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Title: High-dose N-acetylcysteine in the prevention of COPD exacerbations: Results of the PANTHEON study

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Body: BACKGROUND: Mucus hypersecretion, oxidative stress and airway inflammation play important roles in pathogenesis and progression of chronic obstructive pulmonary disease (COPD). The aim of PANTHEON study was to evaluate effectiveness of long-term, high-dose (1200 mg/d) antioxidant N-acetylcysteine (NAC) treatment in reducing exacerbations in COPD patients with and without inhaled corticosteroids (ICS). METHODS: In this prospective, stratified, randomized, double-blind, placebo-controlled, parallel-group trial 1006 COPD patients classified as GOLD II and III in terms of severity (444 treated with maintenance ICS, 562 ICS naive, aged 66.27±8.76 yrs, average post-bronchodilator FEV1 48.95±11.80 of predicted), enrolled in 34 centers in China, after a 2-week run in period were randomly assigned to receive NAC tablets 600mg (Fluimucil®) or placebo twice daily for 1 year. The primary endpoint was the yearly exacerbation rate. RESULTS: 504 patients were assigned to the NAC 1200 mg group and 502 to the placebo group. After 1 year treatment, a 22% reduction of exacerbations (risk ratio 0.78, 95% CI 0.67-0.90, p=0.001) was found in the NAC 1200mg group compared to the placebo group. The reduction of exacerbation was appeared regardless of ICS use. There was a significant interaction between treatment and GOLD stage, with a better improvement with NAC 1200 mg in the GOLD moderate subgroup (39% reduction). NAC 1200mg/d was well tolerated. CONCLUSIONS: NAC 1200mg/d is an effective and safe

treatment in preventing acute exacerbations for moderate to severe COPD patients.