European Respiratory Society
Annual Congress 2013

Abstract Number: 2425

Publication Number: P4080

Abstract Group: 4.3. Pulmonary Circulation and Pulmonary Vascular Disease

Keyword 1: Chronic disease **Keyword 2:** Treatments **Keyword 3:** Pulmonary hypertension

Title: Long-term safety of a new formulation of epoprostenol in pulmonary arterial hypertension

Prof. Marion 1858 Delcroix marion.delcroix@uz.kuleuven.ac.be MD [1], Prof. Gérald 9347 Simonneau (gerald.simonneau@bct.aphp.fr MD [2], Dr. Emmanuel 9348 Bergot bergot.e@gmail.com MD [3], Dr. Anco 9349 Boonstra a.boonstra@vumc.nl MD [4], Dr. John 9350 Granton john.granton@uhn.on.ca MD [5], Dr. David 9351 Langleben david.langleben@mcgill.ca MD [6], Dr. Pilar 9352 Escribano Subias pilar.escribano@telefonica.net MD [7], Prof. Nazzareno 9353 Galiè nazzareno.galie@unibo.it MD [8], Dr. Thomas 9354 Pfister thomas.pfister@actelion.com [9], Mr. Jean-Christophe 9355 Lemarié jean-christophe.lemarie@effi-stat.com [10] and Prof. Olivier 9359 Sitbon olivier.sitbon@bct.aphp.fr MD [2]. [1] Department of Pneumology, Gasthuisberg University Hospital, Leuven, Belgium ; [2] CHU De Bicêtre, Université Paris-Sud, Le Kremlin-Bicêtre, France ; [3] Service De Pneumologie, Hôpital Côte De Nacre-CHU, Caen, France ; [4] Department of Pulmonology, VU University Medical Center, Amsterdam, Netherlands ; [5] Pulmonary Hypertension Programme, University of Toronto, Toronto, ON, Canada ; [6] Jewish General Hospital, McGill University, Montreal, QC, Canada ; [7] Servicio De Cardiología, Hospital Universitario 12 De Octubre, Madrid, Spain ; [8] Institute of Cardiology, University of Bologna, Bologna, Italy ; [9] Department of Clinical Science, Actelion Pharmaceuticals Ltd, Allschwil, Switzerland and [10] Effi-Stat, Effi-Stat, Paris, France .

Body: Purpose: This study investigates the long-term safety of epoprostenol with arginine and sucrose excipients (epo-AS; approved for pulmonary arterial hypertension [PAH] in the USA as Veletri®), an infused prostacyclin with improved stability. Methods: In EPITOME-2 PAH patients were transitioned from epoprostenol with glycine and mannitol excipients (epo-GM; Flolan®) to epo-AS and treated initially for 3 months and then in the ongoing extension until discontinuation or access to commercially available epo-AS. Long-term safety was evaluated based on adverse events (AE), serious AE (SAE) and reasons for premature discontinuation. This analysis includes data from all patients treated between 22 March 2011 and 28 January 2013. Results: 41 patients, median (range) duration of PAH 5.4 (1.6–37.1) years and epo-GM exposure 41 (12–173) months, were transitioned to epo-AS. The median (range) epo-AS exposure was 16.2 (9–22) months. 5 patients discontinued study drug; 4 underwent lung transplant and 1 experienced sudden death. 40 (98%) patients had ≥1 AE; the most frequent (>10%) were collective issues with the delivery system, headache, nasopharyngitis, extremity pain, dyspnoea, jaw pain, flushing, bronchitis, diarrhoea and fatigue. 18 patients had SAE associated with the delivery system, including 6 patients with catheter-related infections. Other SAE included right ventricular failure (n=3) and syncope (n=2). Conclusion: The safety and tolerability profile of epo-AS was typical of that of an infused prostacyclin, and no new safety signals were identified in patients treated with epo-AS up to 22 months.