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Title: Tiotropium reduces asthma exacerbations in asthmatic patients with persistent airflow obstruction uncontrolled despite treatment in accordance with guidelines

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Body: Introduction: Some asthmatics remain symptomatic despite high-dose (HD) inhaled corticosteroids (ICS), long-acting β_2 -agonists (LABA) and additional treatments in accordance with guidelines and may have frequent asthma exacerbations. Methods: We performed a prespecified combined analysis of 2 replicate double-blind, parallel group trials comparing the effect of adding tiotropium Respimat® 5 mcg or placebo on exacerbation frequency in 912 asthmatics receiving at least HD ICS+LABA. At study entry, patients had a postbronchodilator (BD) FEV₁ <80% predicted, asthma control questionnaire score (ACQ) ≥ 1.5 , and at least one severe exacerbation in the preceding year. Severe exacerbations were defined as necessitating systemic corticosteroids for ≥ 3 days. Results: Baseline characteristics were similar between treatment groups. The addition of tiotropium was associated with a 21% risk reduction (HR 0.79, P=0.03) in time to first severe exacerbation. Tiotropium also reduced the risk of any asthma exacerbation by 31% (P<0.0001), defined by significant increase in symptoms or PEF drop $\geq 30\%$ over ≥ 2 days. There were significant improvements in ACQ and Asthma Quality of Life Questionnaire in one trial and a trend towards improvement in the ACQ in the other one. No deaths occurred; adverse events were balanced across treatments in both trials. Conclusion: In asthmatics that remain uncontrolled despite HD ICS+LABA, the

addition of tiotropium significantly reduces the risk of asthma exacerbations requiring treatment with systemic corticosteroids. Study supported by Boehringer Ingelheim and Pfizer.