

DYNAGITO®

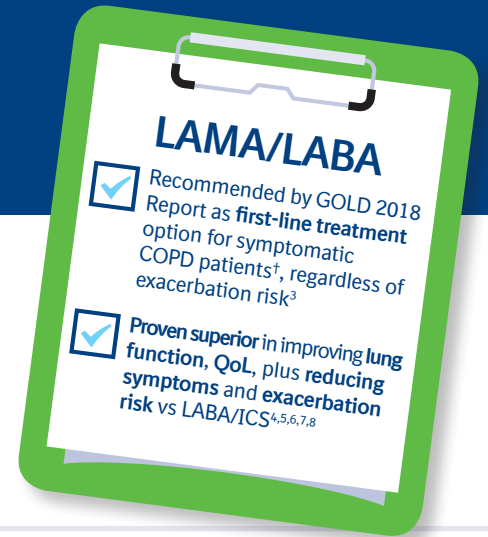
One of the Largest Studies to Date of Exacerbations in COPD



Better protecting people with COPD from exacerbations or 'flare-ups' is critical as they accelerate COPD progression and have a damaging effect on people's lives¹



DYNAGITO® investigated the effect of **Spiolto® Respimat®** (LAMA/LABA)* in reducing the rate of moderate-to-severe COPD exacerbations compared with **Spiriva® Respimat®** (LAMA)²



5 facts on DYNAGITO®



7880 patients



Investigated Tiotropium/olodaterol vs Tiotropium



conducted over 52 weeks



Primary endpoint: Annualised rate of moderate-to-severe exacerbations



>50 countries

DYNAGITO® Key Findings⁹



Lower rate of moderate-to-severe COPD exacerbation (p=0.0498[†])⁹
Targeted significance level of p<0.01 was not met for the primary endpoint

Key secondary endpoint: Time to first moderate-to-severe COPD exacerbation



No significant difference in the time to first moderate-to-severe COPD exacerbation between Spiolto® Respimat® and Spiriva® Respimat® (p=0.1188[†])

Further endpoints:

Fewer exacerbations that required intervention with systemic steroids or with systemic steroids plus antibiotics⁹

↓ 20% lower rate where the use of systemic steroids was needed (p=0.0068[†])⁹



↓ 9% lower rate where the use of systemic steroids plus antibiotics was needed (p = 0.0447[†])⁹

There was **no difference** in exacerbation rate between **Spiolto® Respimat®** and **Spiriva® Respimat®** in exacerbations treated with antibiotics only (p=0.2062[†])⁹



Safety data

No new side effects or safety concerns identified in DYNAGITO®⁹
Spiolto® Respimat® has a similar safety profile to **Spiriva® Respimat®**⁹

TOviTO®

DYNAGITO® adds to existing data from large-scale **TOviTO®** Phase III clinical trial programme investigating the efficacy and safety of **Spiolto® Respimat®** in COPD



Spiolto® Respimat® consistently offers improvements beyond **Spiriva® Respimat®** in **symptom reduction, exacerbation risk reduction, and quality of life** for people with COPD^{9,10,11}

* LAMA (long-acting antimuscarinic antagonist) and LABA (long-acting beta2-agonist) are both long-acting bronchodilators that work by opening airways and helping to keep them open
† GROUP B patients with severe breathlessness and all Group D patients should be started on LAMA/LABA; Group B patients without severe breathlessness should be started on a LAMA or a LABA
‡ The primary endpoint was not met

References: 1. Wedzicha J, et al. Clin Chest Med 2014; 35: 157-63. 2. ClinicalTrials.gov. NCT02296138. Available at: <https://clinicaltrials.gov/ct2/show/NCT02296138?term=NCT02296138&rank=1>. Last accessed: February 2018. 3. Global Initiative for Chronic Obstructive Lung Disease. Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease. 2018. Available at: www.goldcopd.org. Last accessed: February 2018. 4. Beeh KM, et al. Int J COPD 2016; 11: 193-205. 5. Vogelmeier C, et al. Lancet Respir Med 2013; 1: 51-60. 6. Zhong N, et al. Int J COPD 2015; 10: 1015-1026. 7. Wedzicha JA, et al. N Engl J Med 2016; 374: 2222-2234. 8. Horita N, et al. Cochrane Database Syst Rev 2017; 2: CD012066. 9. Calverley et al. Lancet Respir Med 2018 Published Online March 28, 2018 [http://dx.doi.org/10.1016/S2213-2600\(18\)30102-4](http://dx.doi.org/10.1016/S2213-2600(18)30102-4). 10. Singh D, et al. Tiotropium+olodaterol shows clinically meaningful improvements in quality of life. Respir Med. 2015; 10: 1312-1319. 11. Spiolto® Respimat® Summary of Product Characteristics, February 2017.