

## Clinical Research Results Abstract

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### Adding GINA step 5 therapies to ICS/LABA in a real-life moderate to severe asthma population: is inhaler adherence a treatable trait?

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**Aim:** Global Initiative for Asthma step 5 therapies (GINA-5), other than inhaled corticosteroids and long-acting beta agonists in fixed dose combinations (ICS/LABA FDC), often entail more expensive (e.g. monoclonal biologics) or less safe [e.g. maintenance oral corticosteroids (OCS)] treatments. It is therefore important to assess poor inhaler adherence as a possible cause of sub-optimal response to ICS/LABA FDC before additional GINA-5. Our aim was to determine rates of, and time to, additional GINA-5 following first-year ICS/LABA FDC use, and their association with inhaler adherence.

**Method:** Patients initiating ICS/LABA FDC between 2013 and 2017 were identified from Australian national dispensing data. Group-based trajectory modelling was used to estimate medication adherence patterns. Multivariable Cox proportional hazards models were used to examine the association between adherence trajectories and GINA-5 addition during 2-year follow-up.

**Results:** In total, 3062 new ICS/LABA FDC users were identified of whom 120 (3.9%) received additional GINA-5 (OCS:89; LAMA:39; biologics:<3). Mean time to commencing additional GINA-5 was 705.2 (SD 1.7) days. Adherence trajectories were: non-persistent use (20%), seasonal use (8%), poor adherence (58%), and good adherence (13%). Although poor adherence was associated with longer time to additional GINA-5 (adjusted HR: 0.58; 95%CI: 0.35-0.95), over 80% of additional GINA-5 was commenced in poorly-adherent patients. Use of  $\geq 2$  OCS/antibiotic courses also predicted additional GINA-5.

**Conclusion:** Almost one in 20 people with asthma commenced additional GINA-5 after ICS/LABA initiation, most of whom (>80%) were poorly-adherent to inhaled preventers. There is a substantial unmet need for inhaler adherence to be addressed prior to prescribing additional GINA-5.

#### Declaration of Interest

No funding was received for this study. The study was registered at the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (EUPAS28437).