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### Title: Real-World Evidence of baricitinib and upadacitinib treatment in patients with very difficult-to-treat Atopic Dermatitis

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#### Introduction

Baricitinib and upadacitinib, both oral selective Janus kinase (JAK)-inhibitors (JAK-1/2 and JAK-1, respectively) are two of the new advanced systemic treatments for moderate-to-severe atopic dermatitis (AD). Clinical trials showed that baricitinib and upadacitinib are both effective and relatively safe for the treatment of moderate-to-severe AD, however daily practice data are still limited. Therefore, the aim of this study is to assess clinical effectiveness and safety of 16-weeks treatment with baricitinib and upadacitinib in patients with moderate-to-severe AD in daily practice.

#### Materials and methods

Data of patients treated with baricitinib and upadacitinib at baseline, and after 4, 8 and 16 weeks of treatment were extracted from the BioDay registry. Effectiveness of treatment was assessed by the Eczema Area and Severity Index (EASI) and the Numeric Rating Scale (NRS)-pruritus, as well as other patient-reported outcome measurements (PROMs). All effectiveness outcomes were stratified by different treatment groups based on past biological and small molecule treatment (dupilumab vs. non-dupilumab failures and if applicable baricitinib vs. non-baricitinib failures). Side effects were evaluated and laboratory tests were performed at every visit.

#### Results

Data of 51 patients with baricitinib and approximately 60 patients with upadacitinib treatment of the first 16 weeks will be presented. Preliminary results are based on 51 patients with baricitinib and 43 patients with upadacitinib after 8 weeks of treatment of which respectively 50.9% and 65.1% had concomitant immunosuppressive therapy at baseline. Proportion of patients with  $EASI \leq 7$  and  $NRS\text{-pruritus} \leq 4$  were respectively 41.7% and 41.2% for baricitinib and 57.1% and 48.8% for upadacitinib treatment. Respectively 55.6% and 36.1% of the patients with baricitinib treatment and 66.7% and 35.7% of the patients with upadacitinib treatment achieved EASI-50 and EASI-75 at week 8. Most frequently reported adverse events were nausea, urinary tract infections, herpes simplex and acne. No relevant laboratory results were found. In total, 15 patients (29.4%) and 4 patients (9.3%) discontinued baricitinib and upadacitinib treatment respectively due to ineffectiveness and/or side effects.

#### Discussion

These preliminary results show that baricitinib and upadacitinib could be effective treatments for moderate-to-severe AD, even in patients who previously failed on dupilumab treatment. However, effectiveness of baricitinib seems rather be heterogeneous due to a high discontinuation rate in this very difficult-to-treat cohort. Therefore, patient profiling will be of great importance in the future, especially with new emerging advanced systemic therapies for AD. Safety analysis showed no new findings in this cohort.

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