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Efficacy and safety of adalimumab biosimilar GP2017 in a 24-month treatment period for plaque psoriasis: real-life experience from Emilia-Romagna centers, Italy

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Conflict of interest: MML has participated in clinical trials for Janssen, Almirall, Principia Biopharma. VDL has served as a member of advisory boards and/or received speaker honoraria from Abbvie, Amgen, Eli Lilly outside the submitted work; has participated as principal investigator for clinical studies for Almirall, Sanofi, Jansen, Eli Lilly, Novartis. FB declares conflict of interest with Novartis, AbbVie, Janssen-Cilag, UCB, Celgene, Almirall, Leopharma. MR declares conflict of interest with Novartis and AbbVie. MC served as speaker and advisory board for Sanofi, Leopharma, Pfizer, Novartis, Abbvie, Jannsen. FS served as advisory board member and consultant and has participated in clinical trials for AbbVie, Almirall, Leo Pharma, Janssen, Novartis, Sanofi Genzyme, UCB, Boehringer-Ingelheim. AC has been a speaker and/or consultant for Abbvie, Almirall, Leo

Pharma, UCB, Sandoz, Amgen, Biogen, Novartis, Janssen Cilag, Eli Lilly, Pfizer, Boehringer-Ingelheim. FP, MT, and DM have nothing to declare.

Ethics approval and consent to participate: the study was conducted in accordance with local ethical regulations.

Availability of data and materials: data supporting the findings of this study are available upon reasonable request. Please contact Andrea Conti at a.conti.dermo@gmail.com for access to the data.

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Abstract

Adalimumab (ADA), a monoclonal antibody targeting TNF-α, is effective in treating moderate to severe psoriasis. The emergence of biosimilars, such as GP2017 (Hyrimoz®), has raised concerns about their safety and efficacy compared to the originator. This two-year observational study evaluated the effectiveness and safety of GP2017 in 171 patients from Emilia-Romagna, Italy. Patients were divided into two groups: 78 transitioned from the ADA originator, and 93 were biologic-naive. Changes in the Psoriasis Area and Severity Index (PASI) were analyzed. In the switch group, PASI scores remained stable, while the naive group achieved significant improvements (PASI 75: 52% at 3 months, 89% at 6 months). Adverse events leading to discontinuation were rare. The findings confirm that GP2017 is as effective and safe as the ADA originator, supporting its use as a cost-effective alternative in the treatment of psoriasis. Biosimilars play a crucial role in promoting equitable access to biologic therapies.

Adalimumab (ADA), a fully human monoclonal antibody that targets TNF-α, has demonstrated remarkable efficacy in the treatment of moderate to severe psoriasis, and it is now commonly used for managing this inflammatory condition.[1] However, the emergence of various biosimilars for this medication in recent years, coupled with the growing adoption of these alternatives in clinical practice to control healthcare expenditures, has led to concerns regarding potential disparities in safety and effectiveness compared to the originator drug.

The aim of this two-year observational study was to assess the effectiveness and safety of the ADA biosimilar GP2017 (Hyrimoz®, Sandoz GmbH), which received approval from the European Medicines Agency (EMA) in 2018, in patients who had not previously undergone biologic treatment, as well as in those who switched from the ADA originator.[2] Data were collected from the dermatology units of the Emilia-Romagna region in Italy over a two-year observation period, including demographic characteristics, comorbidities, Psoriasis Area and Severity Index (PASI) scores, and adverse events for the 171 patients observed.

The patients were categorized into two groups: the first group (n=78) comprised individuals who switched from the ADA originator to the biosimilar GP2017, while the second group (n=93) included patients who were new to biologic treatments and initiated GP2017. Of the 171 patients, 124 (72%) were male. The naive group had an average age of 52.25±14.6, whereas the switch group had an average age of 57.19±14.88. The body mass index (BMI) for the naive group was 26.48±5.93 kg/m^2,

and for the switch group, it was 26.66±4.39 kg/m^2. Notably, the switch group had a higher proportion of patients with psoriatic arthritis (73% *vs*. 19%).

The effectiveness of the biosimilar was evaluated by measuring changes in PASI scores from baseline to 24 months (Figure 1). Notably, the PASI score (mean ± SD) remained stable in the switch group. After 6 months, the mean PASI score in the naive group closely approximated that in the switch group (1.13±2.45 *vs.* 1.91±2.13, p=0.01). Additionally, in the naive group, a PASI 75 response was achieved by 52% and 89% of patients at 3 and 6 months, respectively. The occurrence of major adverse events leading to drug discontinuation was limited, with one case of subcutaneous abscess in the switch group and one case of cerebral ischemia in the naive group. In the switch group, treatment was discontinued in 3 cases due to loss of efficacy, whereas in the naive group, discontinuation was observed in 11 patients (4 due to primary inefficacy and 7 due to loss of efficacy).

Biosimilars, known for their cost-effectiveness and equivalent efficacy, are a viable option in the treatment of chronic plaque psoriasis.[3,4] The primary finding of this study suggests that patients who responded to the ADA originator can safely transition to the biosimilar GP2017 without experiencing any loss of efficacy or increased risk of adverse events. Furthermore, GP2017 can be used as a first-line therapy, with efficacy and safety profiles comparable to those of the originator drug, corroborating findings from other literature sources.[5]

Clinical studies on the use of biosimilars for chronic plaque psoriasis in real-world settings hold significant importance, given the availability of these reliable treatment alternatives. This study, along with existing research, reaffirms that GP2017 can be considered a dependable substitute for the originator, contributing to greater fairness in psoriasis treatment.

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Figure 1. Psoriasis Area and Severity Index (PASI) score (mean ± SD) in patients with psoriasis treated with the adalimumab biosimilar Hyrimoz®, stratified according to switching (circles and blue line) and naive (triangles and gray line).