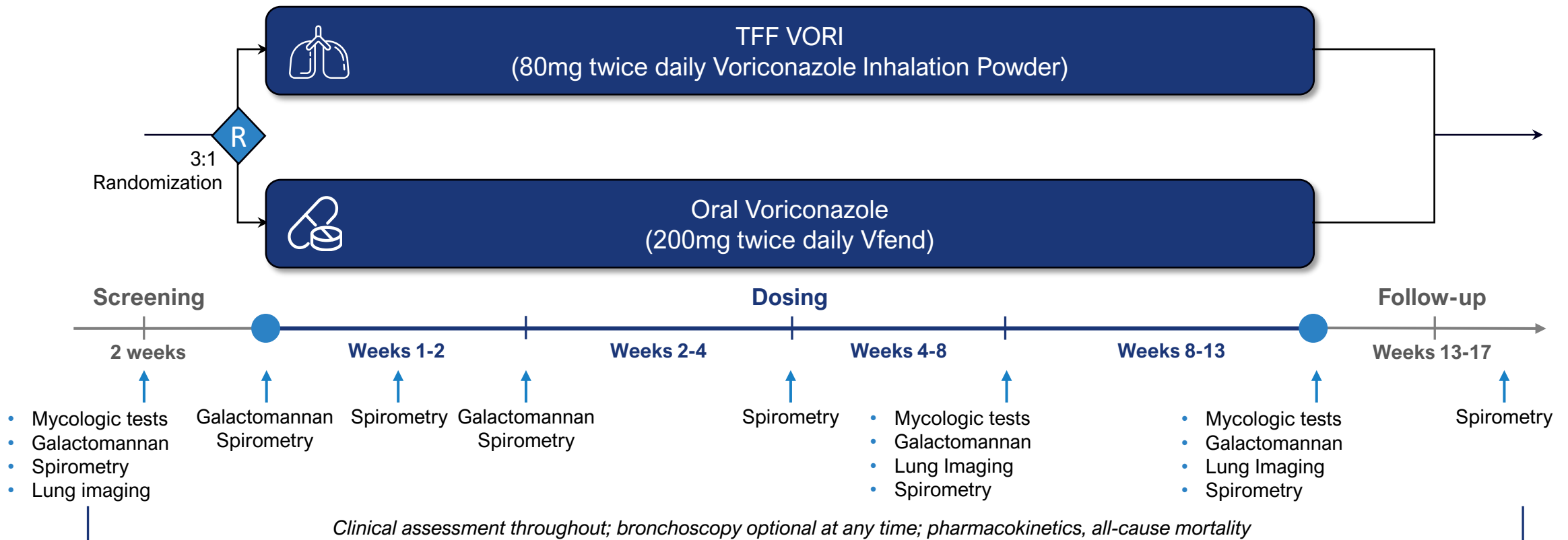
~250,000 invasive aspergillosis (IA) patients worldwide³

≥\$1 billion peak TFF VORI global gross sales forecast⁴

TFF VORI is intended to increase lung delivery to drive efficacy while minimizing systemic exposures, toxicities, and drug-drug interactions

TFF VORI: Phase 2 Trial Design in Patients with Invasive Pulmonary Aspergillosis

- **Design:** Open label randomized study; TFF VORI vs. oral voriconazole
- **Duration:** 13 weeks of treatment
- **Endpoints:** Safety/tolerability, clinical response, radiologic response, mycologic response, all-cause mortality



TFF VORI: Expanded Access Program (EAP)

- The Expanded Access Program (EAP) enrolls patients with the following diagnoses who have limited or no other treatment options or who have had an unfavorable response to adequate standard of care therapy:
 - Pulmonary aspergillosis:
 - Invasive pulmonary aspergillosis (IPA)
 - Chronic pulmonary aspergillosis (CPA)
 - Allergic bronchopulmonary aspergillosis (ABPA)
 - Aspergillus tracheobronchitis
 - Aspergillus bronchoanastomotic infection
 - Voriconazole responsive pulmonary fungal infections
- US expanded access protocol prepared and submitted to the FDA: <https://clinicaltrials.gov/ct2/show/NCT05897294>
- Available in the US, Canada, Australia, UK, and select EU countries

TFF VORI: Summary of Results

IPA is a pulmonary fungal infection with ~30% mortality in 12 weeks

Efficacy

- Of the six patients treated for at least 12 weeks with TFF VORI:
 - Five patients achieved a clinical response (improvement in signs, symptoms and/or spirometry)
 - Five patients achieved a mycologic response (presumed or proven)
 - Three of four patients achieved a radiologic response (4 patients with abnormal baseline and follow up chest CT)
 - No need for continued anti-fungal use after treatment with TFF VORI in all six patients

Safety

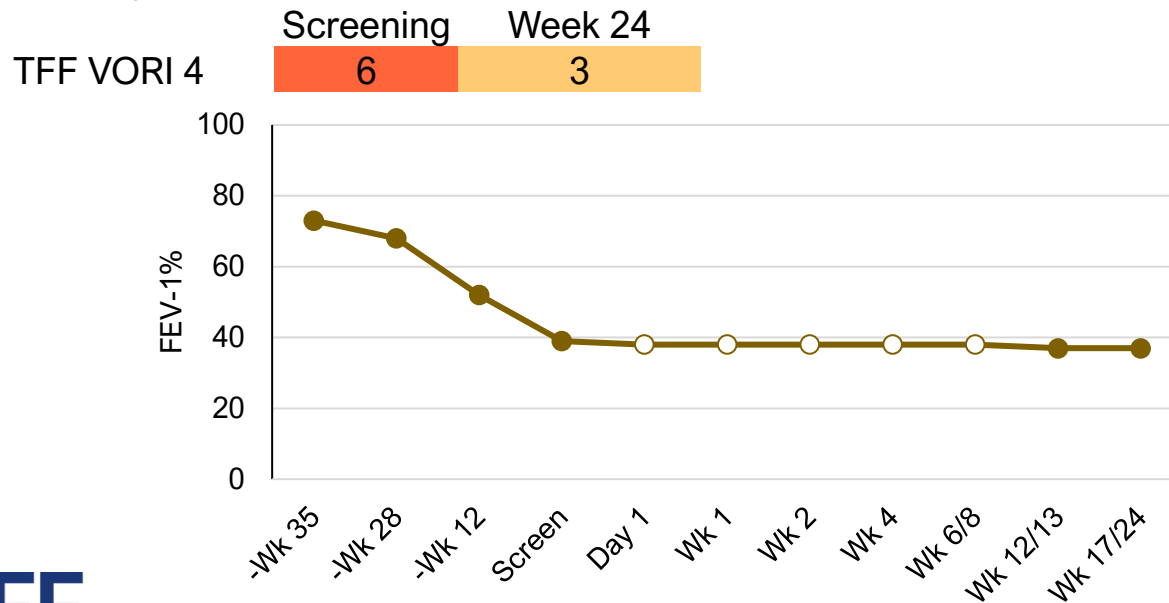
- Of the 8 patients treated with TFF VORI for any length of time with follow-up safety data:
 - No IPA-related mortality
 - No all-cause mortality
 - One TFF VORI discontinuation due to an unrelated AE of COVID infection that required intubation
 - Majority of TEAEs deemed unrelated to TFF VORI
 - Majority of TEAEs were Grade 2 or lower in severity
 - **No hepatic toxicity**
 - **No visual disturbances**

TFF VORI: Patient TFF VORI 4 (EAP)

50-yr-old white male lung transplant recipient with CLAD presented with moderate cough, dyspnea (shortness of breath) and respiratory insufficiency and BAL* evidence of Scedosporium, which is voriconazole sensitive, and Lomentospora

Patient	Treatment duration	Clinical response		Mycologic response	Radiologic response	All-cause mortality
		Improved signs and symptoms	Stable or improved spirometry			
TFF VORI 4	24 weeks	✓	✓	✓	✓	No

Total Symptom Scores



Follow up mycologic assessment:

- BAL* culture for Scedosporium **negative**

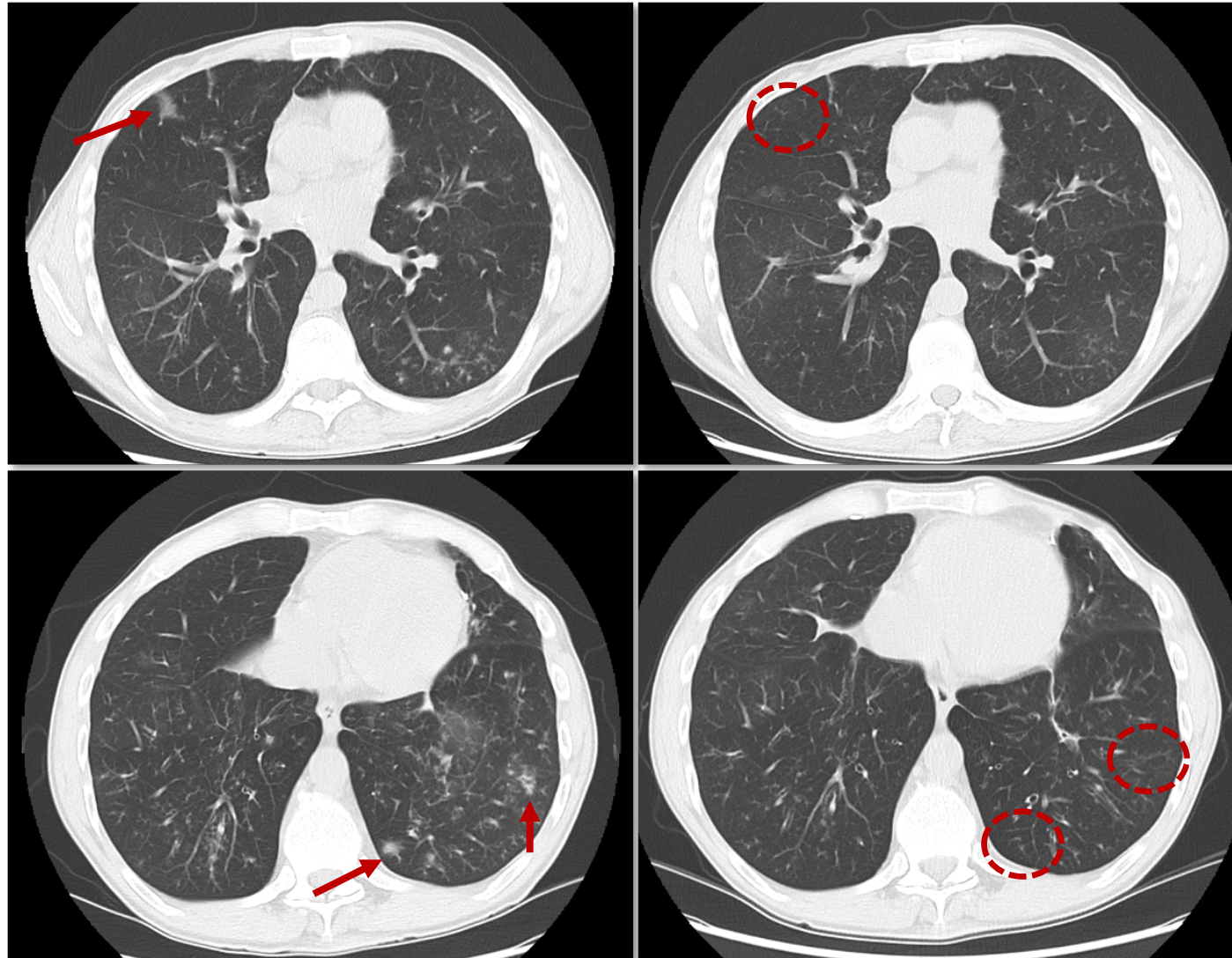
Data is from pre-database lock; Data cut off date: 11/17/23

*BAL: bronchoalveolar lavage

TFF VORI: Patient TFF VORI 4 (EAP)

(a)

(b)



Baseline

~Week 12

Data is from pre-database lock; Data cut off date: 11/17/23

Collaborations

Leveraging TFF's Platform for New Opportunities

Recent Government Collaborations



June 26, 2023

TFF Pharmaceuticals awarded \$2.97 million by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institute of Health (NIH), to develop a universal influenza vaccine using the company's Thin Film Freezing technology.



May 4, 2023

TFF Pharmaceuticals enters into CRADA with the National Institute of Environmental Health Sciences (NIEHS) to develop dry powder formulations of Hyaluronan to prevent and treat respiratory diseases.



May 1, 2023

TFF Pharmaceuticals receives additional funding from Leidos to advance next generation countermeasures for military and healthcare personnel under the DARPA Personalized Protective Biosystems (PPB) program.

Recent grants and contracts with various government agencies is further validation of Thin Film Freezing's potential

Business Development Opportunities for TFF's Platform

Internal Pipeline

- TFF VORI (inhaled voriconazole dry powder)
- TFF TAC (inhaled tacrolimus dry powder)

Vaccines

- Reformulation and development of new vaccines for intranasal and inhalational delivery and eliminating need for cold chain supply requirements

New Chemical Entities (NCEs)

- Formulating new product opportunities for both small and large molecules

Biologics

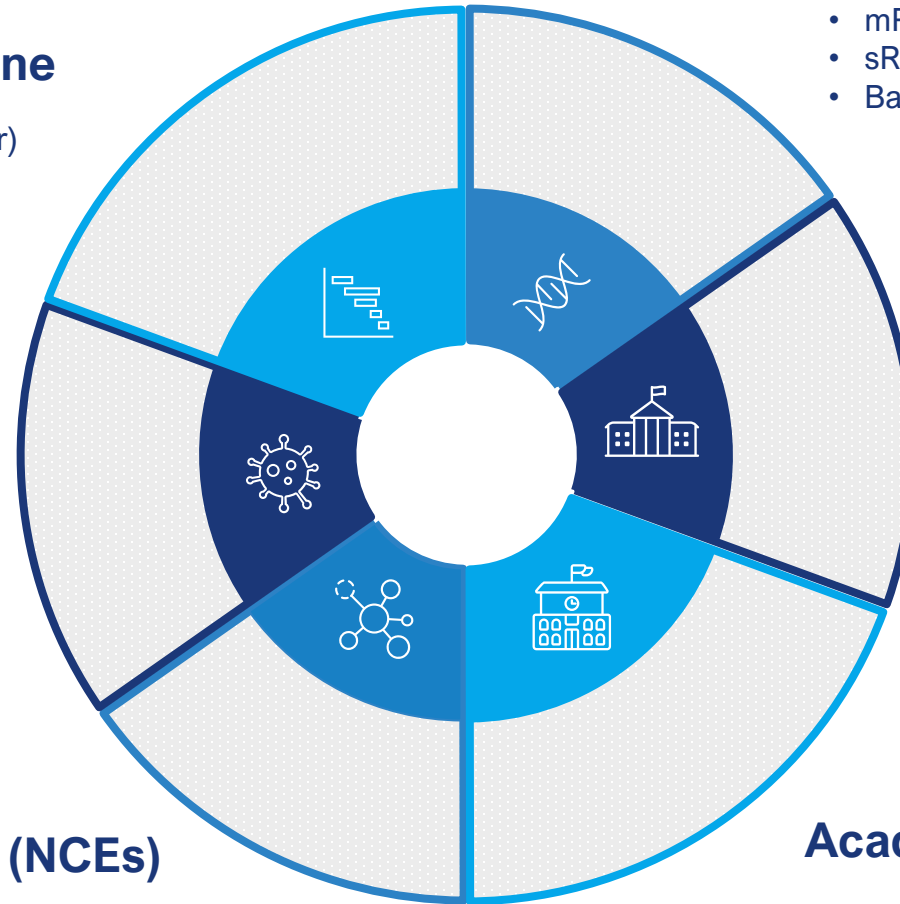
- mRNA
- sRNA
- Bacteriophages
- mAbs
- Peptides
- Peptoids

Government

- CRADA agreements with USAMRIID to formulate dry powder neutralizing antibodies against national priority biodefense threats
- CRADA agreement with NIEHS to develop dry powder formulations of Hyaluronan to prevent and treat respiratory diseases
- LEIDOS/DARPA contract
- SBIR with NIAID, Cleveland Clinic, and University of Georgia

Academia

- R&D collaborations with the Albert Einstein College of Medicine, Georgia Tech, and UPenn to develop biologics



TFF Leadership



Harlan F. Weisman, M.D.
Chief Executive Officer

- 30 years experience as a senior healthcare executive
- Former CEO of Flame Biosciences and Coronado Biosciences
- Former Group Company Chairman and President of J&J Pharmaceutical R&D



Zamaneh Mikhak, M.D.
Chief Medical Officer

- Physician-scientist, board certified in Allergy/ Immunology, with extensive clinical, drug development, and basic and translational research experience
- Previously served in senior clinical research & development roles at Cogent Biosciences, Boston Pharmaceuticals, Kiniksa Pharmaceuticals



Kirk Coleman
Chief Financial Officer

- Over 20 years of financial and accounting experience
- Previously served as an executive officer of Steelhead Capital Management, LLC and Bios Partners, LP



Anthony Hickey, Ph.D.
Senior Scientific Advisor and Chairman of the Scientific Advisory Committee

- Professor Emeritus in Pharmacoengineering & Molecular Pharmaceutics at UNC Chapel Hill
- Former CEO of Cirrus Pharmaceuticals and CSO of Oriol Therapeutics; author of multiple texts on inhalation and pharmaceutical process engineering

TFF Board and Advisors

Board of Directors

Harlan F. Weisman, M.D.
Chief Executive Officer



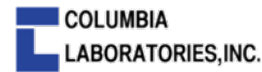
Thomas King
Director



Catherine Lee, J.D.
Director



Robert S. Mills
Director



Michael Patane, Ph.D.
Director



Brandi Roberts
Director



Stephen Rocamboli
Director



Scientific Advisory Board

Anthony Hickey, Ph.D.

Senior Scientific Advisor, and Chairman of the Scientific Advisory Committee

David N. Cornfield, M.D.

Professor of Pulmonary Medicine, Stanford University

Prof. David Denning, FRCP, FRCPath, DCH, FMedSci

Professor of Infectious Diseases, University of Manchester

Jay Peters, M.D.

Chief of Pulmonary and Critical Care Medicine, University of Texas Health Science Center at San Antonio

Ted M. Ross, Ph.D.

Professor, Center for Vaccines and Immunology, Department of Infectious Diseases, University of Georgia

Mike Saag, M.D.

Professor of Medicine, University of Alabama at Birmingham

Drew Weissman, M.D., Ph.D.

Roberts Family Professor, Vaccine Research at the Perelman School of Medicine, University of Pennsylvania

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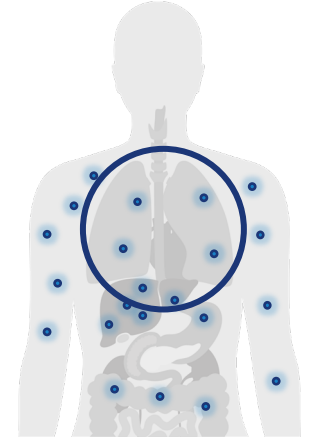
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- Both programs qualify for 505(b)2 pathway

Broadly Applicable Platform

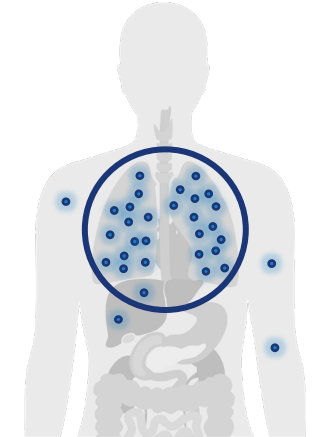
- Created dry powder formulations for a variety of small and large molecules
- Significant number of collaborations in place

Oral



Lower efficacy, Higher adverse events

Inhaled



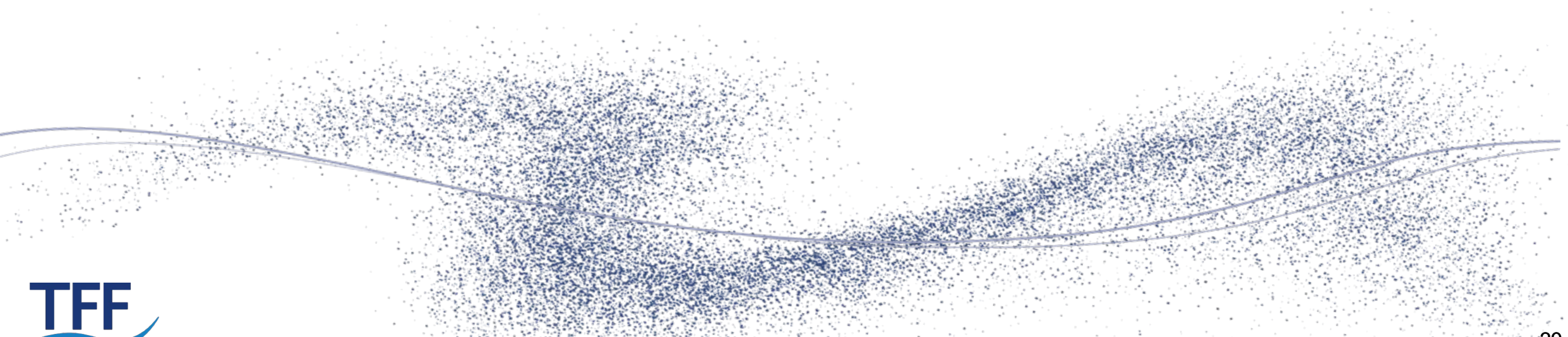
Higher efficacy, Lower adverse events



THANK YOU

TFF TAC Additional Information

Preclinical Data, Phase 1 Study Design, and Phase 1 Data



TFF TAC: Preclinical and Phase 1 provided safety, tolerability, and pharmacokinetic data and enabled Phase 2 planning

Preclinical POC Data:

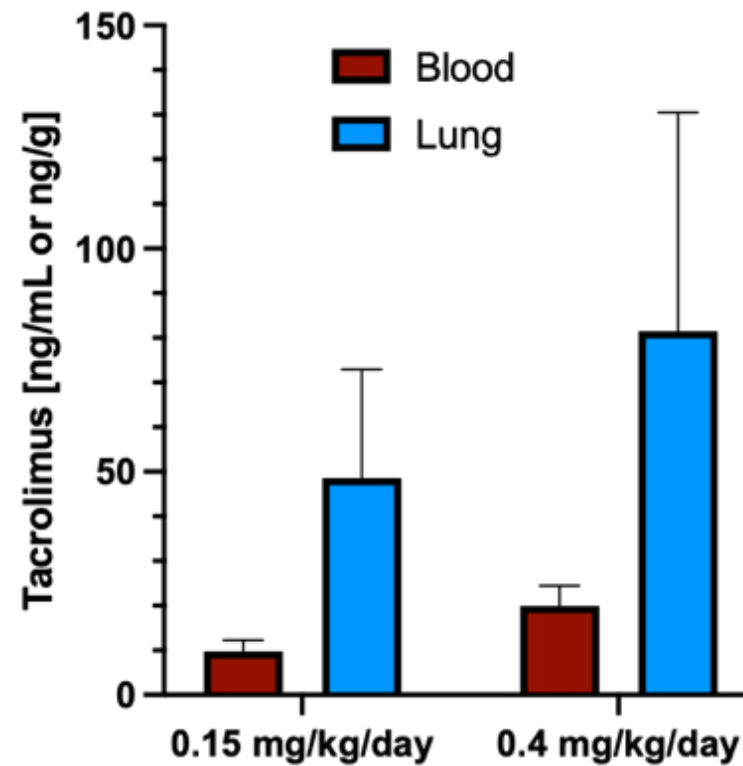
- Inhaled tacrolimus had similar efficacy compared to intramuscular tacrolimus in a rat lung transplant model
- Improved drug delivery to the lung

Phase 1 data:

- Successfully completed single and multiple ascending dosing of TFF TAC in healthy subjects in Phase 1 trial
- Doses up to 5 mg (single dose) and 1.5 mg (repeated dose) daily were generally well tolerated

TFF TAC Preclinical Data – Improved Drug Delivery to the Lung

Favorable lung distribution



Phase 1 Study Design

Study Overview

Design:

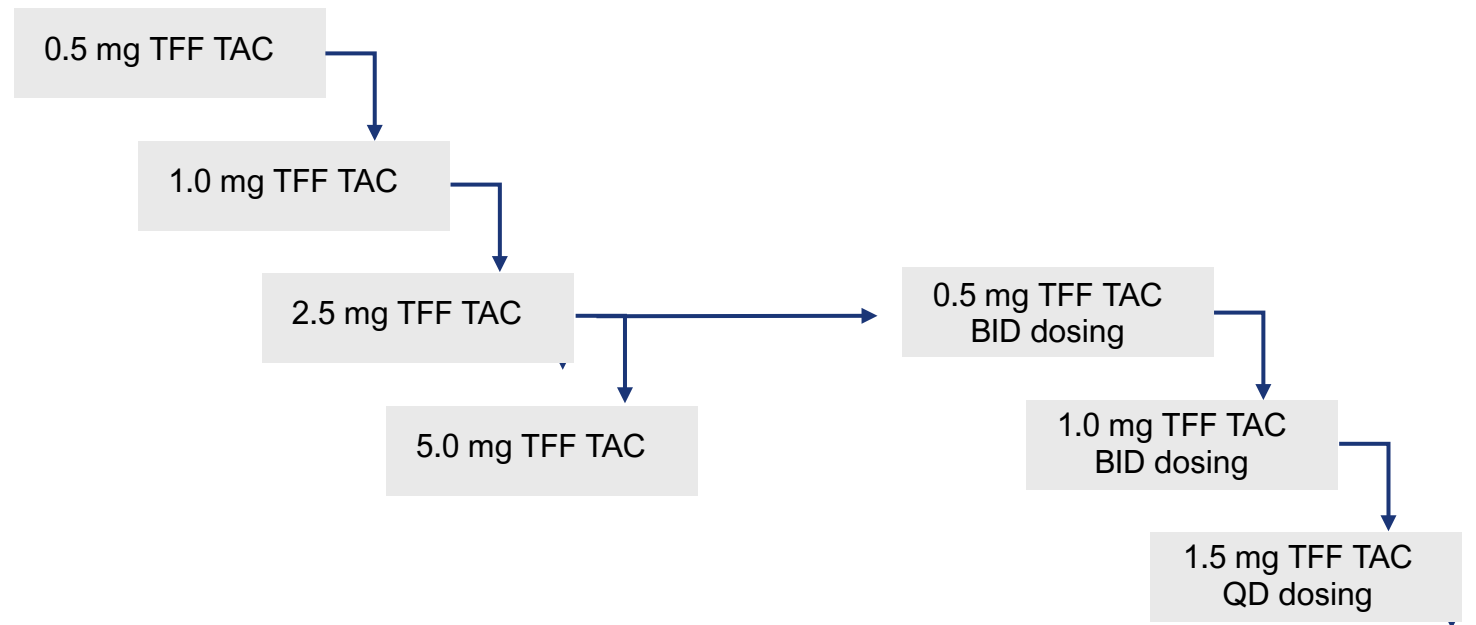
- Randomized, double-blind, placebo-controlled study of TFF TAC in 57 healthy adult volunteers
- Single ascending dose (SAD) and multiple ascending dose (MAD) phases

Endpoints:

- Safety and tolerability
- Pulmonary function
- Pharmacokinetics

PART A: SINGLE ASCENDING DOSE

N=32 healthy volunteers
3:1 active to placebo in each group

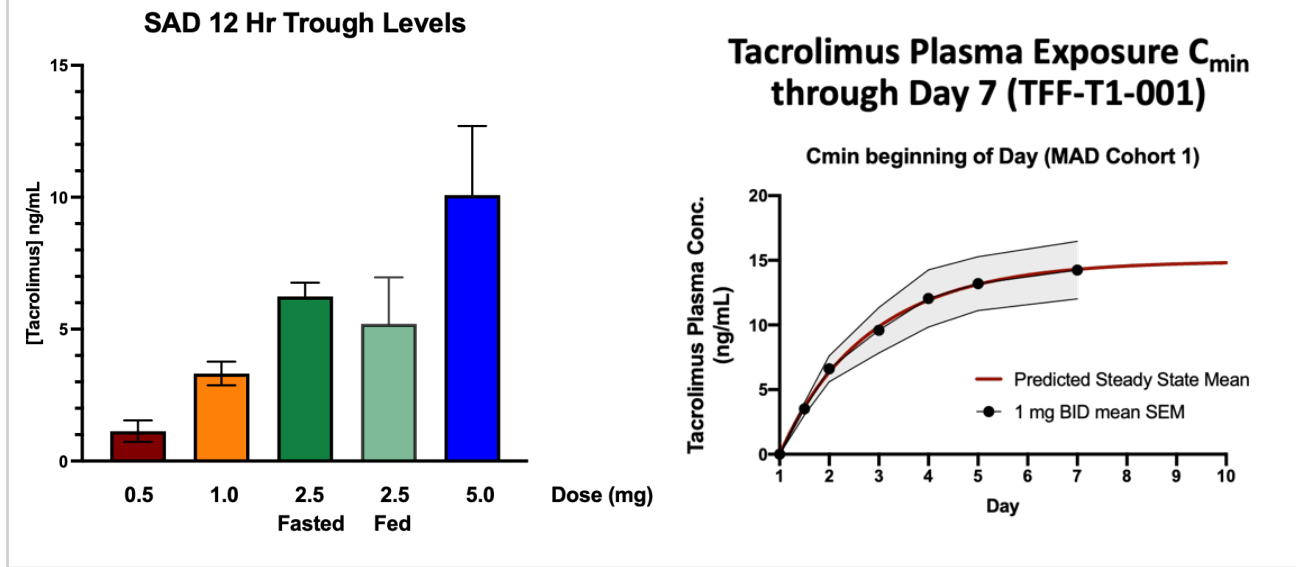


PART B: MULTIPLE ASCENDING DOSE

N=25 healthy volunteers
3:1 active to placebo in each group

Phase 1 Results Showed TFF TAC was Safe and Well-Tolerated

Pharmacokinetics



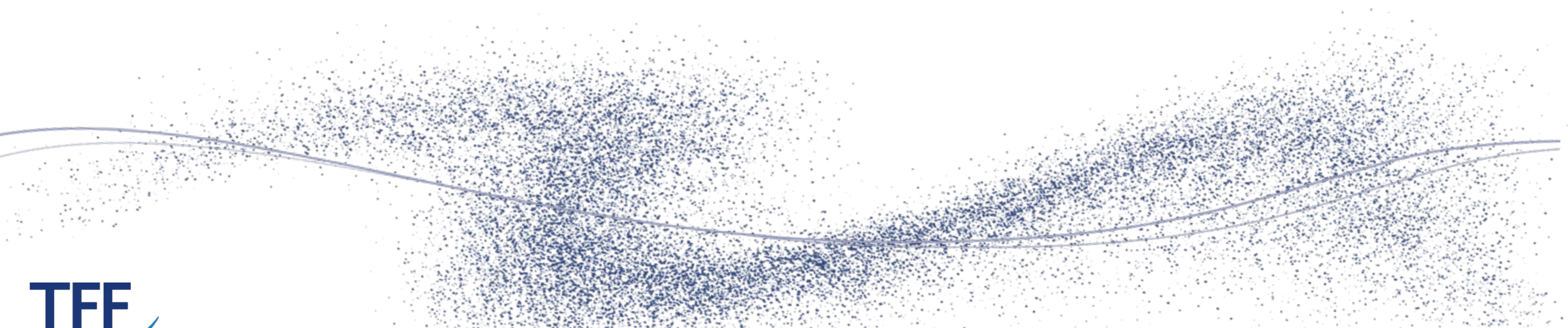
Safety

- ✓ Overall, TFF TAC was safe and well-tolerated
- ✓ No dose-related increase in overall treatment-emergent adverse events (TEAEs) was observed

TFF TAC demonstrated excellent safety and tolerability

TFF VORI Additional Information

Preclinical, Phase 1, and Compassionate Use Data



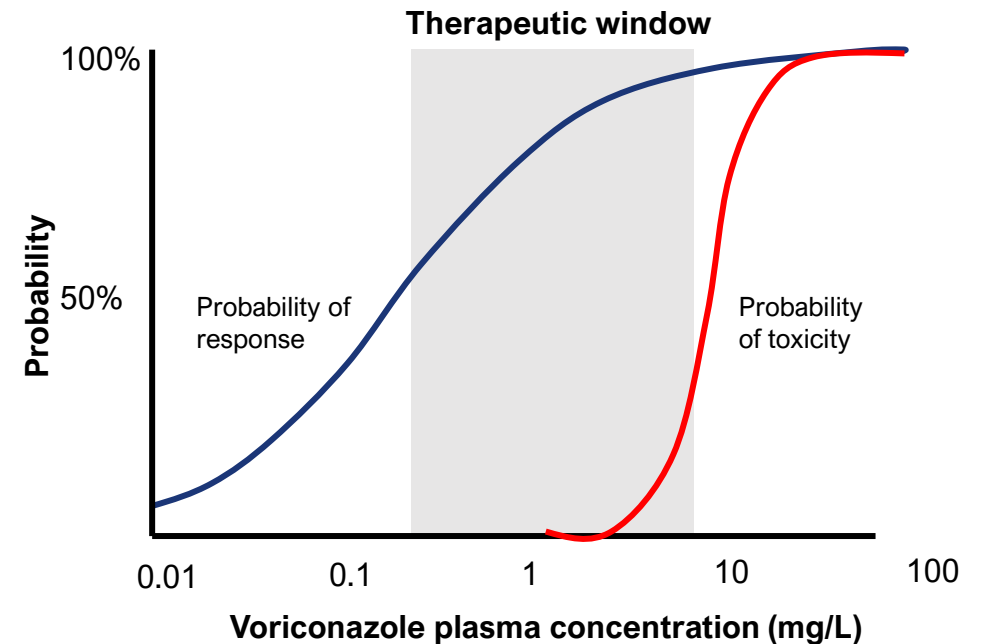
The Problem: Toxicity of IV and Oral Voriconazole

Poor side effect profile

Side Effects:

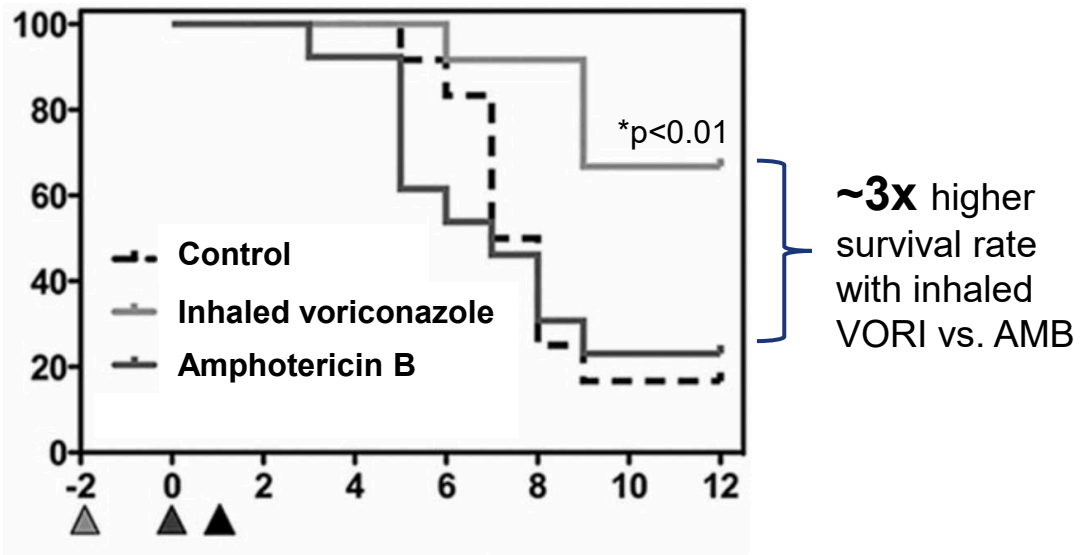
- Hepatic toxicity, arrhythmias and QT prolongation, infusion related reactions, visual disturbances, severe cutaneous adverse reactions, photosensitivity and renal toxicity¹
- **Alternatives:**
Oral and IV amphotericin B, echinocandins, and azoles, which are also limited by a narrow therapeutic window

Current SOC voriconazole has narrow therapeutic window²

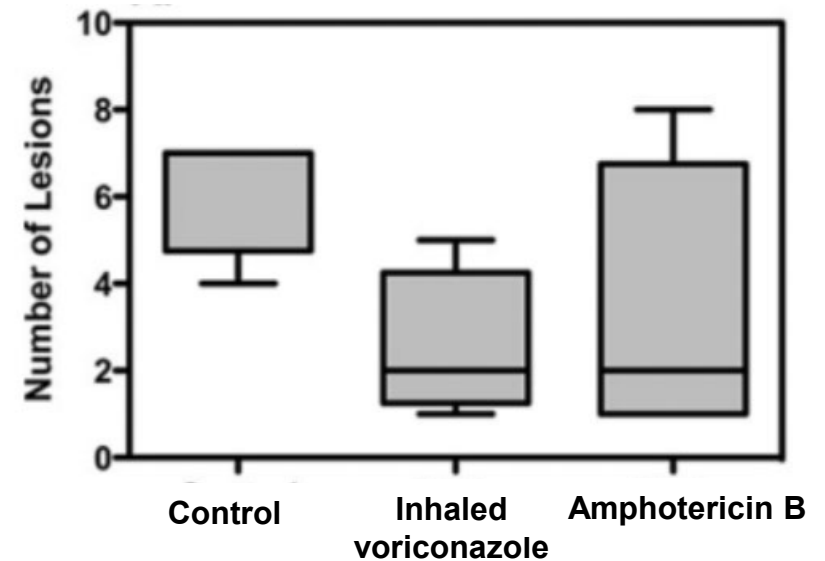


Preclinical Data of Inhaled Voriconazole

Increased survival



Decreased necrotic lesions in the lung



TFF VORI: Phase 1 studies and compassionate use data provided safety, tolerability, pharmacokinetic, and early efficacy data

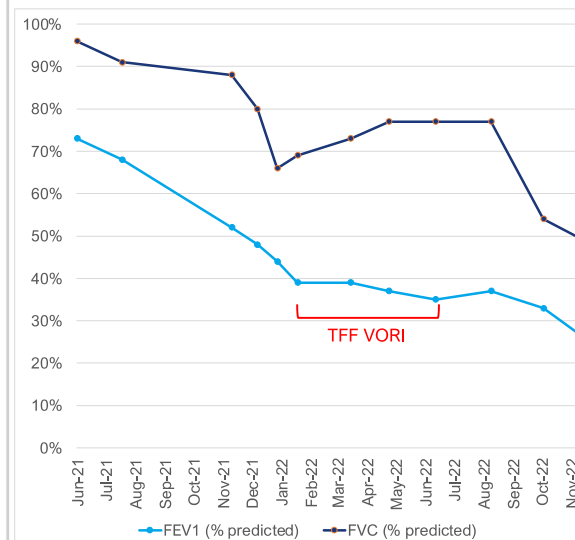
Phase 1 Results:

- Phase 1a (n=65 healthy volunteers) and Phase 1b (n=16 patients with mild stable asthma)
- Doses up to 80mg twice daily were well tolerated and showed no signs of the toxicities previously reported for the oral or intravenous forms.

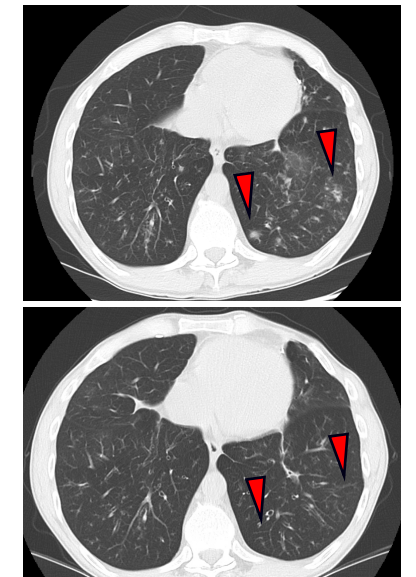
Compassionate Use Results: Two lung transplant recipients with history of recurrent pulmonary fungal infections and toxicities to systemic available standard of care therapy. Following treatment with TFF VORI:

- **Lung function stabilized/maintained**
- **Lung lesions improved**
- **Aspergillus infection cleared**
- **No need for hospitalization**
- **No drug-drug interactions**
- **No adverse events reported**

Stabilized Lung Function



Decreased Lesions



Phase 1 Study Design

Study Overview

Design:

- Randomized, double-blind, placebo-controlled study of TFF VORI in 65 healthy adult volunteers
- Single ascending dose (SAD) and multiple ascending dose (MAD) phases

Endpoints:

- Safety and tolerability
- Pulmonary function
- Pharmacokinetics

PART A: SINGLE ASCENDING DOSE

N=33 healthy volunteers
3:1 active to placebo in each group

10 mg TFF VORI

20 mg TFF VORI

40 mg TFF VORI

80 mg TFF VORI

PART B: MULTIPLE ASCENDING DOSE

N=32 healthy volunteers
3:1 active to placebo in each group
BID dosing

10 mg TFF VORI

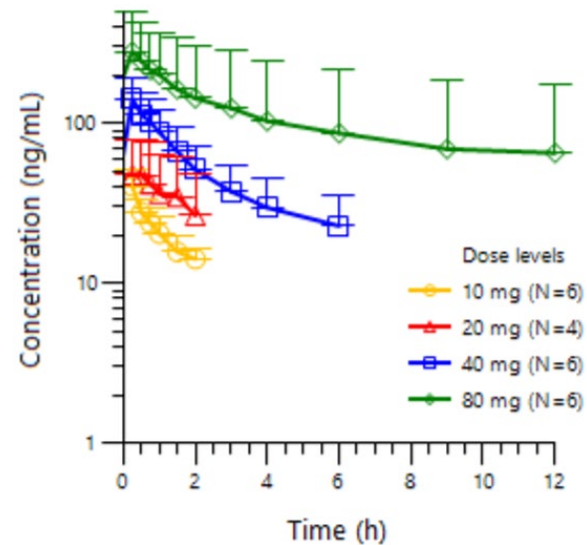
20 mg TFF VORI

40 mg TFF VORI

80 mg TFF VORI

Phase 1 Results Showed TFF VORI was Safe and Well-Tolerated

Multiple Ascending Dose Study Plasma Pharmacokinetics



- ✓ Therapeutic plasma voriconazole levels after oral voriconazole are 1-5.5 $\mu\text{g/ml}$ compared to nanogram levels after inhaled treatment*

Safety

No clinically meaningful differences between TFF VORI and placebo in:

- ✓ % of patients with treatment emergent adverse events (TEAEs)
 - ✓ Safety laboratory test results, vital signs, and pulse oximetry
 - ✓ Pulmonary function tests, electrocardiograms, and eye examination
- Single and multiple doses of TFF VORI (10 mg, 20 mg, 40mg, and 80mg) were well tolerated
 - No dose limiting toxicities
 - Most TEAEs were Grade 1. There were no Grade 3 or higher TEAEs
 - All TEAEs but one (headache) occurred in a single subject

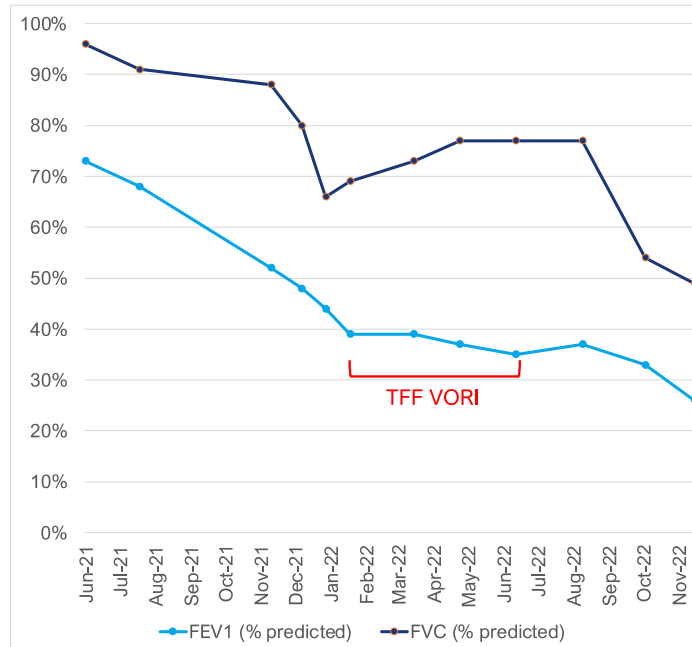
TFF VORI showed 10-50-fold lower plasma exposure compared to oral with excellent safety and tolerability

Compassionate Use: Patient 1

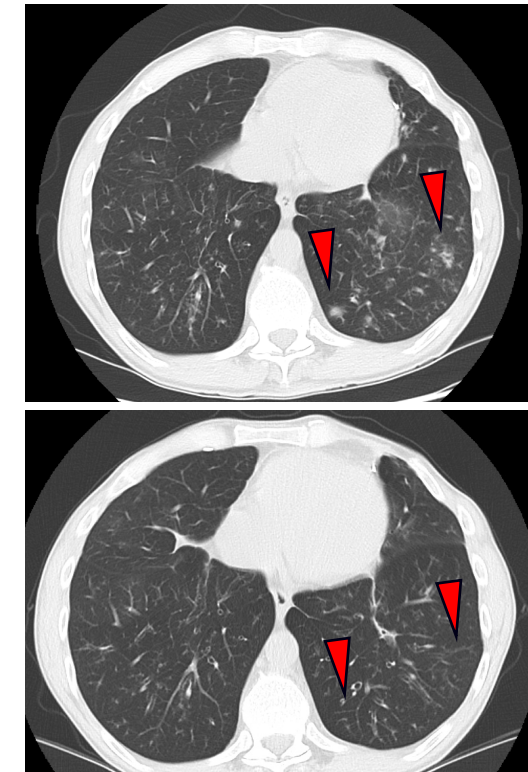
Patient characteristics

- 50-year-old man
- Lung transplant in 2019, treated with tacrolimus
- Multiple prior fungal infections
- Unable to take systemic voriconazole due to prior skin cancers including melanoma
- Posaconazole discontinued due to systemic toxicity
- 6 hospitalizations over 12 months before treatment
- Treated with TFF VORI, 80 mg, BID for 6 months

Stabilized lung function



Decreased lesions



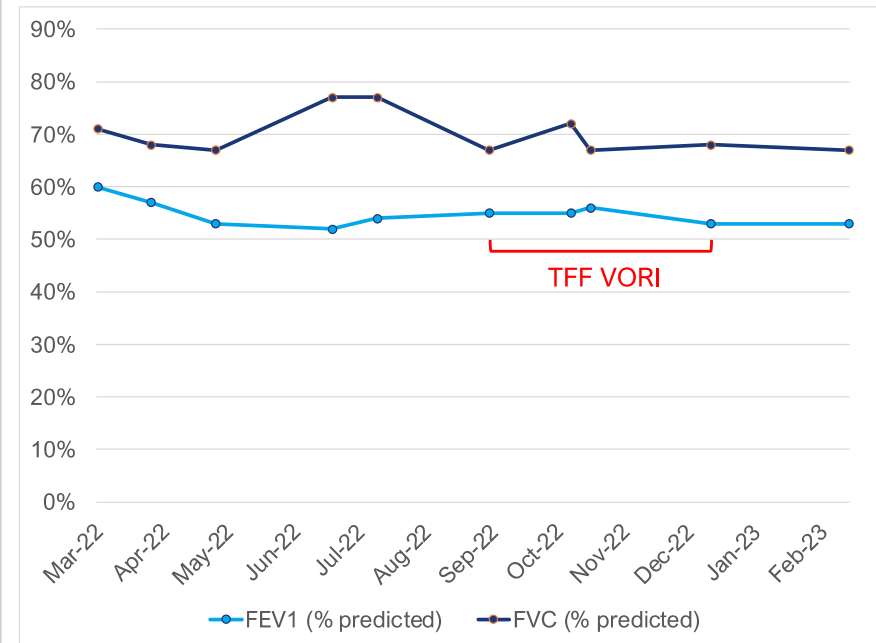
Patient's lung function stabilized; lung lesions improved with no evidence of drug-drug interaction

Compassionate Use: Patient 2

Patient characteristics

- 54-year-old woman
- Lung transplant in 1993, treated with tacrolimus
- Multiple prior fungal infections
- Prior treatment with systemic voriconazole and posaconazole
- Posaconazole discontinued due to systemic toxicities
- Treated with TFF VORI, 80 mg, BID for 13 weeks

Stable lung function



Patient maintained stable lung function; experienced mycological cure in 6 weeks with no drug-drug interactions