



# **Polyphor AG and EnBiotix Inc. Joint Meeting**

## **Proposed Merger and Vision of the Planned Joint Company**

September, 2021

# Forward-looking statement

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# Polyphor and EnBiotix Combination and Rationale

*Combination offers an organic pipeline combination with clinical assets and clear strategic focus*



- EnBiotix Inc., a privately held late clinical-stage rare disease company currently focused on products for rare, chronic respiratory diseases
- Polyphor and EnBiotix have signed a merger agreement planned to be completed in Q4 2021
- EnBiotix lead program is ColiFin® (worldwide rights ex-Europe): Approved in Europe since 2010 as a front-line therapy for lung infections in cystic fibrosis (CF)
- ColiFin® has a proven safety, efficacy and commercial track record which the combined company plans to leverage towards the U.S. and global markets with the initiation of a Ph. 3 study in CF in 2022
- Completion of merger will create a late-stage company with two clinical programs in cystic fibrosis - ColiFin® (Phase 3) and Inhaled Murepavadin (Phase 1)
- Company to strategically focus on rare diseases and orphan indications in oncology
- Opportunity to expand shareholder base, create a strong R&D and attractive equity story

# Proposed Merger and Structure

*Merger planned to close in Q4*



- Completion of merger agreement is expected in Q4 2021 subject to a number of closing conditions including shareholders' consent of both companies.
- Polyphor to acquire all of the outstanding capital stock of EnBiotix in exchange for shares of Polyphor common stock
- Combined company control is expected between 23 to 26% for Polyphor and 74-77% for EnBiotix depending on the planned financing round of EnBiotix prior to merger completion

## Planned Timelines:

September	October	Nov/ Dec
Call for shareholder meeting for approval of Merger	Shareholder meeting to approve merger	Closing & SIX Listing

# Combined Company Near and Mid Term Pipeline Goals



## Near-term Pipeline Goals in Rare Disease (Cystic Fibrosis):

- Initiation of a single Phase 3 trial of ColiFin® for the treatment of CF patients, upon completion of which the combined company plans to seek FDA approval in the US.
- Initiation of a Phase 1 trial of inhaled murepavadin for the treatment of CF patients.

## Mid to Long Term Pipeline Goals in Rare Disease and Oncology:

- EBX-002, a combination of amikacin (AMK) and a potentiator molecule for NTM infections which preclinical studies to date have shown potential for superior activity compared to ARYKACE®.
- Additional oncology and non-oncology indications for balixafortide will be evaluated in collaboration with Fosun Pharma who owns China rights.
- Polyphor's new CXCR4 inhibitors focused on orphan, hematological malignancies.
- Combined company aims to in-license or acquire other rare disease and oncology assets post-closing that will consolidate its position in these therapeutic areas
- ❖ CARBX funded preclinical AB programs to continue given increasing attractiveness of the AMR field

# Asset Purchase Agreement of Inhaled Murepavadin

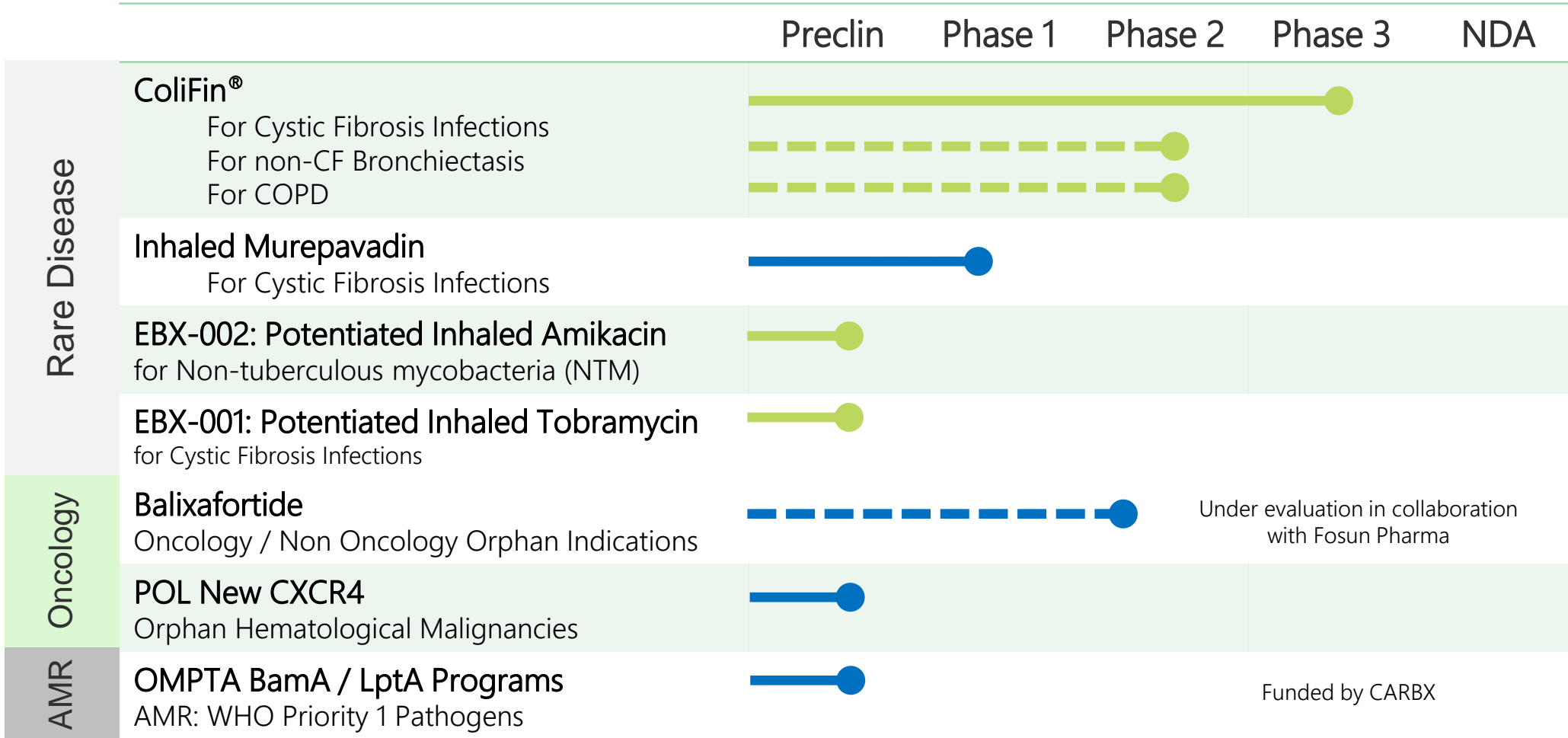
## *Rationale*



- EnBiotix acquires Polyphor's inhaled murepavadin expected to be closed in September prior to planned merger
- Agreed valuation of USD 10 million in exchange for 2'599'655 of common shares of EnBiotix (15.4% fully diluted of EnBiotix).
- Inhaled Murepavadin currently in Phase I development for cystic fibrosis organically fit with ColiFin® which is moving to Phase 3 development for treating lung infections in cystic fibrosis (CF)
- The asset purchase agreement of Inhaled Murepavadin increase attractiveness of the transactions:
  - Immediate equity to Polyphor prior to closing of the merger agreement
  - Expands EnBiotix pipeline in near-term focus area

# Pipeline of the Proposed Combined Company

Strategic Focus on Rare Disease and Oncology



- Combined company aims to in-license or acquire other rare disease and oncology assets

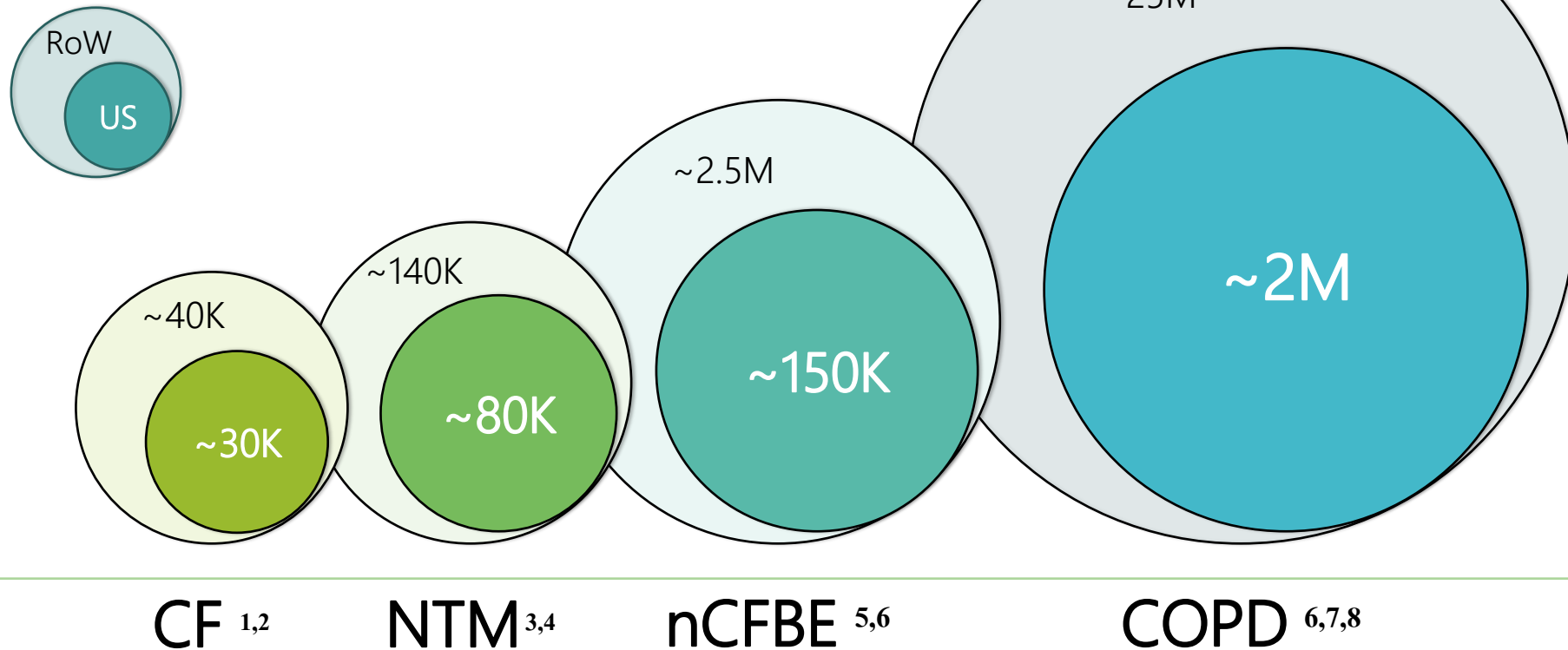
# Treatable Patients With Current & Planned Rare Disease Portfolio

Total US Patient Population:

>2M

RoW:

>25M



CF <sup>1,2</sup>

NTM <sup>3,4</sup>

nCFBE <sup>5,6</sup>

COPD <sup>6,7,8</sup>

1. <https://www.cff.org/Research/Researcher-Resources/Patient-Registry/2019-Patient-Registry-Annual-Data-Report.pdf>

2. <https://www.cff.org/What-is-CF/About-Cystic-Fibrosis/>

3. <https://www.lung.org/lung-health-diseases/lung-disease-lookup/nontuberculous-mycobacteria/learn-about-nontuberculous-mycobacteria>

4. Internal analysis of published NTM epidemiology and primary market research

5. Chron Respir Dis. 2017 Nov; 14(4): 377–384.

6. RWO is an estimate pro-rated for world population due to poor data

7. <https://www.lung.org/research/trends-in-lung-disease/copd-trends-brief/copd-prevalence>

8. <https://thorax.bmj.com/content/64/5/373>

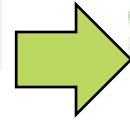




# ColiFin®: Inhaled Colistin For CF

## ColiFin® Validated in EU

- EMA approved 2010
- >15K patients dosed thus far
- Strong efficacy, minimal SAEs
- Front-line Rx for CF in EU
- Licensed to EnBiotix from PARI Pharma GmbH, world leader in nebulized drug delivery



## Leveraging EU Data to US & ROW

- Positive FDA feedback on EU data & clin-reg strategy: only single U.S. P3 trial needed for approval
- P3-start ~6 mos. post-merger
- ColiFin® projected to become front-line Rx as in EU
- Current CF ABXs priced at premium: \$7k - \$10k per 28d course

### EU CF Rx: 3 Major Antibiotics



TOBI



Cayston



ColiFin®

### US CF Rx: 2 ABX rotation



TOBI



Cayston



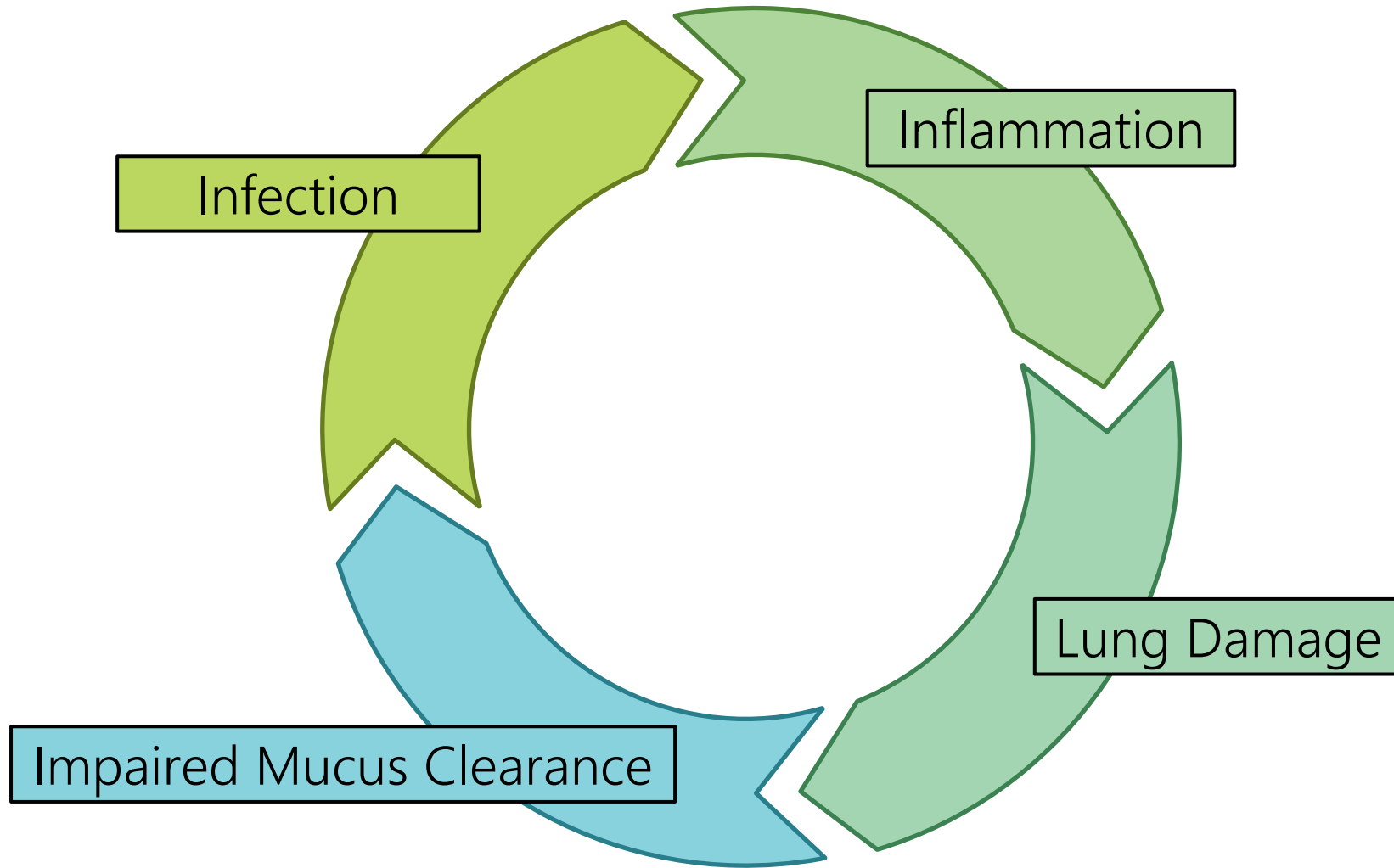
# Why Another Inhaled ABX For CF?

- 1 Because patients and clinicians want it
- 2 CF lung damage requires lifelong inhaled antibiotic Rx
- 3 Current inhaled ABXs inadequate: resistance (up to 40%), tolerability issues, decreased efficacy over time
- 4 Though CFTR correctors available, CFF projects patient population to expand over next 20-30 yrs
- 5 Inadequate *P. aeruginosa* Tx = ↑ hospitalizations = ↑ i.v. ABX use = ↑ toxicities, mortality & costs

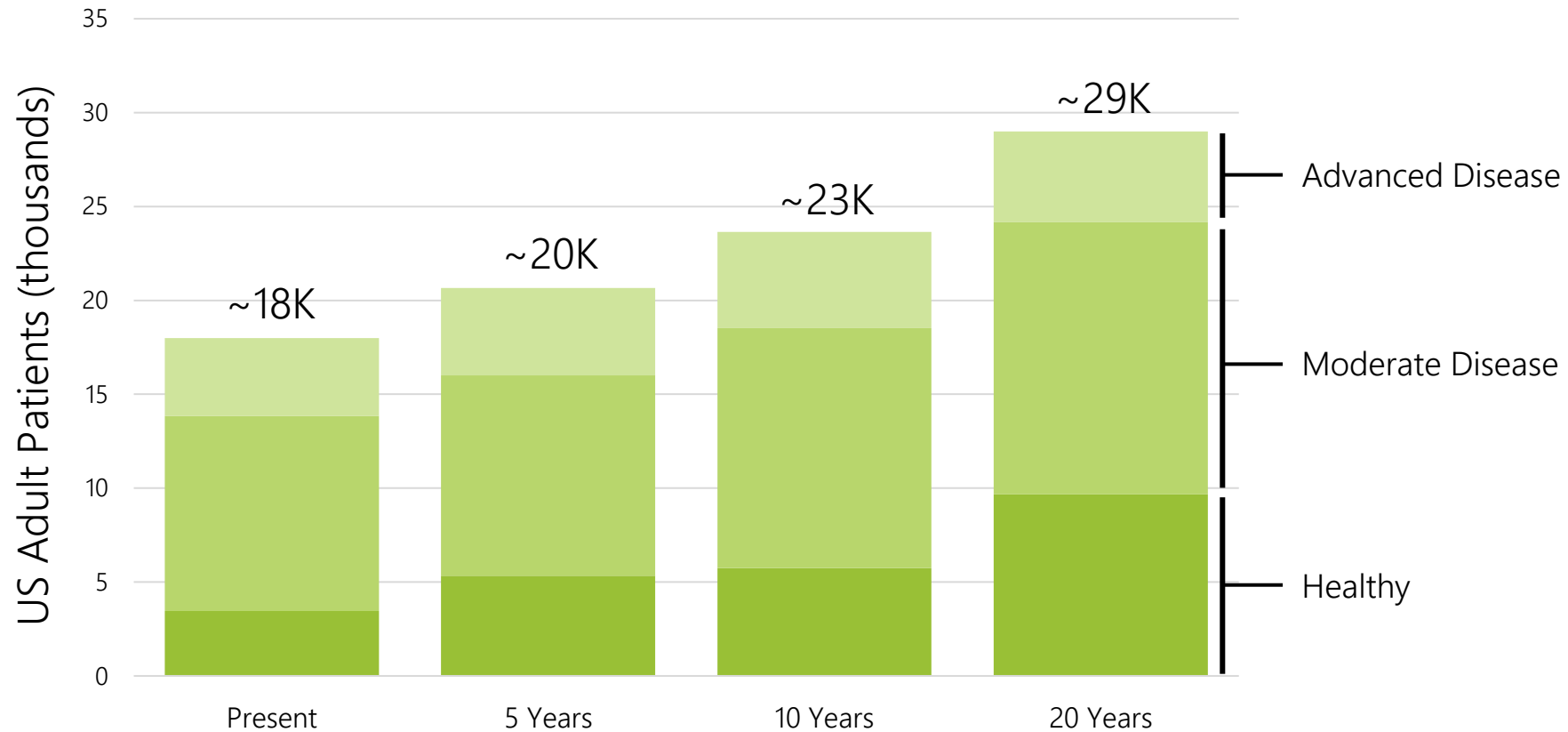
KOLs/patients confirm significant & urgent  
need for additional inhaled ABXs!



# Vicious Cycle of Progressive Lung Damage in CF Patients



# CFTR Modulators Expected to *Increase* CF Patient Population Targeted by ColiFin®



Reduced mortality / slowed disease progression ->  
More patients at all disease stages

# What's The Colifin® Market Opportunity?

## TOBI®/Cayston® set precedent for rapid inhaled ABX growth:

- ~12% of U.S. pts already using unapproved inhaled colistin due to need\*
- Unapproved inhaled tobi/aztreonam also prescribed pre-FDA approval
- Approved products (TOBI®/Cayston®) rapidly replaced unapproved usage (payers cannot force unapproved over approved usage)

## Proprietary device + drug combo

- High substitution barrier & brand-new patent protection

## Focused, low-cost commercial effort

- Almost all patients accessible via ~130 U.S. & ~42 Canadian CF clinical centers

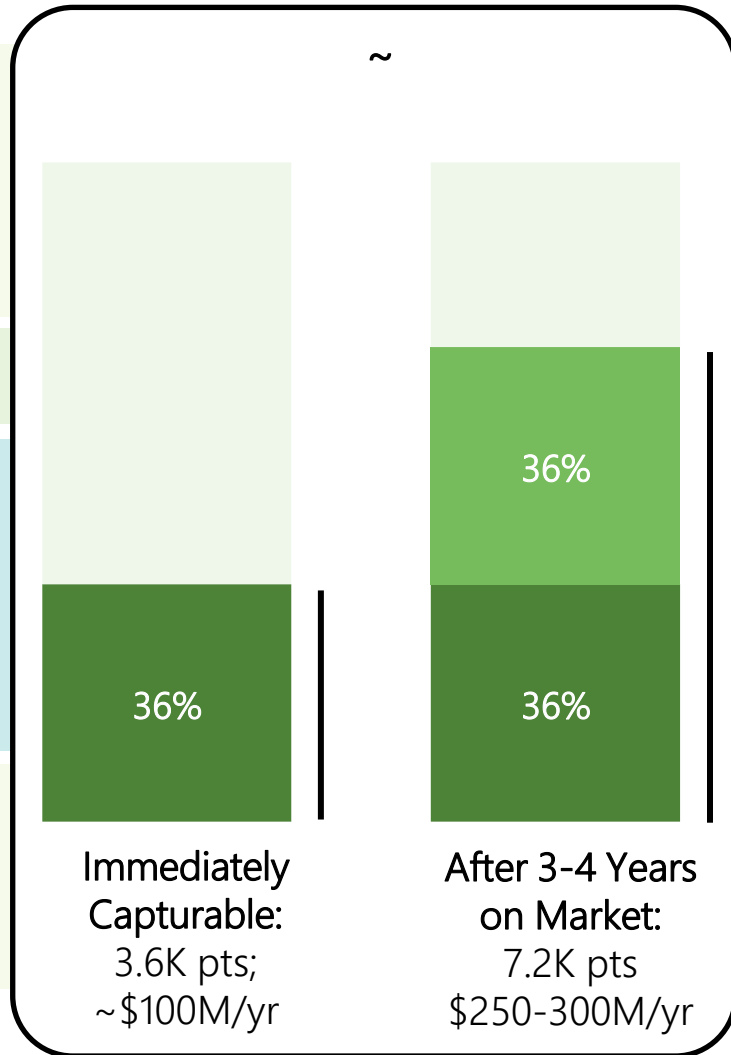
## ~35% ColiFin® mkt share in 3-4 yrs expected

- \$200–300M sales/yr; more with q.d. dosing

\* Internal calculations based on <https://www.cff.org/Research/Researcher-Resources/Patient-Registry/2019-Patient-Registry-Annual-Data-Report.pdf>



# The Colifin<sup>®</sup> Market Opportunity, cont'd



1 CF Foundation estimates ~12% of US CF adults (~36% US CF adults w/ moderate or advanced disease) currently treated w/ unapproved colistin

2 FDA strongly discourages unapproved use







3 @ ~\$25K/yr (low pricing), ColiFin<sup>®</sup> sales to only these patients ~\$100M/year in first full year

TOBI-like penetration grows revenues to \$250-300M/yr

Exact scenario pre-TOBI/Cayston<sup>®</sup> approval ⇒ rapid sales growth of each post-approval

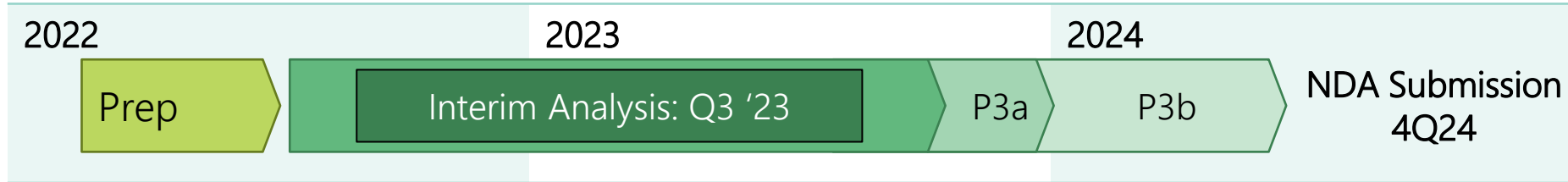
# ColiFin<sup>®</sup> EnBiotix Phase 3 Program Achievements

## *Significant ColiFin<sup>®</sup> Progress Over Last 18 Months*

Date	Regulatory Achievement
 Feb 2020	QIDP Designation Granted = 5 Yrs Market Exclusivity
 March 2020	Orphan Drug Designation Granted = Additional 7 Yrs Market Exclusivity ( <b>12 years total</b> )
 April 2020	IND Filed for Phase 3 Program
 May 2020	P3 "Study May Proceed" Letter Received From FDA
 Nov 2020	"Fast Track" Designation Received: Guarantees Expedited (6 mos) Review of Future NDA
 1H21	CFF's Therapeutic Development Network ("TDN") confirmation of P3 trial design & unmet need

# Colifin® EnBiotix Phase 3 Program Timelines

*Efficacy Readout Expected <12 Mos Post-P3 Start*



Trial Milestone	Time from Prev Milestone	Projected Completion Date
P3 Prep	6 months	Q2 '22
P3a First Patient In	1 month	Q3 '22
<b>Interim Efficacy Analysis</b> (60% P3a complete)	<b>11 months</b>	<b>Q3 '23</b>
P3a Last Patient In	4 months	Q4 '23
P3a Last Patient Out	1 month	Q1 '24
P3a Readout	1 month	Q1 '24
P3b Last Patient Out	5 months	Q2 '24
P3b Readout	1 month	Q3 '24

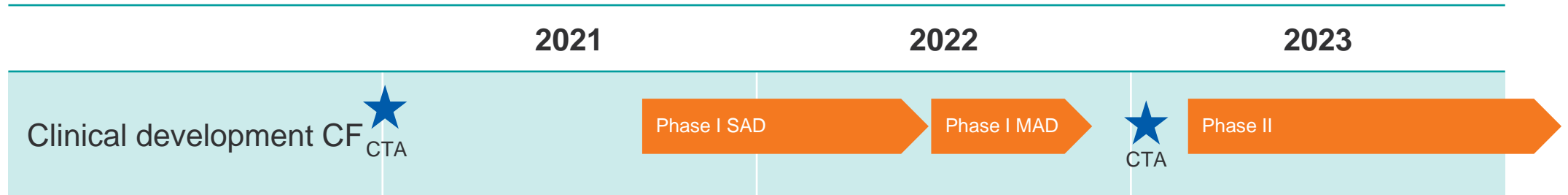


# Inhaled Murepavadin for Cystic Fibrosis

Changing the treatment paradigm in treating chronic *P. aeruginosa* infections in Cystic Fibrosis



Potentially the first pathogen specific new class inhaled antibiotic for *P. aeruginosa*, leading cause of exacerbations, lung function decline and mortality in CF



## Clinical Program Plan and Timelines:

- Clinical Trial Authorization (CTA) granted following preclinical program suggesting broad safety margin and efficacy
- Phase I study plan to include single and multiple dosing in healthy volunteers up to 7 days.
- Patient enrollment start expected in Q4 2021 supported by IMI
- Phase Ib/IIa study planned in patients with CF supported by CF Foundation

## Targeted and attractive rare disease opportunity:

- Attractive orphan market opportunity
- Comparators' \* peak sales (200-400m USD)
- Can be expanded from CF to Non Cystic Fibrosis Bronchiectasis and beyond

Additional indications and combinations beyond Cystic Fibrosis will be jointly assessed

# Current EnBiotix Leadership Team and Board

<p><b>Jeffrey Wager, MD</b> Chairman &amp; CEO</p>	<p>30 yrs VC &amp; CEO leadership; &gt;\$335M VC &amp; \$2.5B in public &amp; M &amp; A capital raised</p>	
<p><b>Juergen Froehlich, MD</b> CMO</p>	<p>30+ yrs CMO/Sen. Reg Affairs experience</p>	
<p><b>Stephan Wehselau</b> CFO</p>	<p>20+ years CEO &amp; CFO experience, ~\$400M raised in career</p>	
<p><b>Dennis Ausiello, MD</b> Director</p>	<p>17yrs Physician-in-Chief, MGH 8 yrs lead director, Pfizer board</p>	
<p><b>Robert Clarke, PhD</b> Director</p>	<p>20+ yrs inhaled R &amp; D, CEO experience</p>	
<p><b>Dan Hartman, MD</b> Director</p>	<p>25+yrs R &amp; D leadership; Head of \$2B Gates malaria portfolio</p>	
<p><b>Roberto Guttman</b> Director</p>	<p>30+ years serial entrepreneur/CEO/investor experience</p>	
<p><b>Dave Knudson</b> Observer</p>	<p>Lead lawyer for billionaire investor T. Denny Sanford; S.D. Senate Majority Leader &amp; 4-term State Senator</p>	

# Current EnBiotix Scientific Advisory Board and Clinical Advisors

## Scientific Advisory Board



**Jim Collins, Ph.D.,**  
**Co-Founder & Chair**

- MIT Termeer Prof. of Bioeng, Vice Chair, Broad; academic co-founder, Wyss Institute



**Donald VanDevanter, PhD**

- Noted inhaled ABX developer for CF/NCFBE/NTM
- Key CF Foundation advisor



**Mark Murcko, Ph.D.**

- CSO Dewpoint
- CSO Relay
- CTO Vertex
- Multiple SABs and Boards



**Jared Silverman, Ph.D.**

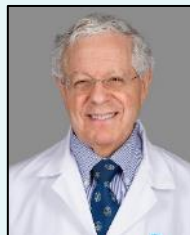
- Head of Translational Discovery at Gates Medical Res. Inst.
- Kaleido, SVP Research
- Cubist, VP Disc. Biol.



**Dao Nguyen, M.D.**

- Leading CF clinician-scientist & *Pae* microbiologist
- Assoc. Prof. Medicine at McGill University

## Clinical Advisors



**Jeff Gelfand, MD**

- Infectious Disease physician MGH
- Clinical Prof. Medicine at Harvard Med
- CSO Boston BioCom



**Henry Dorkin, MD**

- Co-Director of the CF Clinical Center Boston Children's Hospital
- Assoc. Prof. Pediatrics at Harvard Med



**Patrick Flume, MD**

- Dir. CF Center & Prof. Pulmonary & Critical Care Medicine at Medical U of South Carolina



**Mike Konstan, MD**

- Vice Dean for Trans. Res. & Tucker Prof. of Pediatrics, Case Western; leading inhaled colistin KOL



**David Nichols, MD**

- CFF TDN Medical Dir.
- Assoc. Prof. Pediatrics at University of Washington & Seattle Children's Hospital

# Polyphor and EnBiotix Combination

Combination offers an organic pipeline combination with clinical assets and clear strategic focus



- Polyphor and EnBiotix planned merger to be completed in Q4 2021 offers an organic pipeline combination with clinical assets and clear strategic focus
  - A late-stage company with two clinical programs in cystic fibrosis - ColiFin® (Phase 3) and Inhaled Murepavadin (Phase 1) in the near term (*Near-term Goals*)
  - Company to strategically focus on rare diseases and orphan indications in oncology (*Mid-Long term Goals*)
    - Enbiotix rare respiratory disease portfolio with EBX-002: Potentiated Inhaled Amikacin for Non-tuberculous mycobacteria (NTM)
    - Polyphor's new CXCR4 inhibitor for orphan hematological malignancies
    - Balixafortide oncology / non-oncology strategy to be evaluated (inc. China with Fosun Pharma)
    - Combined company aims to in-license or acquire other rare disease and oncology assets post-closing that will consolidate its position in these therapeutic areas
- Opportunity to expand shareholder base, create a strong R&D and attractive equity story