

European Respiratory Society Annual Congress 2013

Abstract Number: 733

Publication Number: P736

Abstract Group: 5.1. Airway Pharmacology and Treatment

Keyword 1: Anti-inflammatory **Keyword 2:** Pharmacology **Keyword 3:** Treatments

Title: Safety, tolerability and pharmacokinetics of a new inhaled once-daily phosphodiesterase (PDE) 4 inhibitor in healthy volunteers

Dr. Oriana 8486 Esposito o.esposito@chiesi.com¹, Mrs. Fabrizia 8487 Mariotti f.mariotti@chiesi.com¹, Mrs. Daniela 8488 Acerbi d.acerbi@chiesi.com¹, Mrs. Anna 8489 Compagnoni a.compagnoni@chiesi.com¹ and Dr. Marie-Anna 8490 Nandeuil ma.nandeuil@chiesifrance.com MD¹.¹ Corporate Clinical Development, Chiesi Farmaceutici SpA, Parma, Italy .

Body: INTRODUCTION: CHF6001 is a novel inhaled PDE4 inhibitor designed to improve efficacy and tolerability versus orally administered compounds of that class. The potent anti-inflammatory activity of CHF6001 has been proven in different animal models of airways inflammation. OBJECTIVE: To investigate the safety, tolerability and pharmacokinetics of inhaled CHF 6001 after single and multiple dosing in healthy volunteers. METHODS: Seven single doses of CHF6001 (20ug to 2000ug) were administered using a dry powder inhaler according to an escalation, alternate crossover design to 20 healthy volunteers. Five dose levels (100ug to 1600ug) were administered once-daily for 7 days according to a sequential dose escalation parallel group design to 54 healthy volunteers. RESULTS: CHF6001 was well tolerated after single administration of doses up to 2000ug and after repeated administration of doses up to 1600ug. No serious or severe adverse events were reported. No dose-related trend in the incidence of adverse events and no relevant adverse cardiovascular or gastrointestinal effects were observed. Systemic exposure to CHF6001 increased approximately dose proportionally. Steady state was reached after 7 days of treatment consistent with the elimination half- life of approximately 30h. CONCLUSIONS: CHF6001 was safe and well tolerated up to the highest doses after both single and repeated administration in healthy volunteers with an absence of gastrointestinal adverse effects related to the drug. Pharmacokinetic analysis supports once-a-day dosing of CHF6001.