1. ABSTRACT

- **Title**

Characteristics and Risk Profile of Adult Patients Treated with Apremilast included in the British Association of Dermatologists Biologic Interventions Register (BADBIR): A Retrospective Database Analysis

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Name and affiliation of main author : [redacted] observational research

- **Keywords (maximum 5)**

Apremilast, Cardiovascular Risk, Psoriasis, Severity, Skin colour

- **Rationale and Background**

Treatment selection for patients with psoriasis relies on various factors, including (but not limited to) the site and extent of body areas affected, functional and/or psychological impairments, and active comorbidities. When assessing disease severity, healthcare professionals are now recommended to make appropriate adjustments due to skin colour. Consequently, there is a growing need to better understand the diversity profile of patients with psoriasis receiving treatment in the real-world settings.

- **Research Question and Objectives**

The primary objective was to describe of the profile of psoriasis patients receiving apremilast in routine clinical practice. Other objectives included estimation of the time from diagnosis of psoriasis to apremilast initiation, and time from discontinuation of the most recent prior therapy for psoriasis to apremilast initiation.

- **Study Design**

Retrospective database study

- **Setting**

Electronic health records data (from October 2015 to March 2021) within the British Association of Dermatologists Biologic Interventions Register (BADBIR) covering 164 dermatology departments (as of February 2021) across the UK and the Republic of Ireland

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

Psoriasis patients aged ≥18 years who were registered with BADBIR and exposed to apremilast were eligible for inclusion. Eligibility criteria were met by 285 patients. Twenty patients were later excluded due to the missing registration or baseline data, no record of chronic plaque psoriasis, skin photoype or inaccurate data. The final study sample included 265 patients.

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

Data reported by healthcare professionals included patients' clinical characteristics (including comorbidities) and disease severity assessed using the Psoriasis Area Severity Index (PASI), physician's global assessment (PGA), and body surface area (BSA) affected. The Framingham risk score was calculated to assess the 10-year probability of cardiovascular event among patients 30-74 years old without pre-existing cardiovascular disease (CVD). Patients' experiences living with psoriasis were captured by the dermatology life quality index (DLQI) and EuroQol five dimensional (EQ-5D-3L) questionnaires. Summary statistics included frequencies (%) for categorical variables and mean (SD) and median (Q1, Q3) for continuous

variables, such as time from diagnosis to treatment initiation. All study outcomes were stratified by Fitzpatrick Skin type (I-III, IV-VI) and by ethnicity (White, non-White).

- **Results**

Among 265 patients, 47.5% (n=126) were women, and median (Q1, Q3) age at apremilast initiation was 50.1 (38.2, 59.5) years. Approximately 10% (n=25) of the study population were non-White. Median (Q1, Q3) age at psoriasis onset was 23 (16, 37) years. Median (Q1, Q3) BMI (n=234) was 29.9 (26.0, 35.3). Current smoking was reported by 21.1% (n=56), and hazardous or harmful drinking by 10.6% (n=28) of participants. Family history of psoriasis was reported among 46.3% (n=113) patients. Median number of concurrent treatments was 2 (0, 5). Prevalent comorbidities included hypertension (23.4%, n=62), depression (21.5%, n=57), psoriatic arthritis (18.1%, n=48), and diabetes (15.8%, n=42). The most common areas affected by psoriasis were scalp (75.5%, n=200), nails (52.8%, n=140), and flexural (39.6%, n=105).

Based on the PGA, 19.2% (n=51) of patients had moderate disease, 36.2% (n=96) had moderate to severe, and 20.0% (n=53) had severe psoriasis. Median (Q1, Q3) PASI score (n=259) was 12.7 (10.4, 17.0). Median (Q1, Q3) DLQI score (n=227) was 15.0 (9.0, 20.0). Among patients with the PASI score ≥10 or BSA ≥10% (n=220), two thirds (64.1%, n=141) had total DLQI score >10.

The risk of developing CVD over the 10 years was calculated among patients aged 30-74 years old and without pre-existing CVD. Among 88 females, 61.3% (n=54) were at a moderate or high risk (Framingham risk score ≥10), and 17.0% (n=15) were at high risk (Framingham risk score >20) of developing CVD. Among 98 males, 65.3%, (n=64) were at a moderate or high risk and 4.1% (n=4) were at a high risk of developing CVD.

Median (Q1, Q3) number of prior therapies was 1 (1, 2). Most common therapies prior to apremilast initiation were methotrexate (29.8%, n=79), and acitretin (27.5%, n=73). The most common reasons of discontinuation were adverse events (32.5%, n=86), and ineffectiveness (29.1%, n=77).

Based on EQ-5D-3L, 57.3% (n=152) of patients experienced moderate or extreme pain or discomfort, and 31.7% (n=84) felt moderately anxious or depressed.

Median (Q1, Q3) time to apremilast initiation since psoriasis onset was 19.1 (11.0, 30.4) years, 12.9 (5.8, 24.6) years since when dermatologist was first seen, and 2.3 (0.2, 8.6) months since discontinuation of the most recent therapy.

Patients with Skin Phototypes I-III more often reported family history of psoriasis than patients with Skin Phototypes IV-VI (50.9% vs 34.8%, respectively), more often experienced extreme pain or discomfort (8.0% vs 2.6%), more felt moderately anxious or depressed (33.7% vs 26.9%), and more often experienced problems in walking (23.5% vs 15.4%). Patients with Skin Phototypes IV-VI more often had scalp (83.3% vs 72.2%) and palm psoriasis (20.5% vs 15%), more often had diabetes (20.5% vs 13.9%) and PASI ≥10 or BSA ≥10 and DLQI >10 (67.2% vs 62.7%).

Small proportion of patients with non-white ethnicity precluded making conclusions about differences in experienced burden by ethnicity.

- **Discussion**

In conclusion, this study showed that patients who initiated apremilast in real-world clinical practice in the UK had a long duration of disease, with moderate to severe psoriasis and had been previously failed systemic

treatment due to lack of efficacy and/or safety. Cardiometabolic and psychiatric comorbidties were prevalent, and the majority of patients were at increased CVD risk. Patients reported an important impact on quality of life, pain and discomfort, and experienced anxiety and/or depression.

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