1. ABSTRACT

- **Title**

Persistence of AMGEVITA® in patients with plaque psoriasis: a retrospective database analysis from the British Association of Dermatology Biologics and Immunomodulators Register (BADBIR)

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- **Keywords (maximum 5)**

AMGEVITA, Biosimilar, Persistence, Psoriasis, Biologic-Naïve

- **Rationale and Background**

Psoriasis (PsO) is a chronic immune mediated disease and is estimated to affect 125 million people worldwide. There are multiple subtypes of psoriasis with plaque PsO being the most common, constituting 80% of cases. Plaques cause itching, stinging and pain, which has a great impact on the patient's quality of life. Critically PsO, is associated with a large number of comorbidities and excess mortality.

Biosimilars (such as adalimumab [AMGEVITA], etanercept, infliximab) have been available in the UK for the treatment of PsO for a number of years but data on persistence to these therapies is lacking.

- **Research Question and Objectives**

This research focusses on understanding the persistence of AMGEVITA (a biosimilar adaliumab) in biologic-naïve (BN) and biologic-experienced (BE) patients with plaque psoriasis (PsO). The primary objective was to describe drug persistence of AMGEVITA-treated patients by prior biologic experience. Secondary objectives assessing the demographics and clinical characteristics of patients treated with AMGEVITA, and the reasons for discontinuing AMGEVITA. Exploratory objectives were to describe the change in DLQI, PASI or PGA at 6-months from initiation of AMGEVITA.

- **Study Design**

Retrospective database study

- **Setting**

Electronic health records data (from October 2018 to July 2021) within the British Association of Dermatologists Biologic Interventions Register (BADBIR) including 164 dermatology departments (as of February 2021) across the UK and the Republic of Ireland

- **Subjects and Study Size, Including Dropouts**

Patients aged ≥18 years diagnosed with PsO who were registered with BADBIR, received at least one dose of AMGEVITA and had at least one follow-up visit (6-months) were eligible for inclusion. A total of 1432 patients were included in the Full Analysis Set.

- **Data Source(s) and Methods**

Data in BADBIR reported by healthcare professionals included patients' clinical characteristics (including comorbidities), disease severity assessed using the Psoriasis Area Severity Index (PASI), physician's global assessment (PGA), and Dermatology Life Quality Index (DLQI). Information on patients' experience living with psoriasis was obtained from patients' completion of the dermatology life quality index (DLQI) questionnaire. Statistics were descriptive in nature, with no statistical testing undertaken to compare the groups evaluated. Summary statistics included frequencies (%) for categorical variables and mean (standard deviations [SD]) and median (Q1, Q3) for continuous variables such as time from diagnosis to treatment initiation.

- **Results**

Among 1432 patients with PsO, 1182 were identified as biologic-experienced (BE) and 249 as biologic-naïve (BN). Forty-percent of patients (n=574/1432) were female, and over half (n=796/1432 [56%]) between the ages of 35-54. In the overall population, the median time (interquartile range Q1, Q3) from psoriasis diagnosis to (and including) AMGEVITA start date was 24 (15, 34) years. At baseline, patients had a median PASI, 6.2 (0.8, 12.8), a median DLQI of 15 (4, 21) and a median PGA of 2 (1, 4). AMGEVITA persistence (95% CI) at 6, 12, 18, and 24 months was 0.94 (0.93-0.95), 0.87 (0.86-0.89), 0.84 (0.82-0.86), and 0.82 (0.80-0.84), respectively.

When analysing outcome measures stratified by prior exposure to biologics, BN patients appeared to have more severe disease, more affected quality of life, and numerically lower persistence than BE patients.

AMGEVITA persistence (95% CI) at 6, 12, 18, and 24 months in the BE population, was 0.94 (0.92-0.95), 0.88 (0.86-0.90), 0.85 (0.83-0.87) and 0.84 (0.81-0.86). At baseline, the median time (interquartile range Q1, Q3) from psoriasis diagnosis to (and including)

AMGEVITA start date was 25 (17 – 35) years, with a median PASI, 1.1 (0, 3.2), a median DLQI of 2.0 (0, 12) and a median PGA of 1 (0, 2).

AMGEVITA persistence (95% CI) at 6, 12, 18, and 24 months in the BN patients persistence was 0.94 (0.91-0.97), 0.84 (0.78-0.88), 0.77 (0.71-0.82) and 0.74 (0.68-0.80), respectively. At baseline, the median time (interquartile range Q1, Q3) from psoriasis diagnosis to (and including) AMGEVITA start date was 18 (10, 30) years, with a median PASI of 12.8 (10.6, 17.1), a median DLQI of 17 (12, 23) and a median PGA of 4 (3, 5).

Overall 18% (n=253/1432) of patients discontinued AMGEVITA during the course of the study, with AMGEVITA discontinuations being 16.1% (n=191/1183) in BE patients versus 25% (n=62/249) in BN patients, respectively.

The median time (Q1, Q3) to discontinuation in the overall population was 8.3 (4.6, 13.2) months; BE patients 7.6 (4.2, 13) months and BN patients 9.7 (6.3, 14.3) months.

The most common reasons for those patients discontinuing AMGEVITA (n=253/1432) were ineffectiveness (n=102/253 [40%]), adverse events (n=74/253 [29%]) and other reasons (for example: contraindications, patient choice, patient non-compliance (n=62/253 [24.5%])).

Among patients with data for PASI, DLQI and PGA at baseline and at 6-months after treatment with AMGEVITA, (n=94 in both groups), median change (Q1, Q3) in PASI score at 6 months was -11 (-14, -8.2) in BN and 0.0 (-1.2, 0.6) in BE patients. Changes were also seen in median DLQI -13 (-19, -7) in BN patients and 0 (-3, 0) in BE patients and PGA -3 (-3, -2) in BN patients and 0 (-1, 1) in BE patients.

- **Discussion**

Over this 24-month study, patients who either initiate AMGEVITA or who transition to AMGEVITA, show high levels of persistence with therapy. These results are consistent with previous adalimumab (Humira®) studies from the BADBIR registry, in patients with plaque psoriasis. (Yiu 2020, Yiu 2022)

Patient characteristics showed that BN patients tended to have a shorter disease duration, were younger, and had more severe psoriasis by location versus BE patients. Biologic-experienced patients tended to have longer disease duration potentially due to cycling through psoriasis therapies or because of better disease control whilst being on a

biologic compared with conventional therapies (i.e. those used in the BN group before the transition to AMGEVITA).

There were minor differences across the groups in relation to co-morbidities. Overall, there were still high levels of co-morbidities specifically in relation to depression, cardiovascular disorders, psoriatic arthritis and hypertension seen in all patients.

This real-world study shows that in patients with chronic plaque psoriasis, initiating AMGEVITA in UK clinical practice, demonstrated high drug persistence over 24-months irrespective of prior biologic use.

Marketing Authorization Holder(s)

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