RESEARCH LETTER

Effectiveness and tolerability of guselkumab in patients with psoriasis: A longitudinal Belgian retrospective multicenter study

To the Editor: We conducted the first Belgian multicentric observational study that investigated the long-term (up to week 88) effectiveness and tolerability of guselkumab in the treatment of plaque-type psoriasis. Guselkumab (Tremfya, Janssen Biotech, Inc) is indicated for the treatment of moderate to severe plaque psoriasis or active psoriatic arthritis and binds selectively to interleukin 23p19.

Last year, we published a study that investigated the short-term (up to week 16) effectiveness and tolerability of guselkumab in a cohort of 112 Belgian patients, demonstrating good efficacy and safety profile.[1] We now collected data from 308 patients (40% female and 60% male) (Table I). The mean age of the study population was 48.9 years, and the mean duration of psoriasis was 18.5 years. The main comorbidities were arterial hypertension (12.3%), depression (10%), cardiovascular events (7.8%), and psoriatic arthritis (6.5%). Among the study population, 57.8% of the patients had already received at least 1 biotherapy prior to receiving guselkumab (bio-experienced group), whereas 42.2% patients received guselkumab as the first biotherapy (bio-naive group). The mean absolute Psoriasis Area Severity Index (PASI) (mean ± standard deviation) at initiation was 17.7 ± 6.4 and decreased to 0.6 ± 1.7 at week 88 (Fig 1, *A*). The percentage of patients who achieved PASI 75, PASI 90, and PASI 100 at week 88 was 95.5%, 91%, and 73%, respectively (Fig 1, *B*).

The main bias of our study is that, of the 308 patients, only 44 reached week 88 and we do not know if missing data represent patients with less or more severe disease. The observed tolerance and safety profile of guselkumab were good and fewer than 1% of the patients reported minor side effects, with the most frequently reported side effect being fatigue (Table I). Our observations reinforce the data published previously for phase III randomized clinical trials VOYAGE 1 and 2 and NAVIGATE that assessed the efficacy of guselkumab in psoriasis.[2,3] Nowadays, the need for studies based on different clinics' experience is of utmost importance to investigate the effectiveness, safety, and tolerability of a drug in the general population compared with highly

Table I. Characteristics of the psoriasis study population

Patients, n	308
Age (y), mean (range)	48.9 (18-87)
Sex, % (n)	
Female	40 (123)
Male	60 (185)
Ethnic origin, % (n)	
White Caucasian	94.5 (291)
Mediterranean	3.6 (11)
North African	1.6 (5)
Asian	0.3 (1)
Weight (kg), mean (range)	83 (58-165)
Smoking, % (n)	
Yes	51.9 (160)
No	48 (148)
Alcohol consumption, % (n)	
Yes	73.8 (227)
No	26.2 (81)
Comorbidities, % (n)	
Hypertension	12.3 (38)
Depression	10 (31)
Cardiovascular events	7.8 (24)
Psoriatic arthritis	6.5 (20)
Diabetes	5.5 (17)
Dyslipidemia	3.9 (12)
Inflammatory bowel disease	1 (3)
Solid malignancies	0.7 (2)
Fibromyalgia	0.7 (2)
Sarcoidosis	0.3 (1)
Ethylic cirrhosis	0.3 (1)
Idiopathic pulmonary fibrosis	0.3 (1)
Erythema elevatum diutinum	0.3 (1)
Multiple myeloma	0.3 (1)
Psoriasis duration (y), mean (range)	18.5 (1-64)
Initial PASI score, mean (range)	17.7 (3.4-37)
Exposure to biologic therapy before receiving guselkumab, % (n)	
Yes (bio-experienced group)	57.8 (178)
No (bio-naive group)	42.2 (130)
Side effects, % (n)	
Fatigue	0.7 (2)
Headache	0.3 (1)
Joint pain	0.3 (1)
Bronchitis	0.3 (1)
Flu-like symptoms	0.3 (1)
Koebner phenomenon on tattoo	0.3 (1)
Injection site reaction	0.3 (1)

PASI, Psoriasis Area Severity Index; *y*, years.

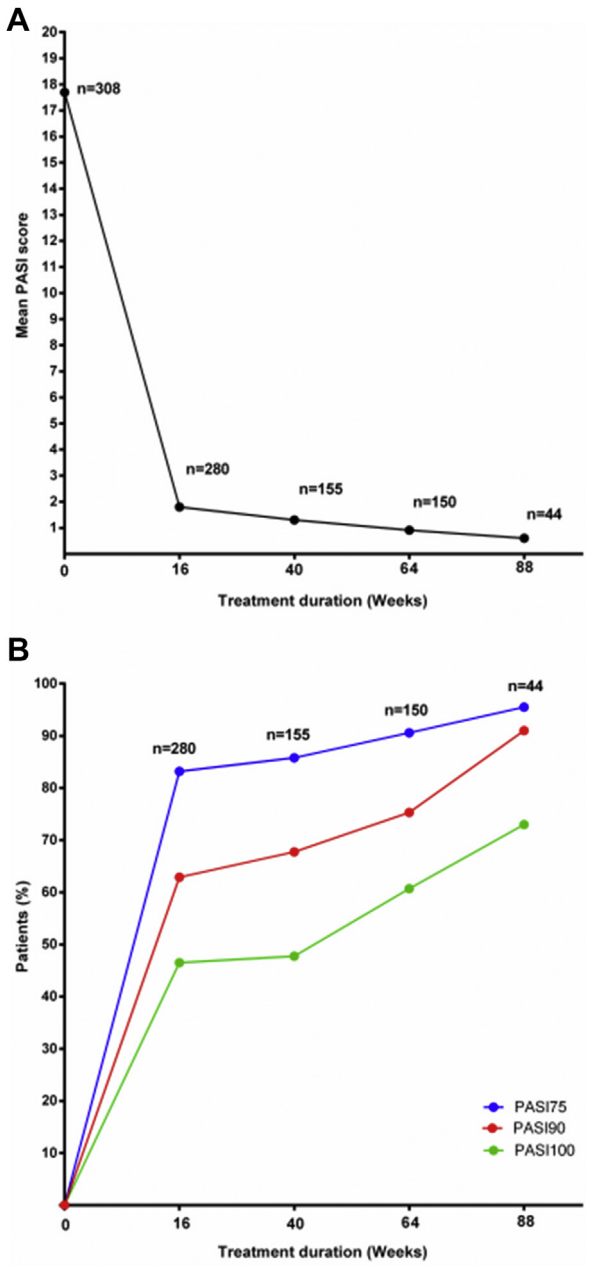

Fig 1. Psoriasis disease activity under the treatment of guselkumab. **A,** Absolute PASI over time. **B,** PASI 75, PASI

selected patients in randomized controlled trials. Observational retrospective studies have been conducted across different countries to assess the short-term real-life effectiveness of guselkumab among very small cohorts of patients with psoriasis, demonstrating good safety and tolerability profile, a PASI 90 up to 73.9%, and a PASI 100 up to 43.5%.[4] However, a few studies based on the experience of different clinics with guselkumab have been conducted past the 1-year time point. A recently published study by Maliyar et al[5] reported that in a population of 79 patients with psoriasis, 35 achieved a PASI 100 after 1.2 years of follow-up, with the most commonly reported side effects being nasopharyngitis, headaches, upper respiratory tract infections, gastrointestinal tissues, and arthralgia. As opposed to these prior studies, our investigation was conducted among a much larger number of patients with psoriasis and showed better long-term effectiveness in terms of PASI 75, PASI 90, and PASI 100 responses. With this retrospective analysis, we hope to inform clinicians about the short- and long-term effectiveness and safety profile of guselkumab for treating patients with psoriasis.

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Conflicts of interest

Dr Ghislain provides consultancy to, receives fees as a speaker and/or investigator from, or receives grants from Pfizer, MSD, AbbVie, Janssen, Serono, Leo, Novartis, UCB, Amgen, Eli Lilly, Galderma, BMS, Meda, Maruho, Flen, Menarini, Almirall, PellePharm, and Viatris. Dr Jo Lambert has been an advisor/speaker for Janssen, Leo Pharma, AbbVie, and Novartis. Dr Grine has been a speaker for AbbVie. Dr Willaert has been an advisor/speaker for Janssen, Leo Pharma, AbbVie, Celgene, and Novartis. Dr Fierens has been an advisor for Janssen, Leo Pharma, and Novartis. Dr Vandaele has been an advisor/speaker for Janssen, Leo Pharma, and Novartis. Dr Boonen has been an advisor/speaker for Celgene, Leo Pharma, Janssen-Cilag, Lily, Novartis, UCB, Almirall, AbbVie, Fresenius Kabi, Mylan, and Sanofi. Dr de Schaetzen has been an advisor/speaker for AbbVie, Novartis, and Leo Pharma. Dr de la Brassinne has received lecture and/or consultation fees and/or travel reimbursement from AbbVie, Almirall, Amgen, Eli Lilly, Janssen, Leo Pharma, Novartis, and Pfizer. Drs Failla, Soenen, Tannous, Guiot, Saerens, Meuleman, Stockman, Belpaire, Swimberghe, Temmerman, Dekeyser, Jean-Michel Lambert, and Benhadou have no conflicts of interest to declare.

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