UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of report (Date of earliest event reported): December 20, 2022

Verona Pharma plc

(Exact name of registrant as specified in its charter)

United Kingdom	**001-39067**	**98-1489389**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

3 More London Riverside
London SE1 2RE
United Kingdom
(Address of principal executive offices) (Zip Code)

+44 203 283 4200
(Registrant's telephone number, including area code)

N/A
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Ordinary shares, nominal value £0.05 per share*	VRNA	The Nasdaq Global Market

** The ordinary shares are represented by American Depositary Shares (each representing 8 ordinary shares), which are exempt from the operation of Section 12(a) of the Securities Exchange Act of 1934, as amended, pursuant to Rule 12a-8 thereunder.*

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

Item 7.01. Regulation FD Disclosure.

On December 20, 2022, Verona Pharma plc (the "Company") posted a slide presentation regarding top-line data from the Phase 3 ENHANCE-1 clinical trial in the "Events & Presentations" portion of its website at *www.veronapharma.com*. A copy of the slide presentation is furnished as Exhibit 99.1 to this Current Report on Form 8-K (the "Current Report").

The information contained in this Item 7.01 of this Current Report (including Exhibit 99.1 attached hereto) shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing. The Company undertakes no obligation to update, supplement or amend the materials attached hereto as Exhibits 99.1.

Item 8.01. Other Events.

On December 20, 2022, the Company announced the following top-line results from the Phase 3 ENHANCE-1 clinical trial evaluating nebulized ensifentrine for the maintenance treatment of chronic obstructive pulmonary disease ("COPD"):

- **Study population (n=763)**:
  - Subject demographics and disease characteristics were well balanced between treatment groups.
  - Approximately 66% of subjects received background COPD therapy, either a long-acting muscarinic antagonist ("LAMA") or a long-acting beta-agonist ("LABA"). Additionally, approximately 21% of all subjects received inhaled corticosteroids ("ICS") with concomitant LAMA or LABA.

- **Primary endpoint met (FEV_1* AUC 0-12 hr)**:
  - Placebo corrected, change from baseline in FEV_1 area under the curve 0-12 hours post dose at week 12 was 87 mL ($p<0.0001$) for ensifentrine.
  - Demonstrated consistent improvements in all subgroups including gender, age, smoking status, COPD severity, background medication, ICS use, chronic bronchitis, FEV_1 reversibility and geographic region.

- **Key secondary endpoints of lung function, symptoms and quality of life measures met**:
  - Placebo corrected, increase in peak FEV_1 of 147 mL ($p<0.0001$) 0-4 hours post dose at week 12.
  - Daily symptoms as measured by E-RS** Total Score in the ensifentrine group improved from baseline to greater than the minimal clinically important difference ("MCID") of -2 units with a statistically significant improvement compared to placebo at week 24. Improvements in symptoms were early and sustained with statistical significance versus placebo at weeks 6, 12 and 24.
  - Quality of Life ("QOL") as measured by SGRQ** Total Score in the ensifentrine group improved from baseline to greater than the MCID of -4 units with a statistically significant improvement compared to placebo at week 24. Improvements in QOL were early and sustained with statistical significance versus placebo at weeks 6, 12 and 24.
  - Placebo corrected, increase in morning trough FEV_1 of 35 mL ($p=0.0421$) at week 12, supporting twice daily dosing regimen.

- **Exacerbation rate and risk reduced**:
  - Subjects receiving ensifentrine demonstrated a 36% reduction in the rate of moderate to severe COPD exacerbations over 24 weeks (p=0.0505) compared to those receiving placebo.
  - Treatment with ensifentrine significantly decreased the risk of a moderate/severe exacerbation as measured by time to first exacerbation when compared with placebo by 38% (p=0.0378).
  - Pooled exacerbation data from ENHANCE-1 and ENHANCE-2, ensifentrine demonstrated a 40% reduction in the rate of moderate to severe COPD exacerbations over 24 weeks (p=0.0012) compared to those receiving placebo. Additionally, ensifentrine significantly decreased the risk of a moderate/severe exacerbation as measured by time to first exacerbation when compared with placebo by 41% (p=0.0008).

- **Favorable safety profile:**
  - Ensifentrine was well-tolerated with very few events occurring in more than 1% of subjects and greater than placebo over 24 and 48 weeks.

*FEV_1: Forced Expiratory Volume in one second, a standard measure of lung function

**E-RS, Evaluating Respiratory Symptoms, and SGRQ, St. George's Respiratory Questionnaire, are validated patient reported outcome tools

The Company plans to submit a New Drug Application to the U.S. Food and Drug Administration (the "FDA") in the first half of 2023. Subject to review and approval by the FDA, the Company anticipates commercial launch of ensifentrine in the second half of 2024.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

The following Exhibit 99.1 relating to Item 7.01 shall be deemed to be furnished, and not filed:

Exhibit No.	Description
99.1	ENHANCE-1 Phase 3 Data Slide Presentation of Verona Pharma plc.
104	Cover Page Interactive Data File (the cover page XBRL tags are embedded within the Inline XBRL document)

Forward-Looking Statements

This Current Report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this Current Report that do not relate to matters of historical fact should be considered forward-looking statements, including without limitation statements regarding the submission of a New Drug Application to the FDA and the timing for such an application and the Company's ability to commercialize ensifentrine and the timing of commercial launch. 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 the Company's actual results, performance or achievements to be materially different from its expectations expressed or implied by the forward-looking statements, including without limitation: general business, financial and accounting risks; the Company's need for additional funding to complete development and commercialization of ensifentrine, which may not be available and which may force the Company to delay, reduce or eliminate development or commercialization efforts; the reliance of the Company's business on the success of ensifentrine, its only product candidate under development; economic, political, regulatory and other risks involved with international operations; the lengthy and expensive process of clinical drug development, which has an uncertain outcome; serious adverse, undesirable or unacceptable side effects associated with ensifentrine, which could adversely affect the Company's ability to develop or commercialize ensifentrine; potential delays in enrolling patients, which could adversely affect the Company's research and development efforts and the completion of its clinical trials; the Company's ability to obtain approval for and commercialize ensifentrine in multiple major pharmaceutical markets; material differences between the Company's "top-line" data and final data; the Company's reliance on third parties, including clinical research organizations, clinical investigators, manufacturers and suppliers, and the risks related to these parties' ability to successfully develop and commercialize ensifentrine; changes in the Company's tax rates, unavailability of certain tax credits or reliefs or exposure to additional tax liabilities or assessments could affect profitability, and audits by tax authorities could result in additional tax payments for prior periods; the Company's vulnerability to natural disasters, global economic factors and other unexpected events, including health epidemics or pandemics like the COVID-19 pandemic, which has and may continue to adversely impact the Company's business, and Russia's invasion of Ukraine; and the other important factors discussed under the caption "Risk Factors" in its Annual Report on Form 10-K for the year ended December 31, 2021 and as any such factors may be updated from time to time in its other filings with the Securities and Exchange Commission. Any such forward-looking statements represent management's estimates as of the date of this Current Report. While the Company may elect to update such forward-looking statements at some point in the future, it disclaims any obligation to do so, even if subsequent events cause its views to change. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date of this Current Report.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

VERONA PHARMA PLC

Date: December 20, 2022

By: /s/ David Zaccardelli
Name: David Zaccardelli, Pharm. D.
Title: President and Chief Executive Officer

ENHANCE-1 Phase 3 data

December 2022

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Forward-looking statements

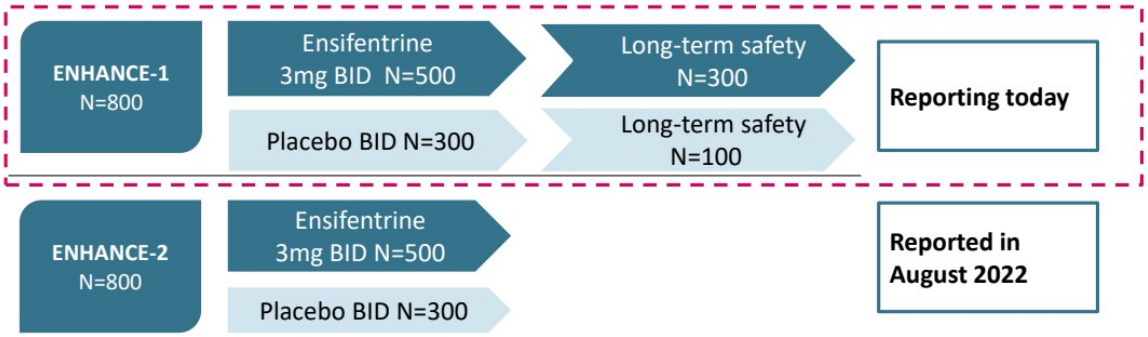
This presentation contains "forward-looking" statements that are based on the beliefs and assumptions and on information currently available to management of Verona Pharma plc (together with its consolidated subsidiary, the "Company"). All statements other than statements of historical fact contained in this presentation are forward-looking statements. Forward-looking statements include information concerning the initiation, timing, progress and results of clinical trials of the Company's product candidate and the timing or likelihood of regulatory filings and approvals for of its product candidate. In some cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "expects," "plans," "anticipates," "believes," "estimates," "predicts," "potential" or "continue" or the negative of these terms or other comparable terminology.

Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause the Company's actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. These risks, uncertainties and other factors include those under "Risk Factors" in the Company's annual report on Form 10-K for the year ended December 31, 2021, and other filings with the Securities and Exchange Commission. Forward-looking statements represent the Company's beliefs and assumptions only as of the date of this presentation. Although the Company believes that the expectations reflected in the forward-looking statements are reasonable, it cannot guarantee future results, levels of activity, performance or achievements. Except as required by law, the Company assumes no obligation to publicly update any forward-looking statements for any reason after the date of this presentation, or to conform any of the forward-looking statements to actual results or to changes in its expectations.

Pivotal Phase 3 program

Two efficacy and safety studies: ENHANCE-1 and ENHANCE-2

Ensifentrine as a **N**ovel in**HA**led **N**ebulized **C**OPD th**E**rapy in moderate to severe COPD



Patient population:

- LAMA or LABA background allowed (approx. 50% of trial population) and ICS (approx. 20% of population)
- 30-70% predicted FEV_1
- Symptomatic (mMRC ≥ 2)

Additional information:

- Long-term safety in ENHANCE-1
- Sites in North America, Europe and Asia

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ENHANCE-1 baseline characteristics

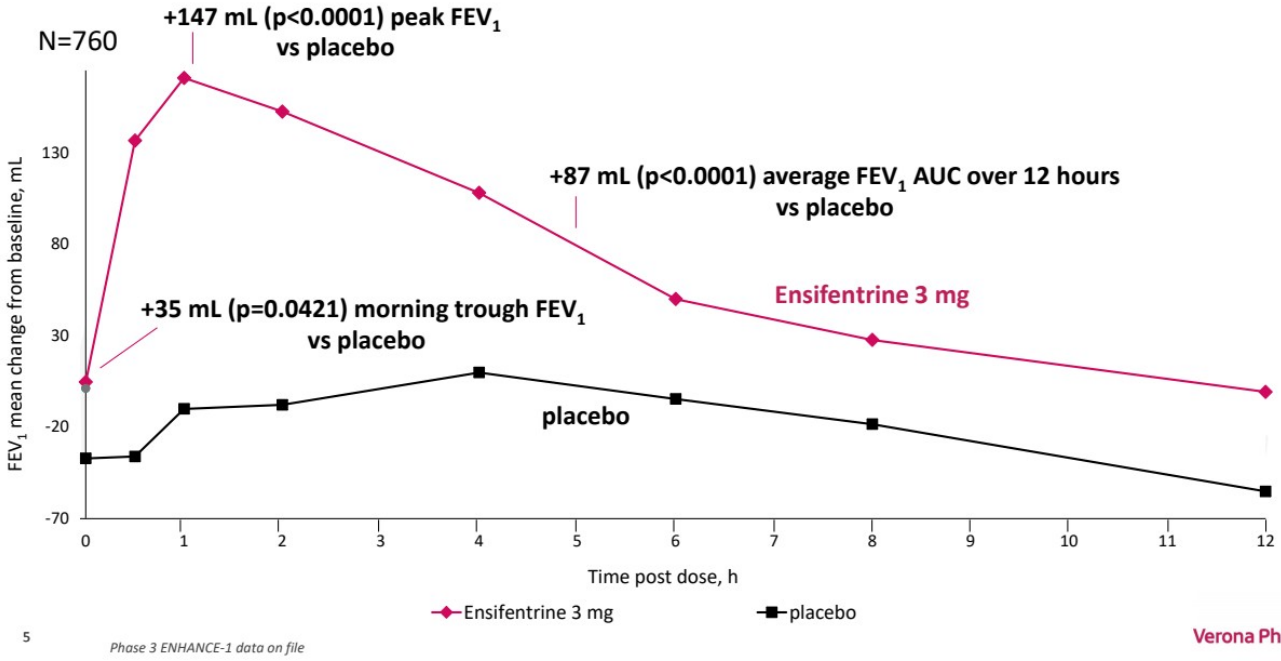
Demographics and baseline characteristics well balanced between groups

Parameter	*Ensifentrine n=479*	*Placebo n=284*	*Total n=763*
Age, mean (SD)	65.1 (7.1)	64.9 (7.7)	65.0 (7.4)
Gender, % Male, n (%)	275 (57.4)	167 (58.8)	442 (57.9)
Moderate / Severe COPD, n (%) Mild / Very Severe COPD, n (%)	295 (61.6) / 180 (37.6) 1 (0.2) / 3 (0.6)	164 (57.7) / 119 (41.9) 0 / 0	459 (60.2) / 299 (39.2) 1 (0.1) / 3 (0.4)
% Predicted FEV_1 mean, (SD)	52.9 (10.3)	51.7 (10.6)	52.5 (10.4)
% with Chronic Bronchitis, n (%)	387 (80.8)	216 (76.1)	603 (79.0)
% Current Smokers, n (%)	269 (56.2)	164 (57.7)	433 (56.7)
Background Meds: Yes, n (%) LAMA LAMA/ICS LABA LABA/ICS	318 (66.4) 138 (28.8) 4 (0.8) 89 (18.6) 87 (18.2)	185 (65.1) 71 (25.0) 3 (1.1) 45 (15.8) 66 (23.2)	503 (65.9) 209 (27.4) 7 (0.9) 134 (17.6) 153 (20.1)
E-RS Baseline, mean (SD)	14.1 (6.8)	13.3 (6.1)	--
SGRQ Baseline, mean (SD)	48.1 (18.3)	46.9 (17.1)	--

Phase 3 ENHANCE-1 data on file

Primary endpoint met in Phase 3 ENHANCE-1

Significant and clinically meaningful improvements in lung function at Week 12



Phase 3 ENHANCE-1 data on file

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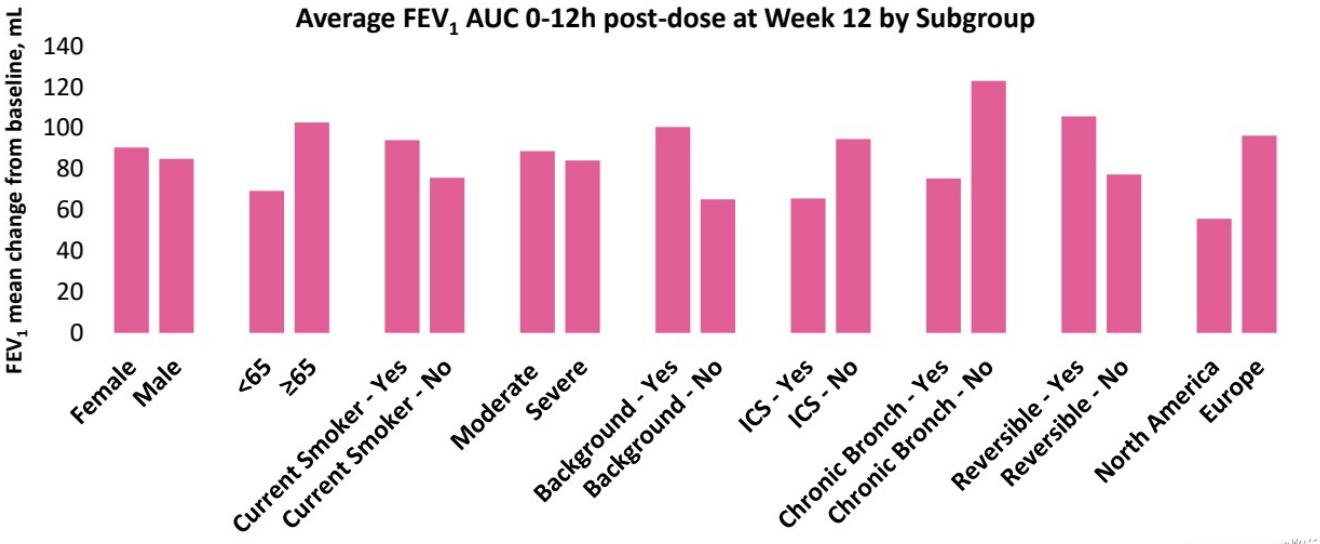
Ensifentrine improved lung function in all subgroups

Consistent effects across all subgroups



Phase 3 ENHANCE-1 data on file

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Ensifentrine reduced exacerbation rate over 24 weeks

36% reduction in rate of moderate or severe COPD exacerbation vs placebo

Treatment	*Annualized Event Rate LS mean, (95% CI)*	*Rate Ratio (95% CI)*	*Exacerbation Rate Reduction*	*P-value*
Ensifentrine 3 mg (n = 477)	0.26 (0.17, 0.40)	0.64 (0.40, 1.00)	**36%**	0.0505
Placebo (n = 283)	0.41 (0.26, 0.62)	--	--	

Exacerbation was defined as a ***worsening of symptoms*** requiring:

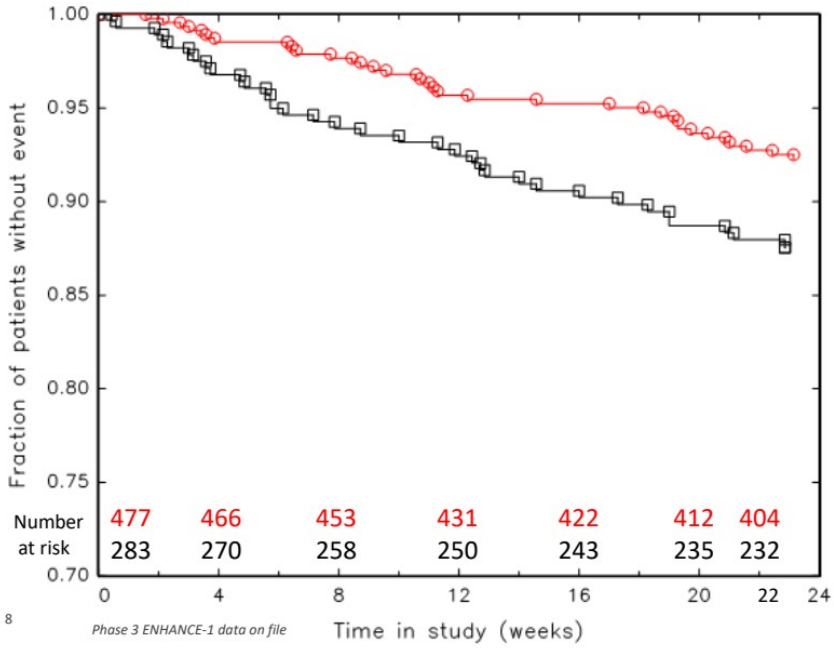
- Minimum of 3 days of treatment with oral/systemic steroids and/or antibiotics ***OR*** hospitalization

Phase 3 ENHANCE-1 data on file

Verona Pharma

Ensifentrine significantly delayed time to first exacerbation

38% reduction in risk of a COPD exacerbation



	Ensifentrine vs. Placebo (N = 760)
Hazard Ratio (95%, CI)	0.62 (0.39, 0.97)
Risk Reduction	**38%**
P-value	0.0378

Phase 3 ENHANCE-1 data on file

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Pooled data: significant 40% reduction in exacerbation rate

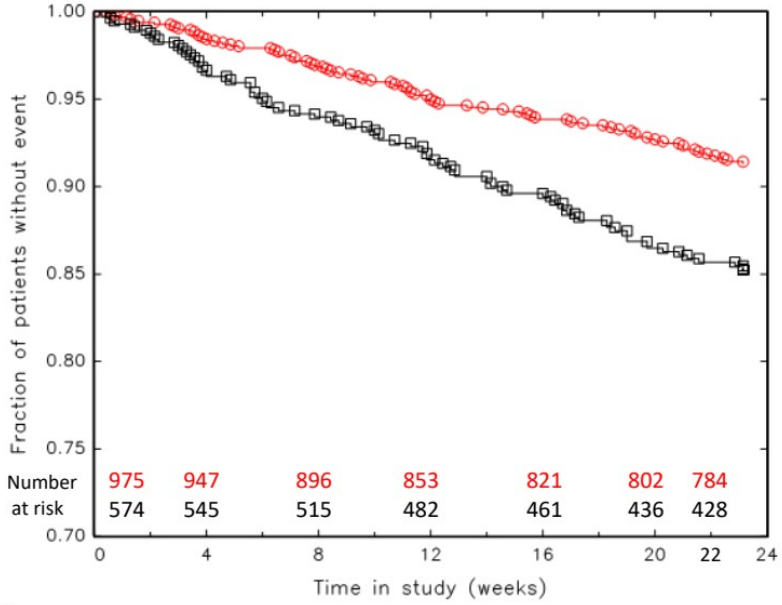
Protocol specified pooled analysis including ENHANCE-1 and ENHANCE-2

Treatment	*Annualized Event Rate LS mean, (95% CI)*	*Rate Ratio (95% CI)*	*Exacerbation Rate Reduction*	*P-value*
Ensifentrine 3 mg (n = 975)	0.27 (0.19, 0.39)	0.60 (0.44, 0.82)	**40%**	0.0012
Placebo (n = 584)	0.45 (0.31, 0.65)	--	--	

Phase 3 ENHANCE-1 data on file

Pooled data: significant 41% risk reduction in time to first exacerbation

Protocol specified pooled analysis including ENHANCE-1 and ENHANCE-2



	Ensifentrine vs. Placebo (N = 1,549)
Hazard Ratio (95%, CI)	0.59 (0.44, 0.81)
Risk Reduction	**41%**
P-value	0.0008

Phase 3 ENHANCE-1 data on file

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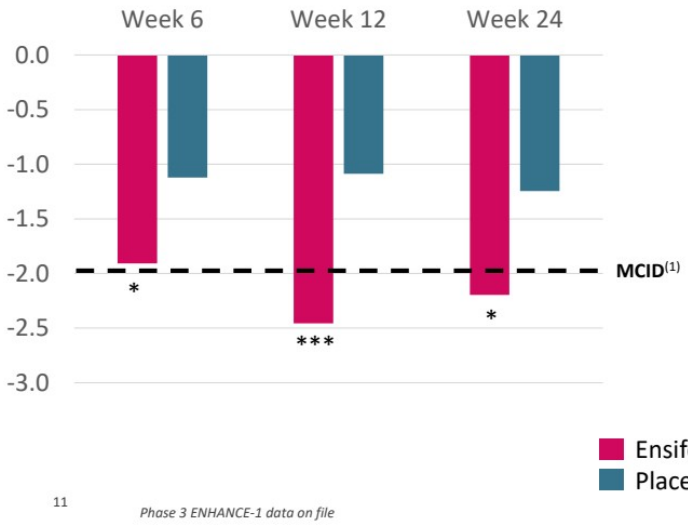
Statistically significant improvement in symptoms and QOL

Early and sustained improvement in ENHANCE-1

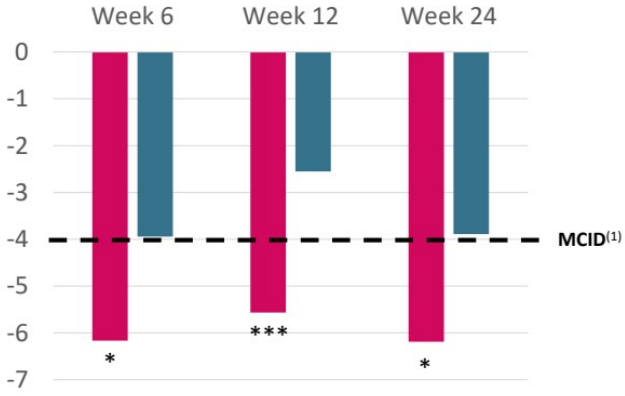
Symptoms

E-RS Total Score by Week (units)



Health-related Quality of Life

SGRQ Total Score by Week (units)



Ensifentrine
Placebo

(1) Minimal clinically important difference

*** P ≤ 0.001
** P ≤ 0.01
* P ≤ 0.05

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Phase 3 ENHANCE-1 data on file

Adverse events reported at low rates over 24 and 48 weeks

Few events greater than 1% and greater than placebo in ENHANCE-1

	Event	*Ensifentrine 3 mg (n = 477)*	*Placebo (n = 283)*
Subjects with at least one TEAE, n (%)		**221 (46.3)**	**114 (40.3)**
Any TEAE >1% and greater than placebo	Hypertension, n (%)	14 (2.9)	4 (1.4)
	Back pain, n (%)	12 (2.5)	1 (0.4)
	Upper respiratory tract infection, n (%)	10 (2.1)	5 (1.8)
	Pneumonia, n (%)	7 (1.5)	1 (0.4)
	Toothache, n (%)	6 (1.3)	2 (0.7)
	Atrial fibrillation, n (%)	6 (1.3)	2 (0.7)

- Similar rates of serious adverse events in ensifentrine and placebo treated subjects (8.8% vs 8.5%)

TEAE: treatment-emergent adverse event
Phase 3 ENHANCE-1 data on file

ENHANCE-1 met primary and all key secondary endpoints

Ensifentrine improved lung function, symptoms, and reduced exacerbation rate and risk

Endpoint	Top-line Measurement	Data
Primary endpoint (at Week 12)	Average FEV_1 AUC (0-12 hours) post dose	+87 mL (p<0.0001) vs placebo
Secondary endpoints (Lung function at Week 12) (Symptoms / QOL at Week 24)	Peak FEV_1	+147 mL (p<0.0001) vs placebo
	Morning Trough FEV_1	+35 mL (p=0.0421) vs placebo
	Symptoms (E-RS Total Score) Quality of Life (SGRQ Total Score)	-1.0 units (p=0.0112) vs placebo -2.3 units (p=0.0252) vs placebo
Exacerbations (over 24 Weeks)	Exacerbation rate Time to first moderate / severe COPD exacerbation	36% (p=0.0505) reduction in rate 38% (p=0.0378) reduction in risk
Safety	Incidence of adverse events	Low incidence of adverse events at 24 and 48 weeks

Phase 3 ENHANCE-1 data on file

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ENHANCE Program summary

ENHANCE-1 and ENHANCE-2 showed positive efficacy and safety in patients with COPD

Top-line Measurement	ENHANCE-1	ENHANCE-2
Average FEV_1 AUC (0-12 hours)	+87 mL (p<0.0001) vs placebo	+94 mL (p<0.0001) vs placebo
Peak FEV_1	+147 mL (p<0.0001) vs placebo	+146 mL (p<0.0001) vs placebo
Morning Trough FEV_1	+35 mL (p=0.0421) vs placebo	+49 mL (p=0.0017) vs placebo
Symptoms (E-RS Total Score)	-1.0 units (p=0.0112) vs placebo	-0.6 units (NS) vs placebo
Quality of Life (SGRQ Total Score)	-2.3 units (p=0.0252) vs placebo	-0.5 units (NS) vs placebo
Exacerbation rate	36% (p=0.0505) reduction in rate	42% (p=0.0109) reduction in rate
Time to first COPD exacerbation	38% (p=0.0378) reduction in risk	42% (p=0.0088) reduction in risk
Pooled exacerbation rate	40% (p=0.0012) reduction in rate	
Pooled time to first COPD exacerbation	41% (p=0.0008) reduction in risk	
Incidence of adverse events	Low incidence of adverse events at 24 and 48 weeks	

Phase 3 ENHANCE-1 and 2 data on file

NS = not significant

Q&A

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