



# Developing innovative therapies for the treatment of respiratory diseases

January 2025

Nasdaq: VRNA | [www.veronapharma.com](http://www.veronapharma.com)



# Forward-looking statements

This presentation contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this presentation other than statements of historical fact should be considered forward-looking statements. Words such as “anticipate,” “believe,” “plan,” “expect,” “intend,” “may,” “potential,” “prepare,” “possible” and similar words and expressions are intended to identify forward-looking statements. These forward-looking statements include, but are not limited to, statements regarding the potential benefits and efficacy of our drug Ohtuvayre™ to treat adult patients in the US with COPD, as well as the continued growth of sales and adoption by HCPs of Ohtuvayre, and statements regarding our two recently initiated Phase 2 clinical trials.

These forward-looking statements are based on management's current expectations. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from our expectations expressed or implied by the forward-looking statements, including, but not limited to, the following: our limited operating history; our need for additional funding to complete development and commercialization of Ohtuvayre which may not be available and which may force us to delay, reduce or eliminate our development or commercialization efforts; our reliance on the success of Ohtuvayre, our only commercial product; our reliance on third-party manufacturers and suppliers; the efficacy of Ohtuvayre™ compared to competing drugs; our ability to successfully commercialize Ohtuvayre; serious adverse, undesirable or unacceptable side effects associated with Ohtuvayre which could adversely affect our ability to commercialize Ohtuvayre; failure to develop Ohtuvayre for additional indications, alternate delivery methods, or as a combination therapy; failure to obtain approval for and commercialize Ohtuvayre in multiple major pharmaceutical markets; lawsuits related to patents covering Ohtuvayre and the potential for our patents to be found invalid or unenforceable; lawsuits related to our licensing of patents and know-how from third parties for the commercialization of Ohtuvayre; changes in our tax rates, unavailability of certain tax credits or reliefs or exposure to additional tax liabilities or assessments that could affect our profitability, and audits by tax authorities that could result in additional tax payments for prior periods; and our vulnerability to natural disasters, global economic factors, geo-political actions and unexpected events, including health epidemics or pandemics. These and other important factors discussed under the caption “Risk Factors” in our Quarterly Report on Form 10-Q for the period ended September 30, 2024 filed with the Securities and Exchange Commission (“SEC”) on November 4, 2024, and our other reports filed with the SEC, could cause actual results to differ materially from those indicated by the forward-looking statements made in this presentation. Any such forward-looking statements represent management's estimates as of the date of this presentation. While we may elect to update such forward-looking statements at some point in the future, we disclaim any obligation to do so, even if subsequent events cause our views to change, except as required under applicable law. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this presentation.

# Ohtuvayre™ is available for the maintenance treatment of COPD in adult patients

Label supports broad use in COPD patients

**Ohtuvayre™**  
(ensifentrine) Inhalation Suspension

3 mg/2.5 mL

***Broad Use / Novel MOA***

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***FY 2024 Net Sales ~\$42M\****

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***FY 2024 >16,000 prescriptions filled and 3,500 unique writers***

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***~One-third of prescriptions were refills***

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**First inhaled COPD treatment providing bronchodilation and non-steroidal anti-inflammatory effects**

Ohtuvayre prescribing information

\*Unaudited net product sales

# Strong financial position to support company growth

Future draws up to \$425M provide optionality beyond 2026<sup>1</sup>

**\$36M**

Approximate Net Revenue  
Quarter ended December  
31, 2024<sup>2</sup>

**\$400M**

Approximate Cash  
and Equivalents  
December 31, 2024<sup>3</sup>

**\$3.9B**

Market Cap  
(Nasdaq: VRNA)  
December 31, 2024<sup>4</sup>

## Potential future draws

- **\$275M** under \$400M debt facility
- **\$150M** under \$250M Revenue Interest Purchase and Sale Agreement<sup>5</sup>

1 - Runway expectations based on cash and equivalents as of December 31, 2024, and future draws on Oaktree/OMERS debt facility and RIPSAs.

2 - Unaudited net product sales.

3 - Includes \$100M of gross ATM proceeds received in Q4 2024.

4 - Approximately 84.6M ADSs outstanding as of December 31, 2024 (equivalent to ~ 667M ordinary shares).

5 - Repayment capped at 1.75x of the amount funded.

# Verona Pharma's respiratory product pipeline

Ensifentrine provides multiple product opportunities

Product	Indication	Pre-clinical	Phase 1	Phase 2	Phase 3	Approved / Available
Ensifentrine (Nebulizer)	Maintenance treatment of COPD					
	Non-Cystic Fibrosis bronchiectasis					
	Cystic Fibrosis					
	Asthma					
Ensifentrine + LAMA (Nebulizer)	Maintenance treatment of COPD					
Ensifentrine (DPI / MDI)	Maintenance treatment of COPD					
	Asthma					
	Cystic Fibrosis					

LAMA: Long-acting muscarinic agent

DPI: Dry powder inhaler, pMDI: Pressurized metered-dose inhaler

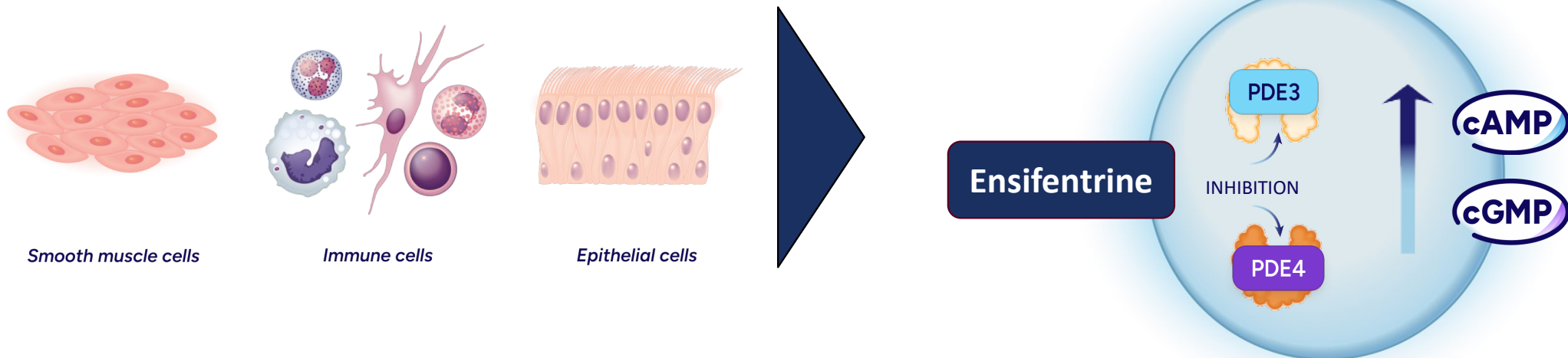


# Ensifentrine: Novel selective inhibitor of PDE3 and PDE4

## Downstream bronchodilation and non-steroidal anti-inflammatory effects

PDE3 and PDE4 enzymes are present in lung cells associated with COPD pathology:

Selective inhibition of PDE3 and PDE4 results in accumulation of intracellular levels of signaling molecules, cAMP and cGMP



### This mechanism of action produces:

- Bronchodilation
- Decreased inflammatory response
- Increased ciliary function

cAMP = cyclic adenosine monophosphate; cGMP = cyclic guanosine monophosphate; PDE3 = phosphodiesterase 3; PDE4 = phosphodiesterase 4.

<sup>1</sup>Calzetta L, et al., *J Pharmacol Exp Ther*. 2013;346(3); <sup>2</sup>Calzetta L, et al., *Pulm Pharmacol Ther* 2015;32:15-23; <sup>3</sup>Matera MG, et al., *Am J Respir Crit Care Med* 2013;187:A1495; <sup>4</sup>Venkatasamy R, et al., *Br J Pharmacol* 2016;173(15):2335-2351; <sup>5</sup>Boswell-Smith V, et al., *J Pharmacol Exp Ther* 2006;318(2):840-848; <sup>6</sup>Franciosi LG, et al., *Lancet Respir Med* 2013;1(9):714-727; <sup>7</sup>Schmidt D, et al., *Br J Pharmacol* 2000;131(8):1607-1618; <sup>8</sup>Turner MJ, et al., *Am J Physiol Lung Cell Mol Physiol* 2016;310(1):L59-70

# Phase 3 data published in *American Journal of Respiratory and Critical Care Medicine*

Endpoint	ENHANCE-1 (N=760)	ENHANCE-2 (N=789)
Average FEV <sub>1</sub> AUC (0-12 hours)	+87 mL (p<0.0001) vs placebo	+94 mL (p<0.0001) vs placebo
Peak FEV <sub>1</sub>	+147 mL (p<0.0001) vs placebo	+146 mL (p<0.0001) vs placebo
Morning Trough FEV <sub>1</sub>	+35 mL (p=0.0413) vs placebo	+49 mL vs placebo <sup>a</sup>
Symptoms (E-RS Total Score)	-1.0 units (p=0.0111) vs placebo	-0.6 units vs placebo <sup>b</sup>
Quality of Life (SGRQ Total Score)	-2.3 units (p=0.0253) vs placebo	-0.5 units vs placebo <sup>b</sup>
Exacerbation rate	36% reduction in rate <sup>c</sup>	43% reduction in rate <sup>c</sup>
Time to first COPD exacerbation	38% reduction in risk <sup>c</sup>	42% reduction in risk <sup>c</sup>
Incidence of adverse events (AEs ≥1% and greater than placebo)	Back Pain 1.8% vs 1.0% Hypertension 1.7% vs 0.9% UTI 1.3% vs 1.0% Diarrhea 1.0% vs 0.7%	

<sup>a</sup> Result was not statistically significant due to failure higher in the analysis hierarchy

<sup>b</sup> Not significant

<sup>c</sup> Pre-specified other endpoints were not part of the formal testing hierarchy

UTI = Urinary tract infection

# Pipeline expansion : Non-cystic fibrosis bronchiectasis (NCFBE)

Chronic disease marked by recurrent infection and progressive lung damage

~370,000 US Patients<sup>1,2</sup>  
No Approved Treatments

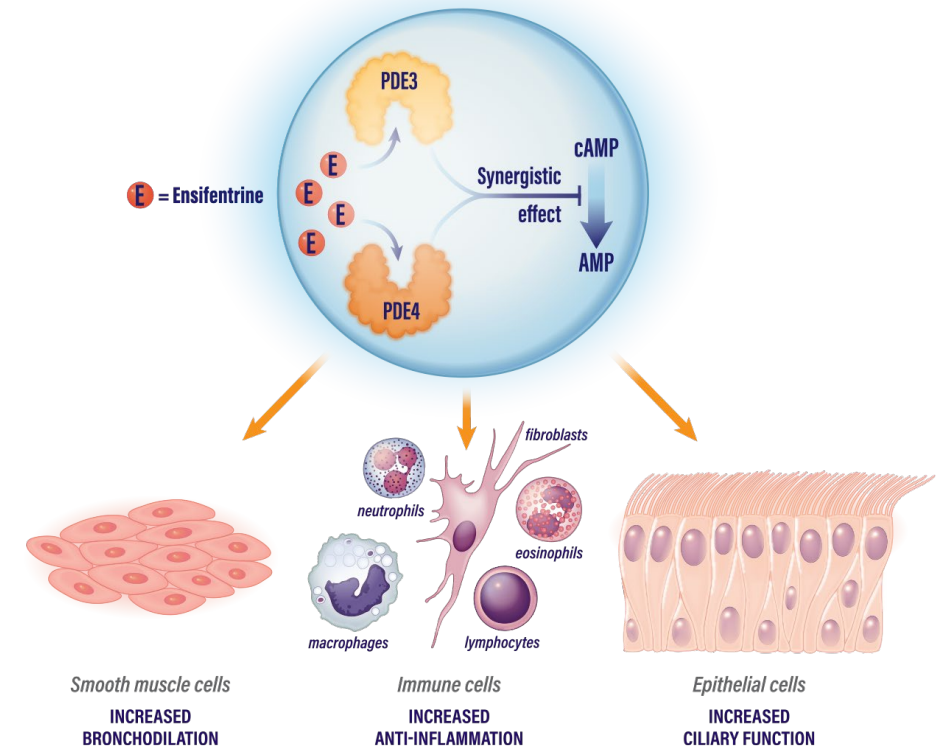
## Key Issues

- Exacerbations (neutrophilic driven)
- Cough & sputum production

## Unmet Needs

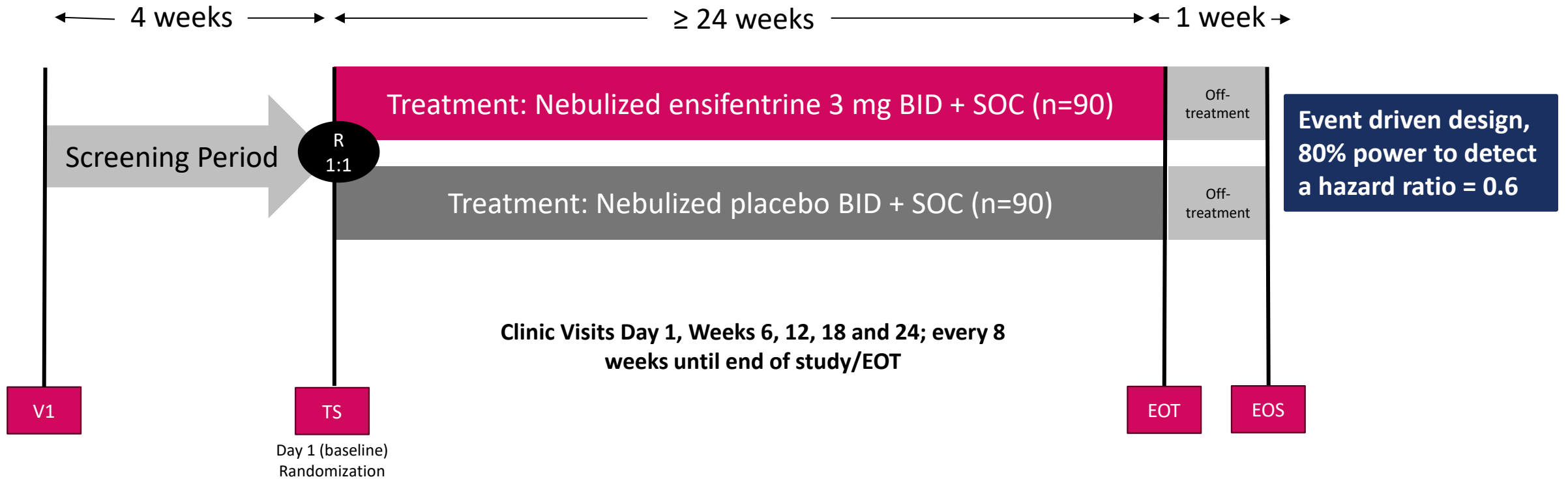
- High level of unmet need due to lack of approved options
- Anti-inflammatory drugs (international guidelines on bronchiectasis discourage use of corticosteroids)

Ensifentrine Targets Neutrophilic Inflammation,  
Impacts Exacerbations & Key NCFBE Symptoms





# Bronchiectasis Phase 2 Design



**Primary endpoint:** Protocol-defined pulmonary exacerbation rate

**Secondary endpoints:**

- Time to first pulmonary exacerbation
- Patient Reported Outcomes: E-RS cough and sputum domain, QoL-B (respiratory), SGRQ, CAAT
- Lung function (pre and post-dose)

# Pipeline expansion: Fixed dose combination

COPD market has progressed to combination products to maximize efficacy given chronic, progressive disease

## Rationale for Ensifentrine + Glycopyrrolate

- Synergistic effect demonstrated on bronchial smooth muscle and isolated bronchi with ensifentrine + glycopyrrolate<sup>1</sup>
- >400 subject Phase 2b study completed with ensifentrine added on to a LAMA<sup>2</sup>
- >400 subjects were dosed with ensifentrine or placebo + LAMA in the ENHANCE program over 24 weeks
- Data supports strong improvement in lung function, symptoms, QoL and exacerbations added on to a LAMA<sup>3</sup>
- Combines 2 bronchodilator mechanisms with non-steroidal anti-inflammatory effects

## Phase 2 program design supports dose selection for Phase 3

- **Glycopyrrolate dose ranging (n=40, >80% power)**
  - 4 x 1 week treatment periods with 1 week washouts
  - 3 doses + placebo
  - Endpoints: Day 7 Trough FEV<sub>1</sub>, peak FEV<sub>1</sub>, average FEV<sub>1</sub> AUC<sub>0-12</sub>
- **Fixed-dose combination versus glycopyrrolate and ensifentrine individual components (n=480, >80% power)**
  - 4 week parallel group design
  - 6 dose arms: 2 combination doses + 3 individual component arms + placebo
  - Endpoints: Week 4 average FEV<sub>1</sub> AUC<sub>0-4</sub>, peak FEV<sub>1</sub> average FEV<sub>1</sub> AUC<sub>0-12</sub>, COPD symptoms



# Ohtuvayre™ Commercial Opportunity



**Verona Pharma®**  
Breath of Innovation

# COPD patients need new treatment options<sup>1,2</sup>

~50% of patients remain persistently symptomatic

**~8.6M** Maintenance Treated COPD Patients<sup>3</sup>

**50%**

*Persistently Symptomatic COPD Patients  
Regardless of Therapy<sup>2</sup>*

**~4.3M**

*Persistently symptomatic patients*

Persistent Symptoms drive  
referrals to  
Pulmonologists

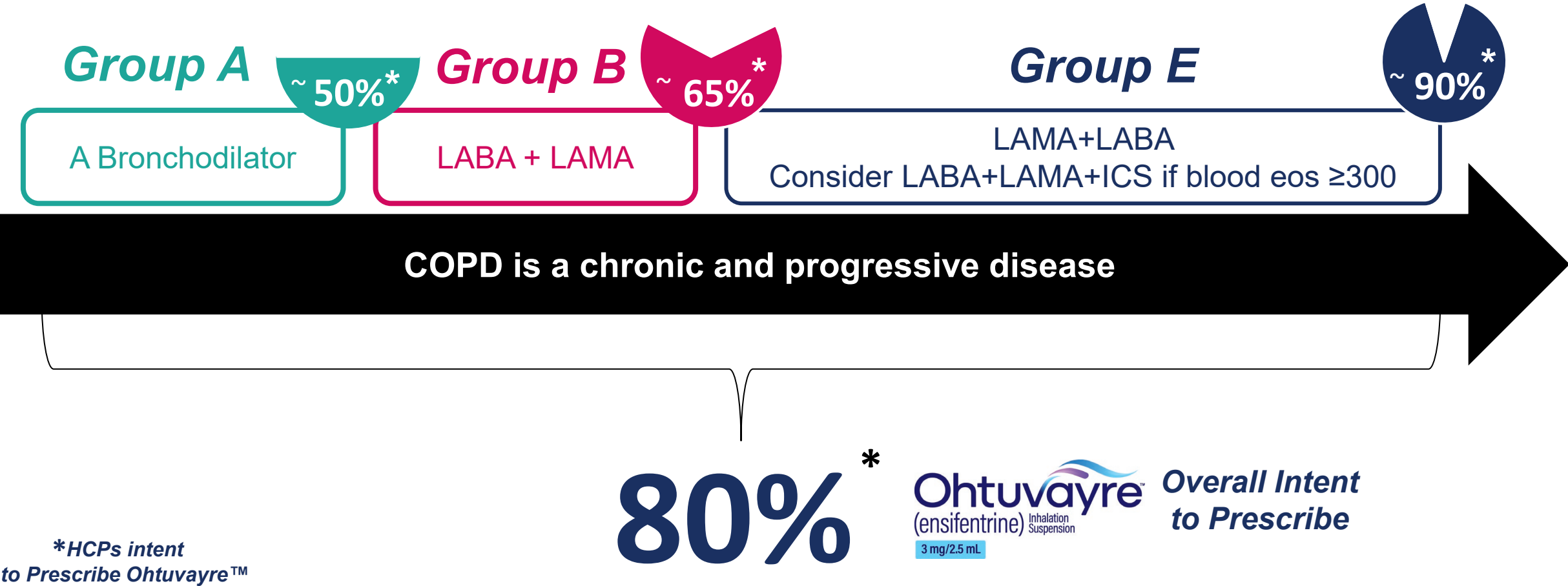
Launch Focus

**Ohtuvayre**<sup>™</sup>  
(ensifentrine) Inhalation  
Suspension

3 mg/2.5 mL



# HCPs have high willingness to use Ohtuvayre™ across all COPD patient groups<sup>1</sup>



Market Research Question: assume this patient was complaining of the following symptoms. Based on their clinical characteristics and current treatment, would you consider **prescribing Product X** to this patient, assuming it is now available?  
TPP Tested consistent with current label



# Patients have significant symptom burden and want different treatment options

Patients are motivated by Ohtuvayre™ profile

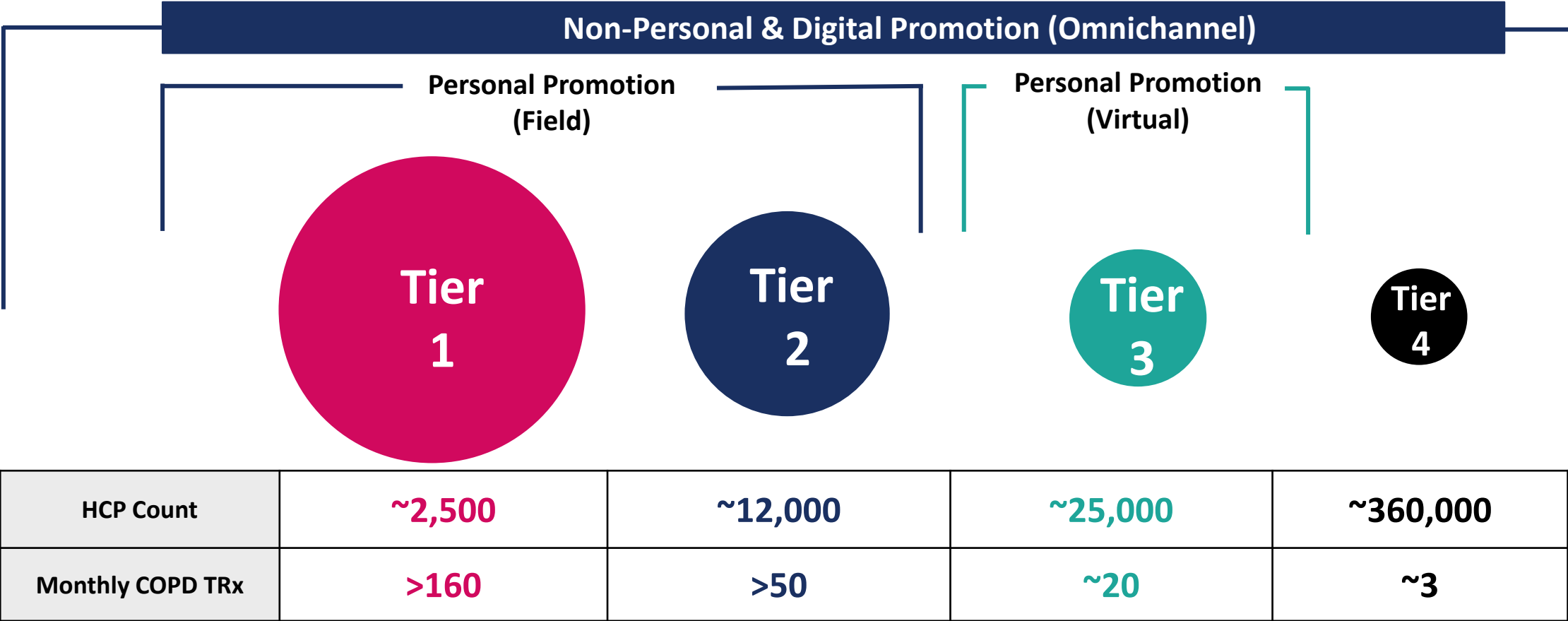
**>50%** patients report persistent monthly symptoms<sup>1,2</sup>

**~75%** patients use a nebulizer at home<sup>3</sup>

**High** motivation to try / ask HCP about novel, steroid free COPD treatment<sup>4</sup>

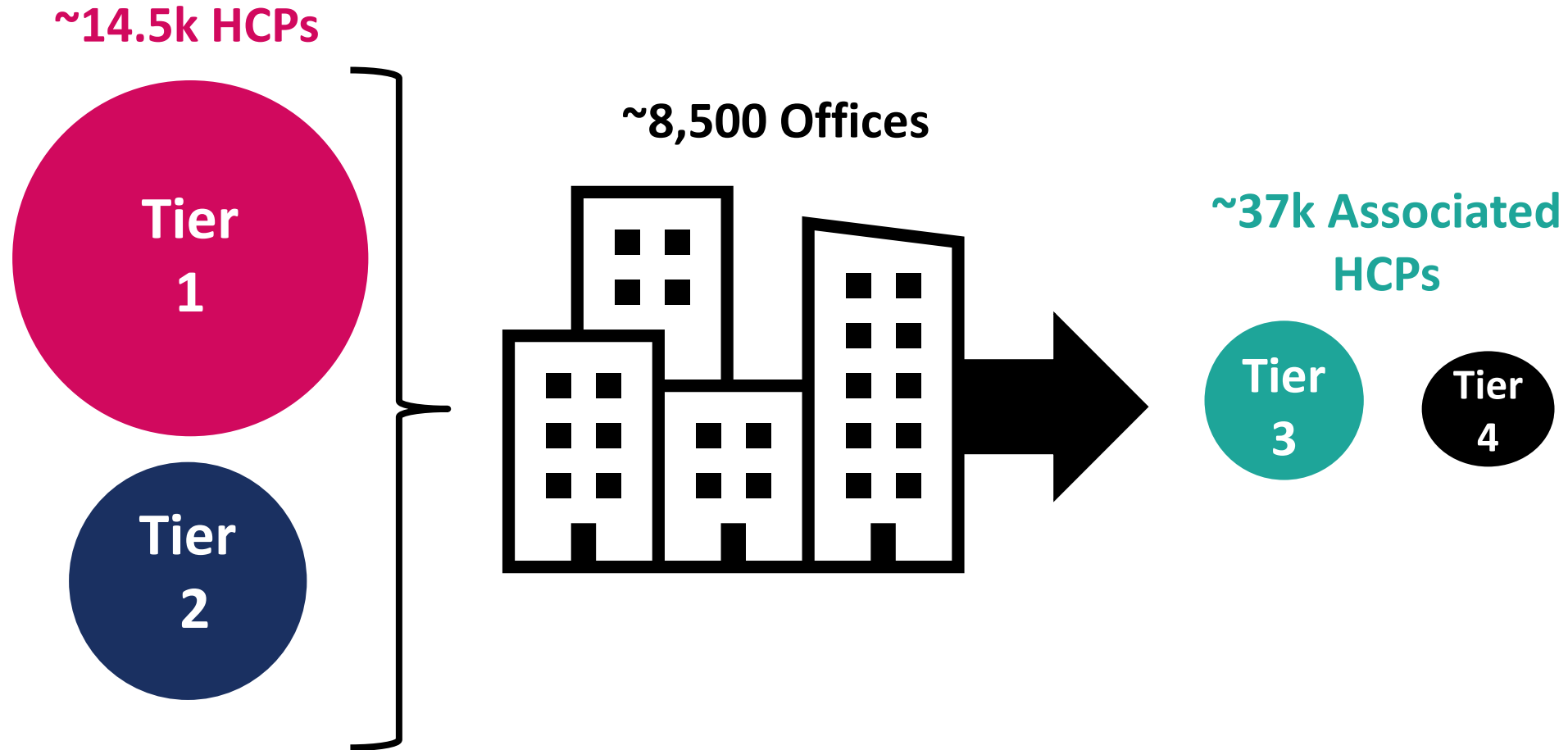
# Verona is promoting to the most active HCPs

Ohtuvayre™ promotion through a variety of channels

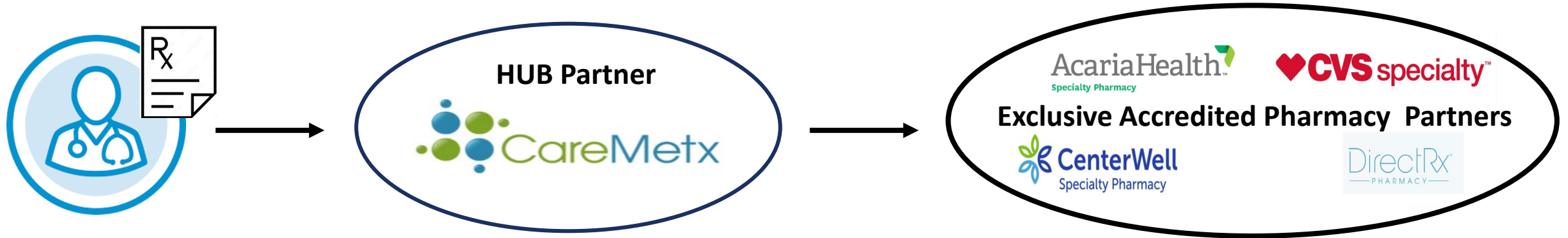


# Verona promotional efforts cover ~8,700 offices

Reps interact within offices that have ~50K HCPs



# Verona Pathway Plus™ Ensuring patient access and customer support



## Prescription Fulfillment

- 98% of patient lives covered
- Verona Care Coordinator & Field Reimbursement Team



## Coverage and Affordability

- Benefit verification
- Prior authorization / appeals assistance
- Financial support resources for eligible patients



## Support and Education

- Ongoing education and treatment support
- 24/7 access to clinical pharmacist

# Ohtuvayre: Multi-billion dollar opportunity

Ohtuvayre™ can be used in all symptomatic COPD patients regardless of background therapy

## Ohtuvayre Opportunity

Market Size	~8.6M <sup>1</sup> Treated Patients	<div>Every 1% share of treated patients</div> <div>~\$1.1B Net revenue</div>
Pricing / Month	\$2,950 <sup>2</sup>	
Months of Therapy / Year	6	
GtN Discount	25%	

## Current COPD Patient Shares<sup>3</sup>

21%	Symbicort® (LABA/ICS)
12%	Trelegy (LAMA/LABA/ICS)
11%	Spiriva® (LAMA)
5%	Anoro (LAMA/LABA)
1%	Daliresp® (PDE4)



# Ensifentrine strategy in ROW

Strategic collaborations to maximize ensifentrine's commercial value

United States:  
~\$10B in Sales<sup>1</sup>



**Ohtuvayre™ Available**

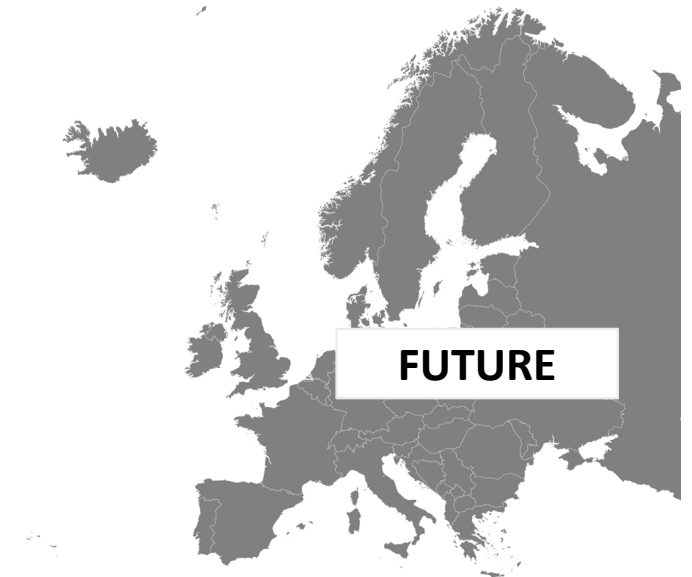
Prevalence of COPD in US:  
~8.6M treated chronically<sup>2</sup>

China:  
~\$1B in Sales  
(expected to double by 2030)<sup>1</sup>



**~1B in sales (expected to double by 2030)<sup>1</sup>**

EU:  
~\$2B Euros in Sales (2020)<sup>1</sup>



**~2B Euros in sales (2020)<sup>1</sup>**

# Patent protection through the mid 2030s

3 Orange Book-listed patents; 6 more potentially eligible

Invention	Granted/Pending Application	Estimated Patent Expiry
Polymorph*	Granted US, Europe, China, Japan, other	2031
Ensifentrine Suspension formulation*	Granted US, Europe, China, Japan, other	2035
Ensifentrine Suspension Formulation – Low PH buffer*	Granted US, Europe, China, Japan, other	2035
Manufacturing process	Granted Europe, US, China, Japan, other	2037
Combinations with anti-muscarinics	Granted US, Europe, China, Japan, other	2034
Ensifentrine/glycopyrrolate formulation	Granted Europe, UK, other. Pending US, China, Japan	2041
Treatment of moderate COPD**	Pending US and PCT application	2043
Trough lung function**	Pending US and PCT application	2043
Reduction in COPD exacerbation**	Pending US and PCT application	2043
PK Profile**	Pending US and PCT application	2043
Renal impairment**	Pending US. PCT	2045
Purity Profile**	Pending UK, Taiwan, US and PCT application	2044

\* Patents Orange Book listed

\*\*Patents potentially eligible for Orange Book listing

**Up to 5 years potential patent term extension on select patent**

# Ohtuvayre™ launched Q3 2024

## Large Market with significant unmet need

- *Millions of patients remain symptomatic and unsatisfied with current therapies<sup>1-5</sup>*
- *Ohtuvayre's Novel MOA is compelling to HCPs and patients*

## Ohtuvayre is available

- *>16k dispensed prescriptions and >3,500 HCP writers in 2024*
- *Robust refill rates: One-third of >16K prescriptions filled were refills*

## Reimbursement pathway to ensure early access

- *>80% of dispensed patients have <\$10 copay*

## People and financial resources to support launch

- *FY 2024 net sales of ~\$42M\**
- *Cash and anticipated net revenue expected to provide runway beyond 2026*

\*Unaudited net product sales.



**Thank you**



**Verona Pharma<sup>®</sup>**  
Breath of Innovation