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RPL554-CO-205: A 4-Week Phase 2b Study of Ensifentrine Added on to Tiotropium in Patients with COPD

Summary of Top-Line Results
January 13th, 2020

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Large Phase 2bTrial to support Phase 3 design

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Four Week Ensifentrine Phase 2b Study in >400 Patients with Moderate to Severe Symptomatic COPD Already Treated with Tiotropium

Trial Description	Phase 2b, 4-week, randomized, double-blind, placebo controlled, dose-ranging study to assess the effect of nebulized ensifentrine (RPL554) added on to tiotropium in patients with moderate to severe COPD
Patient Population	416 moderate to severe symptomatic COPD patients, post-bronchodilator 30-70% predicted FEV1, males and females, age 40-80
Locations	46 US sites
Study Arms and Ensifentrine Dosage	Five arm parallel design, twice-daily dosing with ensifentrine at 0.375 mg, 0.75 mg, 1.5 mg, 3 mg or placebo treatment added on to once daily tiotropium *(Spiriva® Respimat®)*

Ensifentrine Provides Significant, Clinically Meaningful, Dose-Ordered Improvement in Lung Function on Top of Tiotropium

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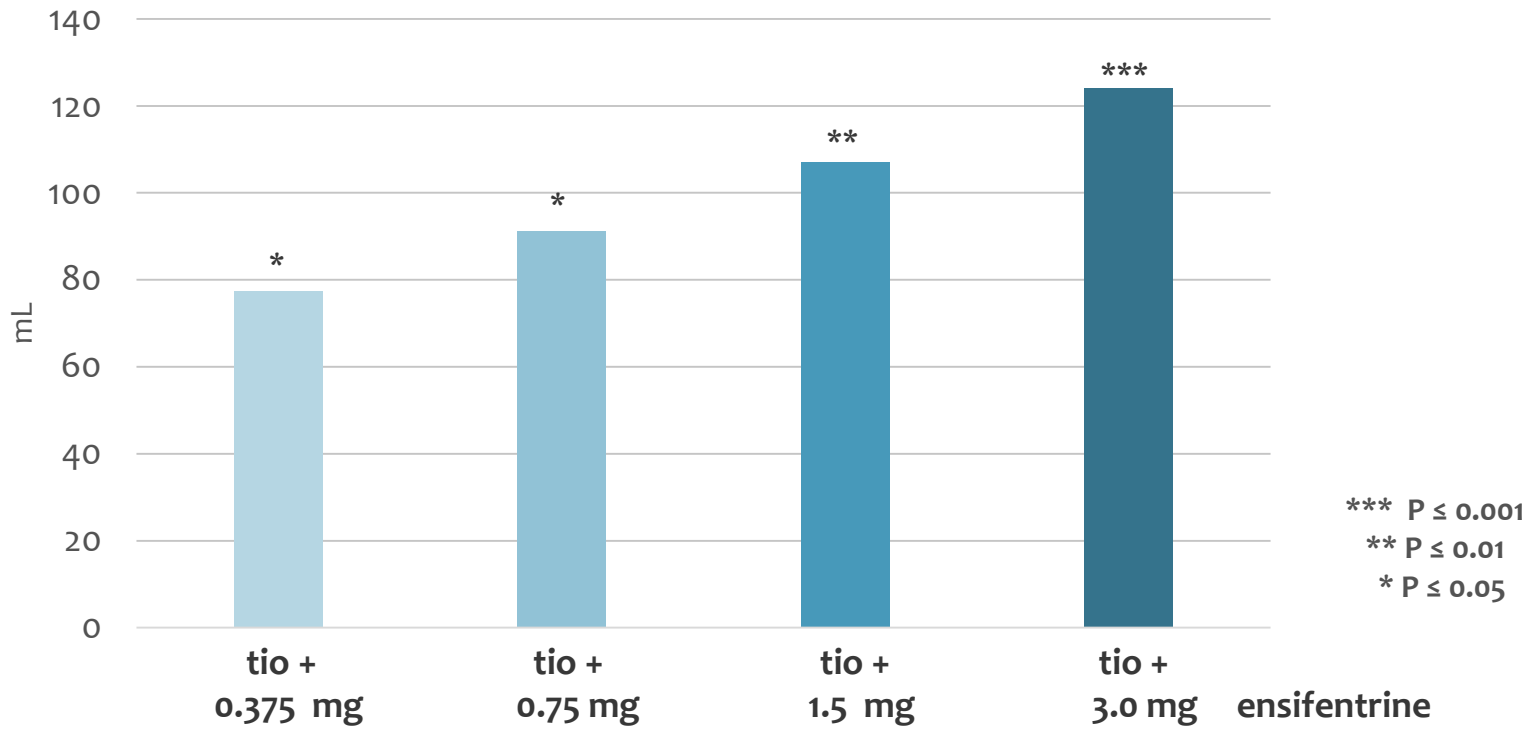
Peak Change from Baseline in FEV1 (mL) at Week 4; placebo corrected

- Clear dose response observed
- Consistent improvement over 4 weeks on top of tiotropium



Full Analysis Set

Ensifentrine Improved Quality of Life (SGRQ-C) on Top of Tiotropium after 4 Weeks

Progressive and statistically significant effect at 4 weeks

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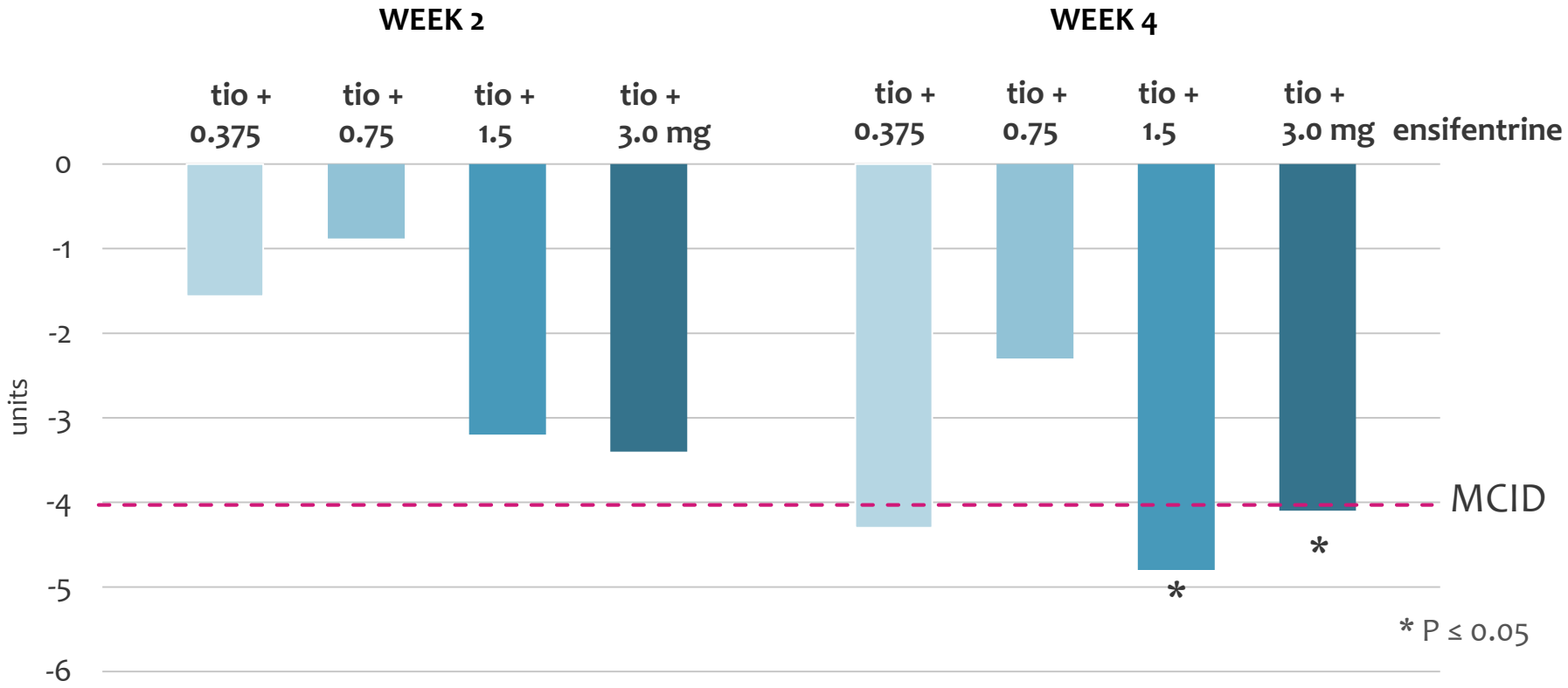
SGRQ-C Mean Change from Baseline; placebo corrected



Full Analysis Set; MCID = minimal clinically important difference

Ensifentrine Improves Lung Function and QoL when Added on to Tiotropium in Symptomatic Patients with COPD who Require Additional Treatment

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Summary of Top-Line Data:

- **Primary endpoint met** at all doses: statistically significant and clinically meaningful improvement in lung function at week 4.
- **Dose dependent improvements in lung function were observed** on both peak FEV1 and AUC 0-12 hours.
- **12-hour duration:** Statistically significant improvement in average FEV1 AUC 0-12 hours for the 3 mg dose supportive of twice daily dosing (p=0.0111).
- **Clinically meaningful and significant improvements in health related quality of life** (mean SGRQ-C) were observed on top of tiotropium, exceeding the MCID of 4 units at week 4 compared to placebo with the two highest doses.
- **Ensifentrine was well tolerated at all doses** with an adverse event profile similar to placebo
- **These data support dose selection for Phase 3**

Next Steps – Focus on Phase 3

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Key activities leading up to Phase 3 in maintenance treatment in COPD with nebulized ensifentrine:

- FDA End-of-Phase 2 meeting preparation underway
- Pivotal clinical trials in the COPD maintenance setting expected to start in 3Q 2020

Value-added activities to expand the ensifentrine portfolio

- China development of nebulized ensifentrine
- Ensifentrine inhaler formulations
  - DPI substantial bronchodilator effect recently reported and
  - MDI single-dose Ph2a data expected 1Q 2020