

For patients with COPD who require maintenance therapy,

# YUPELRI is the first and only once-daily nebulized LAMA<sup>1,2</sup>

### Established Nebulized LAMA Since 2018<sup>1</sup>

More than **28 million doses** of YUPELRI have been filled<sup>3</sup>



#### Indication

YUPELRI<sup>®</sup> inhalation solution is indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD).

#### **Important Safety Information**

YUPELRI is contraindicated in patients with hypersensitivity to revefenacin or any component of this product.

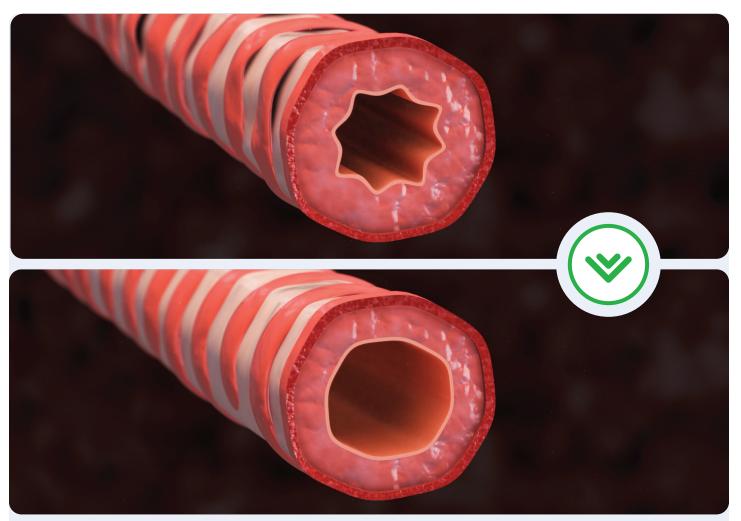
YUPELRI should not be initiated in patients during acutely deteriorating or potentially life-threatening episodes of COPD, or for the relief of acute symptoms, i.e., as rescue therapy for the treatment of acute episodes of bronchospasm. Acute symptoms should be treated with an inhaled short-acting beta<sub>2</sub>-agonist.

Please see additional Important Safety Information throughout and the accompanying Full Prescribing Information.

# YUPELRI is a once-daily nebulized LAMA with defined pharmacologic characteristics<sup>1</sup>

### Novel chemical structure

The chemical structure of YUPELRI is a novel biphenyl carbamate tertiary amine structure that is distinct, making it the first inhaled LAMA of its class for COPD.<sup>4</sup>



When administered, YUPELRI exhibits pharmacological effects through inhibition of M3 receptors at the smooth muscle leading to bronchodilation.<sup>1</sup>

#### Important Safety Information (cont'd)

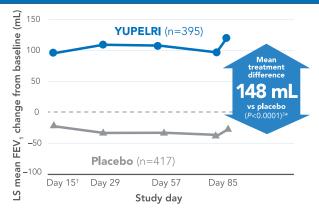
As with other inhaled medicines, YUPELRI can produce paradoxical bronchospasm that may be life-threatening. If paradoxical bronchospasm occurs following dosing with YUPELRI, it should be treated immediately with an inhaled, shortacting bronchodilator. YUPELRI should be discontinued immediately and alternative therapy should be instituted.

YUPELRI should be used with caution in patients with narrow-angle glaucoma. Patients should be instructed to immediately consult their healthcare provider if they develop any signs and symptoms of acute narrow-angle glaucoma, including eye pain or discomfort, blurred vision, visual halos or colored images in association with red eyes from conjunctival congestion and corneal edema.

# **YUPELRI delivers consistent** control over 12 weeks<sup>1</sup>

YUPELRI met its primary efficacy endpoint of change from baseline in FEV, vs placebo at day 85 in two 12-week, randomized, double-blind, placebo-controlled, parallel-group confirmatory studies (Studies 1 and 2) that evaluated the efficacy of YUPELRI vs placebo in patients with moderate to very severe COPD (n=395).<sup>1</sup>





Pooled data from Studies 1 and 2. Primary efficacy endpoint: change from baseline in trough (predose) FEV, at day 85 vs placebo. A secondary endpoint, overall treatment effect (OTE), showed trough FEV, across the 12-week study.

#### Studies 1 and 2: Primary endpoints<sup>1,3</sup>

- In Study 1, LS mean change from baseline in trough FEV<sub>1</sub> on day 85 was 127 mL (YUPELRI, n=189) and -19 mL (placebo, n=191), with a statistically significant difference vs placebo of 146 mL (P<0.0001)
- In Study 2, LS mean change from baseline in trough FEV<sub>1</sub> on day 85 was 102 mL (YUPELRI, n=181) and -45 mL (placebo, n=187), with a statistically significant difference vs placebo of 147 mL (P<0.0001)

#### Studies 1 and 2: Patient characteristics<sup>1</sup>

- Mean age of 64 years (range, 41-88 years); mean smoking history of 53 pack-years (48% current smokers); moderate to very severe COPD (mean post-bronchodilator % predicted FEV, of 55%)
- 37% of patients studied were on concomitant LABA or **ICS/LABA therapy**

\*LS mean difference from placebo (SE) is 148.1 mL (16.8). Pooled estimate adjusts the LS mean for placebo as well.<sup>3</sup> <sup>†</sup>The first measurement was taken at 2 weeks.

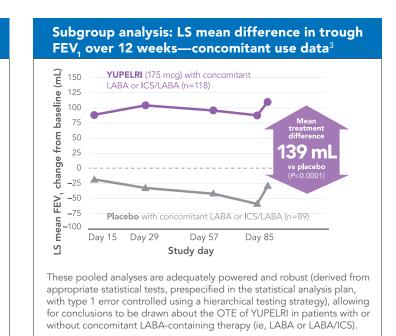
#### Important Safety Information (cont'd)

Worsening of urinary retention may occur. Use with caution in patients with prostatic hyperplasia or bladder-neck obstruction and instruct patients to contact a healthcare provider immediately if symptoms occur.

Please see additional Important Safety Information throughout and the accompanying Full Prescribing Information.







#### YUPELRI with concomitant LABA or ICS/LABA vs placebo with concomitant LABA or ICS/LABA<sup>3</sup>

- LS mean change from baseline in trough FEV, on day 85 was 111.82 mL (YUPELRI, n=118) vs -27.37 mL (placebo, n=89) (P<0.0001)
- LS mean difference from placebo was 139.19 mL (95% CI, 82.87-195.51)
- The safety and efficacy of mixing therapies with YUPELRI in a nebulizer have not been established

#### YUPELRI only vs placebo only (data not shown in graph above)<sup>3</sup>

- LS mean change from baseline in trough FEV, on day 85 was 117.66 mL (YUPELRI, n=192) vs -33.27 mL (placebo, n=207) (P<0.0001)
- LS mean difference from placebo was 150.93 mL (95% CI, 110.26-191.61)

#### YUPELRI® (revefenacin) inhalation solution improves lung function for a full 24 hours of better breathing<sup>1</sup>

In Studies 1 and 2, a prespecified exploratory analysis was performed in a subset of patients over 24 hours on days 84/85. In Study 1, LS mean changes from baseline in FEV<sub>1</sub> ranged from 55.8 mL to 240.4 mL in the YUPELRI group, and from -113.6 mL to 59.6 mL in the placebo group. In Study 2, LS mean changes from baseline in FEV<sub>1</sub> ranged from 19.8 mL to 148.5 mL in the YUPELRI group, and from -176.4 mL to -13.0 mL in the placebo group<sup>3</sup>

#### YUPELRI is the only LAMA you can use with any standard jet nebulizer<sup>1,2</sup>

• Administered in approximately 8 minutes once daily\* to conveniently fit into your patients' day<sup>1</sup>

Single-use vials: Unlike MDIs, SMIs, or DPIs, may avoid wasted medication; 1 vial per day of stay<sup>1,5</sup>

\*Using the PARI LC Sprint® nebulizer connected to a PARI Trek® S compressor under in vitro conditions.<sup>1</sup>

#### The safety profile of YUPELRI has been demonstrated in 3 clinical studies<sup>1</sup>

- Safety database included 2285 patients with COPD in two 12-week efficacy studies and one 52-week long-term safety study
- A total of 730 patients received YUPELRI 175 mcg once daily

#### YUPELRI is covered for up to 100% for patients who have Medicare Part B<sup>+</sup>

- For patients with supplemental insurance (over 80% of beneficiaries), coinsurance costs can be as low as \$0
- Medicare Part B covers most nebulizers as durable medical equipment (DME) for patient use at home<sup>6</sup>

<sup>t</sup>This is not a guarantee of coverage. Site of Care will determine coverage. Check with your patient's insurance provider for coverage rules and restrictions. In certain limited instances, YUPELRI may be covered through a patient's Medicare Part D pharmacy benefit.



#### The YUPELRI Hub by Gifthealth

A dedicated prescription fulfillment option that supports patient access to YUPELRI via an extensive network of partner pharmacies.

#### For more information, call (833) 614-4438

#### Important Safety Information (cont'd)

Immediate hypersensitivity reactions may occur after administration of YUPELRI. If a reaction occurs, YUPELRI should be stopped at once and alternative treatments considered.

The most common adverse reactions occurring in clinical trials at an incidence greater than or equal to 2% in the YUPELRI group, and higher than placebo, included cough, nasopharyngitis, upper respiratory infection, headache and back pain.

Coadministration of anticholinergic medicines or OATP1B1 and OATP1B3 inhibitors with YUPELRI is not recommended.

YUPELRI is not recommended in patients with any degree of hepatic impairment.

#### Please see additional Important Safety Information throughout and the accompanying Full Prescribing Information.

References: 1. YUPELRI [package insert]. Morgantown, WV: Mylan Specialty L.P. 2. Global Initiative for Chronic Obstructive Lung Disease (GOLD). *Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease (2024 Report)*. Global Initiative for Chronic Obstructive Lung Disease, Inc.; 2024. Accessed May 16, 2024. https://goldcopd.org/2024-gold-report-2/ 3. Data on file, Mylan Specialty L.P., a Viatris Company. 4. Pudi KK, Barnes CN, Moran EJ, et al. A 28-day, randomized, double-blind, placebo-controlled, parallel group study of nebulized revefenacin in patients with chronic obstructive pulmonary disease. *Respir Res.* 2017;18(1):182. 5. Long-acting medication use in COPD: opportunities for minimizing medication waste in the hospital setting. *Pharm Times*. November 2017. Accessed May 16, 2024. https://pharmacytimes.s3.amazonaws.com/v1\_media/RESP242-17-%20Pharmacy%20Times%20Unused%20Canister%20White%20Paper\_FINAL.pdf 6. Nebulizers—Policy Article. Centers for Medicare & Medicaid Services website. Published October 1, 2015. Updated January 1, 2024. Accessed May 16, 2024. https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleld=52466

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