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**Title:** Tiotropium provides sustained bronchodilation in asthmatics with persistent airflow obstruction uncontrolled despite treatment in accordance with guidelines

Prof. Dr Huib 9315 Kerstjens h.a.m.kerstjens@umcg.nl MD <sup>1</sup>, Prof. Dr Pierluigi 9363 Paggiaro lpaggiaro@dcap.med.unipi.it MD <sup>2</sup>, Dr. Mark 9391 Vandewalker drmlvand@aol.com MD <sup>3</sup>, Dr. Ekkehard 9396 Beck beck@ifg-forschung.de MD <sup>4</sup>, Dr. Michael 9397 Engel michael.engel@boehringer-ingenelheim.com MD <sup>5</sup>, Ralf 9501 Sigmund ralf.sigmund@boehringer-ingenelheim.com <sup>6</sup>, Dr. Wolfgang 9513 Seibold wolfgang.seibold@boehringer-ingenelheim.com MD <sup>7</sup>, Dr. Petra 9520 Moroni-Zentgraf petra.moroni-zentgraf@boehringer-ingenelheim.com MD <sup>8</sup> and Prof. Eric 9570 Bateman Eric.Bateman@uct.ac.za MD <sup>9</sup>. <sup>1</sup> Department of Pulmonary Medicine and Tuberculosis, University Medical Center, Groningen, Netherlands, 9700RB ; <sup>2</sup> Dipartimento Cardio-Toracico, U.O. Pneumologia e Fisiopatologia Respiratoria, Ospedale di Cisanello, Pisa, Italy, 56124 ; <sup>3</sup> Clinical Trials, Clinical Research of the Ozarks, Columbia, MO, United States, 65203 ; <sup>4</sup> Medical Department, IFG - Institut für Gesundheitsförderung GmbH, Rüdersdorf Brandenburg, Germany, 15562 ; <sup>5</sup> TA Respiratory Diseases, Boehringer Ingelheim Pharma GmbH & Co. KG, Biberach an der Riss, Germany, 88397 ; <sup>6</sup> Biostatistics, Boehringer Ingelheim Pharma GmbH & Co. KG, Biberach an der Riss, Germany, 88397 ; <sup>7</sup> Clinical Research, Germany, Boehringer Ingelheim Pharma GmbH & Co. KG, Biberach an der Riss, Germany, 88397 ; <sup>8</sup> TA Respiratory Diseases, Boehringer Ingelheim Pharma GmbH & Co. KG, Ingelheim am Rhein, Germany, 55216 and <sup>9</sup> Department of Medicine, University of Cape Town, South Africa, 7700 .

**Body:** Introduction: In some asthmatics airflow obstruction persists despite high-dose (HD) inhaled corticosteroid (ICS) and long-acting  $\beta_2$ -agonist (LABA) use. In a recent study, adding a long-acting anticholinergic (tiotropium) showed favourable effects over 8 weeks (wks) (Kerstjens HA, et al. JACI. 2011). Methods: In 2 replicate 48-wk, doubleblind, parallel-group trials a total of 912 asthmatics with postbronchodilator (BD) FEV<sub>1</sub> <80% predicted and asthma control questionnaire score  $\geq 1.5$  while on at least HD ICS+LABA were randomised to additional tiotropium Respimat® 5 mcg or placebo. Prespecified co-primary endpoints included peak and trough FEV<sub>1</sub> at 24 wks. Secondary endpoints were FEV<sub>1</sub> at other time-points, FVC, and daily PEFs. Results: Baseline characteristics were similar between trials and treatment groups (mean post-BD FEV<sub>1</sub> 62% [ $\pm 13$ ]). Mean change from baseline tiotropium vs placebo after 24 wks in peak pre-BD FEV<sub>1</sub> was 86 ( $\pm 34$ ) mL (P=0.01) or 154 ( $\pm 32$ ) mL greater (P<0.001), and in trough FEV<sub>1</sub> 88 ( $\pm 34$ ) mL (P=0.01) or 111 ( $\pm 30$ ) mL greater (P<0.001) in trials 1 and 2, respectively. Improvements in FVC and daily PEFs were also significantly greater with tiotropium. There were no signs of tachyphylaxis over 48 wks. No deaths occurred; adverse events were balanced across treatments in both trials. Conclusion: In asthmatics uncontrolled despite at least HD ICS+LABA, adding tiotropium provided

significant lung function improvement at 24 wks which was sustained over 48 wks. Tiotropium is likely to improve severe uncontrolled asthma on top of treatment in accordance with guidelines. Study supported by Boehringer Ingelheim and Pfizer.