|  |
| --- |
| **High-strength BDP/FF/G before biologics is effective in asthmatics (PAL; high eosinophils)** |
| Marielle van der Deijl1, Maxim Kots1, Alberto Papi2, Leonardo Fabbri2, Giorgio Walter Canonica3,4, Andrea Vele5, Eva Topole5, George Georges5 |
| *1Global Medical Affairs, Chiesi Farmaceutici, S.p.A., Parma, Italy;*  *2Respiratory Medicine, Department of Translational Medicine and for Romagna, University of Ferrara, Ferrara, Italy;*  *3Department of Biomedical Sciences, Humanitas University, via Rita Levi Montalcini 4, 20090 Pieve Emanuele, Milan, Italy;*  *4Asthma & Allergy Unit-IRCCS Humanitas Research Hospital, via Manzoni 56, 20089 Rozzano, Milan, Italy;*  *5Global Clinical Development, Chiesi Farmaceutici, S.p.A., Parma, Italy.* |
| **Introduction/Aim:**  High-dosetriple therapy with ICS/LABA/LAMAis recommended for adults with uncontrolled asthma in GINA Steps 4-5 and is often administered concomitant with or prior to initiation of biologic treatment. Previously, we reported in a post-hoc analysis of two large randomized clinical trials (TRIMARAN & TRIGGER) that patients with asthma uncontrolled on ICS/LABA and exhibiting persistent airflow limitation (PAL) may particularly benefit from the addition of LAMA (Singh D et al. Eur Respir J 2020). Here we explore the efficacy of high-dose ICS triple therapy in patients not controlled by high-dose ICS/LABA exhibiting both PAL and high blood eosinophil count, a phenotype that is considered for a step-up to biologic therapy.  **Methods:**  Using the dataset from the TRIGGER study, we conducted a post-hoc analysis in subjects with asthma uncontrolled by high dose ICS/LABA exhibiting PAL (post-salbutamol FEV1≤80% and FEV1/FVC≤0.7) and a blood eosinophils count higher than 150 cell 109/L at screening, to evaluate the annualized rate of moderate to severe exacerbation following a 52 week treatment with high-dose extrafine beclometasone dipropionate/formoterol fumarate/glycopyrronium (BDP/FF/G 800mcg/24mcg/40mcg total daily dose pMDI) or high dose extrafine beclometasone dipropionate/formoterol fumarate (BDP/FF 800mcg/24mcg total daily dose pMDI).  **Results:**  The TRIGGER study population included 1142 patients on BDP/FF/G or BDP/FF out of which 511 (44.7%) met the criteria of PAL and high blood eosinophil count. After 52 weeks of therapy, the reduction in the rate of “severe” and “moderate and severe” asthma exacerbations with BDP/FF/G vs BDP/FF was 35.8% (rate ratio = 0.642; 95% CI: 0.445-0.926; p=0.018) and 28.3% (rate ratio = 0.717; 95% CI: 0.573-0.898; p=0.004), respectively.  **Conclusion:**  Treatment with high-dose extrafine BDP/FF/G is effective in patients with asthma uncontrolled on high-dose ICS/LABA who exhibit PAL and high blood eosinophils count. Exploring triple therapy before initiation of biologic treatment is an option that merits further investigation.  **Grant Support:**  This study was funded by Chiesi Farmaceutici SpA.  **Conflict of Interest:**  Marielle van der Deijl is an employee of Chiesi Farmaceutici SpA.        **Grant Support:** |