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Title: Inhaled mannitol for non-cystic fibrosis bronchiectasis - results of a 12 month, multi-centre, double-blind, controlled study

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Body: Bronchiectasis, characterised by abnormal bronchial dilatation, is associated with increased mucus and sputum production, impaired mucocilliary clearance, mucus accumulation, cough and recurrent bacterial infection. Inhaled dry powder mannitol is an osmotic agent that increases clearance of mucus both acutely & over 24 hrs in patients with bronchiectasis. Studies at 2 wks with mannitol have shown benefits in QoL & symptoms, however information on the longer term efficacy & safety of mannitol is needed. Aims: The primary objective was to evaluate the difference between mannitol & control for pulmonary exacerbations over 12 mths in patients with non-CF bronchiectasis. Secondary endpoints were: QoL (SGRQ), antibiotics prescribed for pulmonary exacerbations, time to first exacerbation, 24 hr sputum volume, Epworth Sleepiness Scale, lung function & safety including adverse events, airway reactivity & sputum microbiology. Methods: This was a double-blind, multicentre, phase III study in patients 18 to 85 yrs with a confirmed diagnosis of non-CF bronchiectasis & an $FEV_1 \geq 40\%$ & $\leq 85\%$ predicted & ≥ 1.0L. 485

patients were randomised to mannitol (400mg bd) or control (bd) in a 1:1 ratio. Preliminary baseline data: mean age (SD) 59.7 (13.57), 62.7% female, 95.7% Caucasian, 39.6% ex-smokers, mean age (SD) of diagnosis of bronchiectasis 43 (22.3), and mean (SD) % Predicted FEV_1 62.3 (13.46). Results: Study results will be presented at the annual scientific meeting. The last patient visit takes place in March with planned database lock April 2013. The B-305 study is the largest study of the long-term safety and efficacy of a therapeutic agent in non-CF bronchiectasis.