

Biosimilars for the Treatment of Moderate to Severe Chronic Plaque Psoriasis

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Abstract: Psoriasis is an immune-mediated chronic inflammatory skin disease affecting over 60 million adults and children worldwide and can occur at any age, from childhood to adulthood. If the patient has a diffuse form of psoriasis, affecting more than ten percent of the body surface, or involving sensitive areas such as the face, scalp, nails, and/or palmoplantar region, he or she is a candidate for systemic therapy. Currently, several drugs are approved for the treatment of moderate to severe chronic plaque psoriasis in Europe and US. These are classified into conventional systemics, biologics, and small molecules. These immunomodulatory agents are available in different forms of administration, such as oral, subcutaneous, and intravenous. Novel treatments, including biologics and small molecules, can provide reliable disease control with a good safety profile even in the long term and have greatly improved the quality of life for many patients. Nevertheless, biologics can be expensive, placing a significant burden on national healthcare systems and creating a barrier to access for patients in need of these life-changing therapies. A biosimilar drug is a biologic medical product that is highly similar to an already approved reference biologic drug (also known as the originator). Biosimilars have no clinically meaningful differences in terms of safety, purity, and efficacy compared to the reference product. Biosimilar drugs have been on the market—and therefore in clinical practice—for several years now, helping to overcome these challenges. Biosimilars have the potential to improve access to biologic therapies for psoriasis while reducing healthcare costs. The aim of this narrative review is to describe biosimilars and the potential cost-saving benefits their use can offer. In this review, we will discuss adalimumab, infliximab, etanercept, and ustekinumab, as well as their corresponding biosimilars.

Keywords: psoriasis, biologics, biosimilars, originator, cost

Introduction

Psoriasis is an immuno-mediated chronic inflammatory skin disease affecting over 60 million adults and children worldwide and occurring at any age, from childhood to adulthood.¹ Genetic and acquired factors contribute to disease pathogenesis. HLA-C*06:02 risk allele is the major genetic susceptibility factor for the disease.^{1,2} Numerous environmental factors, such as streptococcal infection, stress, smoking, air pollution, obesity and alcohol consumption, have been reported as potential triggers of the disease in predisposed individuals.^{3,4} Several clinical phenotypes of psoriasis have been described, but the most frequent is chronic plaque or psoriasis vulgaris.⁵ TNF, interleukin-17 (IL) and IL-23 play a key role in its pathogenesis and represent the immune targets of biologic therapies.⁶

More than a few drugs are currently approved for the treatment of moderate to severe chronic plaque psoriasis in Europe and US. They are classically classified into conventional systemics, biological and small molecules. These immunomodulatory agents are available in different forms of administration such as oral, subcutaneous and intravenous.⁶ Novel treatments, including biologicals and small molecules, have not only demonstrated reliable disease control and a good safety profile in pre-marketing clinical trials, but have also shown sustained effectiveness and tolerability in the long term.⁷ This is further confirmed by a pharmacovigilance analysis conducted over four years on 733 patients treated with biologic drugs. During the study period, only 5 patients experienced severe adverse events, while 187 reported common and mild side effects. The most frequent were fatigue, followed by mild inflammatory reactions at the injection

site, headaches, and transient gastrointestinal disturbances. These findings highlight the significant improvement in quality of life offered by these therapies.⁸ Nevertheless, biological drugs can be expensive, which has placed a high cost on national healthcare systems and created a barrier of access for patients in need of these life-changing therapies.⁹ A biosimilar drug is a biologic medical product that is highly similar to an already approved reference biologic drug (also known as the originator). Biosimilars have no clinically meaningful differences in terms of safety, purity, and efficacy compared to the reference product.¹⁰ Biosimilar drugs have been on the market and therefore in clinical practice for some years now, making it possible to overcome these difficulties. The aim of this narrative review is to describe biosimilars and the potential cost-saving benefit that their use can offer. The list of reference biological drug, its biosimilar and trade name that are today available is reported in Table 1.

Approval Process

Biologic medicines are derived from natural sources or produced using living systems and are significantly larger and more complex than chemically synthesized drugs.¹¹ Many biologics are proteins developed through recombinant DNA technology, requiring a proprietary and technically challenging manufacturing process.¹¹ Biosimilars are created through reverse engineering requiring a new production process to achieve high similarity to the originator.¹¹ Due to the complexity of biologics, exact copies cannot be produced, so biosimilar developers are required to demonstrate that their product is highly similar to the reference drug (originator), with no clinically meaningful differences in safety, purity, and efficacy.¹² The development and approval of biosimilars are well regulated by guidelines provided by health authorities including European Medicines Agency (EMA), Food and Drug Administration, Health Canada, and World Health Organization. Regulatory agencies recommend a stepwise approach to demonstrate biosimilarity, starting with extensive analytical assessments.^{13,14} Regulatory requirements for biosimilars focus on a detailed comparison of the primary amino acid sequence, structural analyses, and evaluations of post-translational modifications to ensure close similarity to the originator in structure and function, while aspects such as excipients, preservatives, dosage volume, or

Table 1 List of Reference Biologic, Its Biosimilar, Trade Name and Year of Authorization (EMA)

Reference Biologic	Biosimilar	Trade Name	Year of Authorisation
Adalimumab	ABP 501	Amgevita®-Solymbic®	2017
	SB5	Imraldi®	2017
	BI 695501	Cyltezo®	2017
	FKB327	Hulio®	2018
	GP2017	Hyrimoz®-Hefiya®-Halimatoz®	2018
	MSB11022	Idacio®- Kromeya®	2019
	PF-06410293.	Amsparity®	2020
	CT-P17	Yuflyma®	2021
	AVT02	Hukyndra® - Libmyris®	2021
Infliximab	CT-P13	Inflectra® - Remsima®	2013
	SB2	Flixabi®	2016
	PF-06438179/GP1111	Ixifi® - Zessly®	2018
Etanercept	SB4	Benepali®	2016
	GP2015	Erelzi®	2017
	YLB113	Nepexto®	2020
Ustekinumab	AVT04	Uzpruvo®	2024
	SB17	Pyzchiva® - Eksunbi®	2024
	ABP 654	Wezenla®	2024
	FYB202	Fymskina®	2024
	DMB-3115	Imuldosa®	2024
	CT-P43	SteQeyma®	2024
	KFCE	Yesintek®	2025

delivery device are not subject to the same regulatory scrutiny, provided they do not impact safety, efficacy, or immunogenicity. However, in clinical practice these attributes can influence patient preference and adherence. For instance, for patients with needle phobia, a biosimilar featuring a finer needle gauge, reduced injection volume or frequency, fewer excipients, or a user-friendly autoinjector may improve treatment acceptance and reduce injection-site pain. Similarly, when switching a patient who experienced intolerance to the reference product, opting for a biosimilar with fewer excipients or a reduced injection volume may mitigate adverse reactions. The availability of multiple authorized biosimilars thus enables personalized therapy, accommodating patient-specific needs while maintaining efficacy and safety.¹⁵ In Europe today, there are several biosimilars approved by the EMA for the treatment of chronic plaque psoriasis.¹⁶ The originators for which the data exclusivity period has expired include Humira®, Enbrel®, Remicade® and Stelara®. The first biosimilar approved in Europe for psoriasis was CT-P13, (Inflectra®/Remsima®), in 2013.¹⁶ Other biosimilars of secukinumab are also in clinical development.¹⁷

Infliximab

The originator Infliximab (Remicade®) was the first biologic drug with an indication for the treatment of moderate-severe psoriasis, which was followed by the production of a biosimilar. In 2013, CT-P13, (Inflectra®/Remsima®) was released. This was later followed in 2016 by the release of SB2 (Flixabi®) and in 2017 of PF-06438179/GP1111 (Ixifi®/Zessly®). Several randomised controlled trials (RCTs) have compared the infliximab originator to the biosimilar CT-P13 (Inflectra®/Remsima®) in patients with ankylosing spondylitis^{18,19} and rheumatoid arthritis,^{20,21} including the 52-week, randomised, double-blind, non-inferiority NOR-SWITCH trial, which demonstrated that switching from the infliximab originator to CT-P13 was not inferior to continued treatment with the originator in patients with Crohn's disease, ulcerative colitis, spondyloarthritis, rheumatoid arthritis, psoriatic arthritis, and chronic plaque psoriasis.²² Similarly, PF-06438179/GP1111 has been shown to be noninferior to the originator in terms of efficacy, safety and immunogenicity^{23–26} and for SB2 in patients with rheumatoid arthritis.^{27–29}

Etanercept

Three biosimilars of Etanercept are currently approved in Europe. The first to be approved was SB4 (Benepali®) in 2016. Subsequently, GP2015 (Erelzi®) in 2017 and YLB113 (Nepexto®) in 2020. Similar efficacy and safety profile between SB4 and the originator were demonstrated by Emery et al³⁰ in patients with active rheumatoid arthritis. The EGALITY trial compared originator etanercept and GP2015 in patients with chronic plaque psoriasis, using a multiple-switch design. Patients were randomized with a 1:1 ratio to treatment with GP2015 or the originator twice weekly subcutaneously. Patients achieving Psoriasis Area and Severity Index (PASI) 50 at week 12 were re-randomized to continue the same treatment on a once-weekly dosing schedule or to undergo a sequence of three treatment switches between biosimilar and the originator until week 30. Thereafter, patients continued treatment with the product they had been assigned to last, up to week 52. Results showed that switching treatments repeatedly had no negative impact on drug efficacy.³¹ SB4 was compared with Etanercept in a real-life, single-center study involving 65 patients. PASI 75, 90, and 100 were assessed before therapy initiation and at months 1, 3, 6, 12, 18, and 24. At the same time, Visual Analogue Scale (VAS) itching, VAS pain, and Dermatology Life Quality Index (DLQI) were also evaluated. The results demonstrated equivalence between the two drugs in terms of absolute PASI and non-inferiority in the rates of achieving PASI 75 and 90. Equivalence was also confirmed for the other parameters analyzed.³²

Adalimumab

Adalimumab is the biological drug with the largest number of biosimilars approved in Europe. The first biosimilar to be approved by EMA was ABP 501 (Amgevita®/Solymbic®) in 2017. Subsequently, numerous other biosimilars were approved over the years, some of which were withdrawn from the market. Specifically, Halimatoz®, Kromea®, Cyltezo®, Solymbic®, Fyzoclad® and Trudexa® were withdrawn.³³ SB5 (Imraldi®) and BI 695501 (Cyltezo®) were approved in 2017. FKB327 (Hulio®) and GP2017 (Hyrimoz®-Hefiya®-Halimatoz®) were approved in 2018. MSB11022 (Idacio®- Kromea®) was approved in 2019. PF-06410293 (Amsparity®) was approved in 2020. CT-P17 (Yuflyma®) and AVT02 (Hukyndra®- Libmyris®) were approved in 2021. The Phase III, randomized, controlled, double-blind, study in

patients with moderate-to-severe plaque psoriasis showed that ABP 501 and adalimumab originator (Humira®) have similar clinical efficacy, safety and immunogenicity profiles over 52 weeks.^{34,35} SB5 and the originator were both well tolerated, with comparable safety and efficacy profiles in patients with rheumatoid arthritis.^{36,37} Switching from the originator to SB5 and vice versa did not result in increased incidence of adverse events, increased immunogenicity, or loss of efficacy.^{36,37} Pharmacokinetic equivalence between BI 695501 and the reference product has been demonstrated in patients with chronic plaque psoriasis (VOLTAIRE-X trial).³⁸ The biosimilars FKB327, GP2017, and MSB11022 are also comparable to reference adalimumab in terms of efficacy and safety in patients with rheumatoid arthritis.^{39–43} These results are also maintained in the long term for PF-06410293.^{44,45} In Phase 3 studies, CT-P17 and AVT02 demonstrated clinical equivalence to the originator in patients with moderate to severe chronic plaque psoriasis.^{46,47} Further supporting these findings, adalimumab biosimilars, used for the treatment of psoriasis, were compared with Humira® in a large multinational cohort study including 7,387 biosimilar new users and 3,654 switchers matched to Humira® users. No differences in all-cause discontinuation were found between biosimilar and Humira® new users. However, switching from Humira® to biosimilars was associated with a higher discontinuation rate compared to remaining on Humira®, with similar patterns observed for discontinuation due to ineffectiveness or adverse events. Importantly, the risk of serious adverse events (SAEs) was comparable between biosimilar and Humira® users, regardless of whether patients were new users or had switched.⁴⁸ Additionally, data from the British Association of Dermatologists Biologics and Immunomodulators Register (BADBIR) showed no significant differences in the probability of achieving a PASI score of ≤ 2 or ≤ 4 at 12 months between patients initiating adalimumab originator and those starting adalimumab biosimilars (ABP 501 or SB5), nor between patients who switched from adalimumab originator to these biosimilars and those who continued adalimumab originator.⁴⁹ A nationwide cohort study conducted using data from the Biological Treatment in Danish Dermatology (DERMBIO) registry evaluated outcomes in patients with moderate to severe psoriasis undergoing a mandatory switch from adalimumab originator to adalimumab biosimilars (GP2017 or SB5). The study found similar 1-year drug retention rates between biosimilars and the originator, with no differences in changes in disease severity.⁵⁰

Ustekinumab

The first biosimilar of ustekinumab to be approved by EMA was AVT04 (Uzpruvo®) in early 2024. This was followed by more recent approvals of SB17 (Pyzchiva®, Eksunbi®), ABP 654 (Wezenla®), FYB202 (Fymiskina®), DMB-3115 (Imuldosa®), CT-P43 (SteQeyma®).^{51,52} The last one approved in mid-February 2025 was Yesintek®.⁵³ A randomized, double-blind, multicentre study compared the efficacy, safety, tolerability, and immunogenicity of AVT04 to the originator ustekinumab (Stelara®) in patients with moderate-to-severe chronic plaque psoriasis, demonstrating therapeutic equivalence and similar safety and tolerability between the two. The results showed that AVT04 maintained comparable efficacy, safety, and tolerability to the originator up to week 16 and through week 52, with immunogenicity profiles having no clinically meaningful impact on efficacy, safety, or pharmacokinetics; furthermore, the similarity observed between the switching and non-switching arms, along with the long-term persistence of therapeutic effects, reinforces the demonstration of equivalence in the treatment of moderate-to-severe chronic plaque psoriasis.⁵⁴

The clinical similarity between SB17 and the reference product ustekinumab was assessed by a randomized, double-blind, Phase III trial conducted by Feldman et al in patients with psoriasis.⁴⁹ SB17 maintained long-term comparable efficacy with originator until week 52.^{55,56} In a clinical trial led by Papp et al, CT-P43 demonstrated equivalent efficacy to the originator ustekinumab in patients with moderate to severe plaque psoriasis, with comparable pharmacokinetic, safety, and immunogenicity profiles; the primary efficacy endpoint was the mean percentage improvement from baseline in PASI score at week 12, while secondary endpoints included PASI scores, proportions of patients achieving PASI 50/75/90/100 responses, Physician's Global Assessment (PGA) scores of 0 (clear) or 1 (almost clear), changes in DLQI scores, and assessments of pharmacokinetics, safety, and immunogenicity.⁵⁷

A randomized, double-blind, active-controlled, single-transition comparative clinical study was conducted to compare the efficacy, safety, and immunogenicity of ABP 654 and ustekinumab originator in patients with moderate-to-severe plaque psoriasis. The results demonstrated that ABP 654 and ustekinumab originator are clinically similar across these parameters, and that a single transition from Ustekinumab originator to ABP 654 at week 28 had no impact on efficacy,

safety, or immunogenicity through week 52, supporting the conclusion of no clinically meaningful differences between the two treatments.⁵⁸

Real World Evidence

Numerous real-world studies have been conducted that have confirmed the clinical equivalence between biosimilar drugs and their respective originators in patients with psoriasis, leading to results consistent with randomized clinical trials. Indeed, patients with chronic plaque psoriasis who respond to the originator infliximab switched to the biosimilar CT-P13 without experiencing a significant change in clinical response or additional adverse events.^{59,60} In the PERFUSE study SB2 was proven safe and effective in naïve patients with rheumatoid arthritis and in patients transitioned from originator.⁶¹ Girolomoni et al reported that the average real life treatment persistence of SB5 in patients with psoriasis was about 2.5 years, ie similar to the originator.⁵⁶ Data extrapolated from the Psobiosimilars Registry show that patients with chronic plaque psoriasis who responded to etanercept and switched to SB4 did not experience a significant change in efficacy or safety.⁶² Even in a real-life setting, the overlapping clinical efficacy between ETN and SB4 was confirmed, reinforcing that, also in uncontrolled environments, biosimilars represent a valuable opportunity to reduce healthcare costs and expand access to effective and innovative treatments for a broader patient population.³² The case of a 35 male patient who is effectively treated with adalimumab biosimilar is reported in [figure 1](#).

Cost Saving

Biologics has greatly improved the quality of life of patients with moderate to severe psoriasis because they allow a safe and long-term disease control.⁶³ They have proven to be superior to conventional drugs allowing a larger proportion of patients to achieve disease remission.^{59,60} In particular, IL17-, IL12/23-, IL23-, and TNF-inhibitors are more effective than the non-biological systemic agents, in term of proportion of patients reaching PASI 90.⁶⁴ Biologic users had a higher overall satisfaction than nonbiologic users.⁶⁵ However, some barriers to the prescription of biologics have been reported including the economic burden they have on healthcare system.⁶⁶ Biosimilars may provide a lower-cost alternative to the originators. Several studies on infliximab, etanercept, and adalimumab biosimilars suggest that switching from the originator to them does not affect efficacy, safety, or immunogenicity, whereas it can offer a significant cost saving for health care systems. Indeed, a budget impact analysis including 1,863 patients showed that switching from reference adalimumab to its biosimilar resulted in a cumulative cost savings of \$5,756,073 in case of slow conversion (10%-20% over 3 years) and \$28,780,365 in case of fast conversion (50%-100% over 3 years).⁶⁷ Moreover, biosimilars can reduce the economic burden on the health care system also by creating competition between manufacturers of reference drugs and biosimilars, as found in Denmark.⁶⁸

Considerable differences exist in the price of TNF inhibitor biosimilars across European countries.⁶⁹ In particular, Geat et al reported the highest prices in Germany and the lowest in Spain and Italy, while France and Denmark had intermediate prices. Specifically, for adalimumab biosimilars, Germany had the highest cost per unit dose (€494.51), whereas Spain had the lowest (€21.00). Similarly, for etanercept biosimilars, Germany recorded the highest cost (€282.52) and Italy the lowest (€11.69). In the case of infliximab biosimilars, the highest unit dose cost was again in Germany (€716.45), while the lowest was in Spain (€167.65).⁶⁹

The interplay between the clinical benefits (ie efficacy, safety and immunogenicity) and costs of biosimilars for autoimmune diseases was recently evaluated in a systematic analysis.⁷⁰ Saving of up to USD 22.98 million and USD 33.83 million for adalimumab and infliximab, respectively, can be achieved with a 100% switch to biosimilars in China.⁷⁰ This would allow an additional 6,700 and 9,863 patients to be treated, respectively.⁷⁰ Gisondi et al assessed the cost per responder of adalimumab biosimilars (MSB11022 and ABP 501) versus the originator and methotrexate for psoriasis treatment. They found that the 16-week cost per PASI75 responder was €500 for MSB11022 and €968 for ABP 501, compared to €1,831 and €1,949 for the originator, respectively. The study confirms that biosimilars significantly reduce treatment costs, supporting their role as a cost-effective strategy in psoriasis management.⁷¹ The availability of TNF inhibitor biosimilars is reshaping the treatment landscape for psoriasis, potentially allowing for earlier and broader access to biologic therapies.⁷² This shift could lead to improved patient outcomes and reduced healthcare costs, making

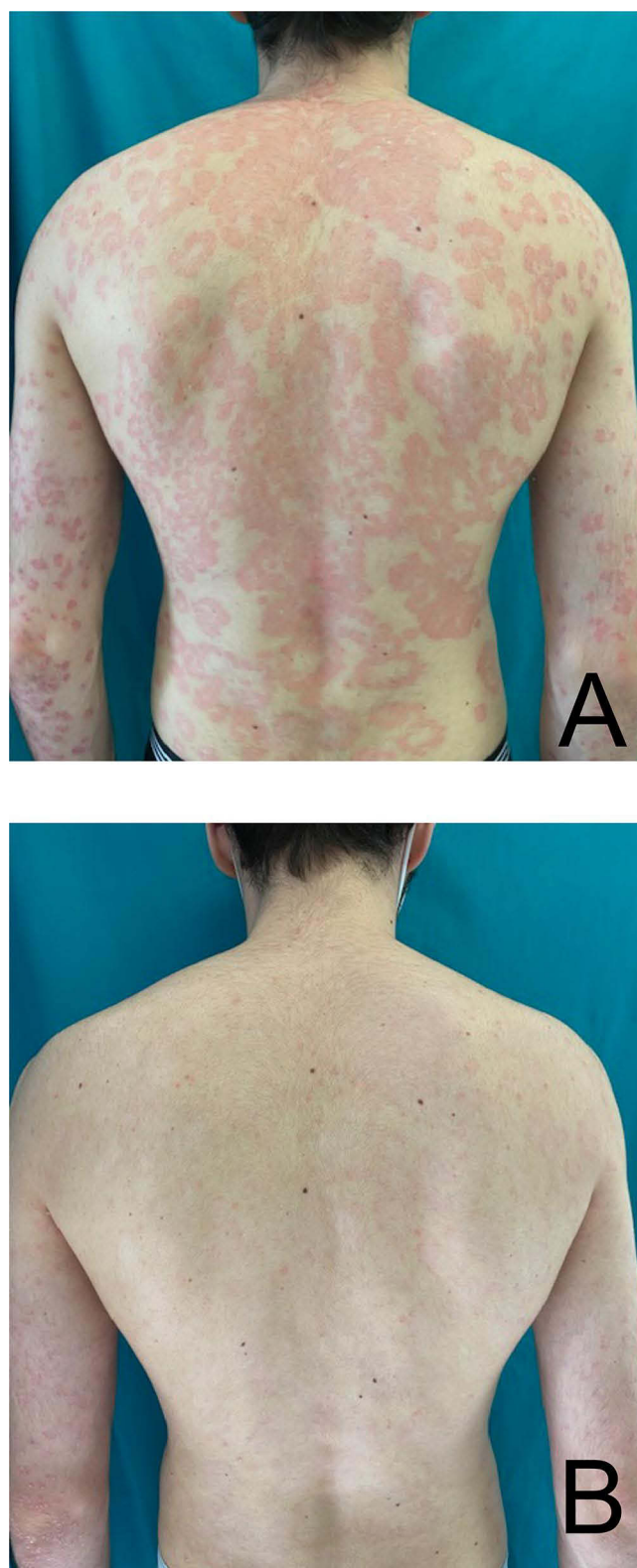


Figure 1 35 years old male with diffuse psoriasis on the back before **(A)** and three months after **(B)** therapy with adalimumab biosimilar.
Abbreviations: AUC, area under the curve; LS, least squares; NE, not estimable.

biosimilars an attractive option for first-line systemic treatment in moderate-to-severe plaque psoriasis.⁷² Moreover, the introduction of first-line TNF-inhibitor has been associated with improved drug survival.⁷³

Conclusion

Biosimilars have the potential to improve access to biologic therapies for psoriasis by reducing healthcare costs and helping to overcome barriers to prescription, such as the economic burden they place on healthcare systems.⁷⁴ As lower-cost alternatives to originator biologics, biosimilars can also generate savings that may be reinvested in innovative treatments. Biosimilars of adalimumab, etanercept, infliximab, and ustekinumab are now available, supported by robust safety and efficacy data that validate both their use and the switch from originators. Looking ahead, the number of available biosimilars is expected to grow, with biosimilars of secukinumab currently in clinical development. The availability of multiple authorized biosimilars also enables more personalized treatment approaches, allowing clinicians to tailor therapies to individual patient needs while maintaining efficacy and safety. Differences in prescribing policies across countries may influence biosimilar adoption; however, educating physicians about biosimilar development and interchangeability can support more informed clinical decision-making. Broader use of biosimilars could improve treatment adherence and overall health outcomes in patients with psoriasis.⁷⁵

Disclosure

Gisondi P received honoraria for lectures from AbbVie, Amgen, Boehringer-Ingelheim, Leo Pharma, UCB, Janssen, Almirall, Novartis, Eli Lilly; Girolomoni G served as consultant and/or speaker for AbbVie, Abiogen, Almirall, Amgen, Biogen, Boehringer-Ingelheim, Bristol-Meyers Squibb, Celltrion, Eli-Lilly, Genzyme, Leo Pharma, Menlo therapeutics, Novartis, Pfizer, Regeneron, Samsung, Sandoz, Sanofi and UCB. Bellinato F and Curic Tea have no conflict of interest to declare.

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