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Characteristic of chronic plaque psoriasis patients treated with biologics in Italy during the COVID-19 Pandemic: Risk analysis from the PSO-BIO-COVID observational study

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ORIGINAL RESEARCH

Characteristic of chronic plaque psoriasis patients treated with biologics in Italy during the COVID-19 Pandemic: Risk analysis from the PSO-BIO-COVID observational study

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ABSTRACT

Background: The susceptibility of patients with chronic plaque psoriasis and the risks or benefits related to the use of biological therapies for COVID-19 are unknown.

Few data about prevalence, clinical course and outcomes of COVID-19 among psoriatic patients were reported. The aims of this study were 1) to assess the prevalence and severity of COVID-19 in psoriatic patients treated with biologic agents during the first phase of the emergency (22 February to 22 April 2020) in Italy, and 2) to report the clinical outcomes of patients who have been exposed to individuals with confirmed SARS-CoV-2 infection.

Methods: Patients with moderate-to-severe chronic plaque psoriasis, aged ≥18 years and undergoing treatment with biologic agents as of 22 February 2020, were eligible to be included in PSO-BIO-COVID study. Demographic and clinical characteristics of patients using any biologic for psoriasis treatment between 22 February and 22 April 2020 were registered.

Results: A total of 12,807 psoriatic patients were included in the PSO-BIO-COVID study.

In this cohort 26 patients (0.2%) had a swab confirmation of SARS-CoV-2 infection. Eleven patients required hospitalization and two died.

Conclusion: The incidence of COVID-19 observed in our cohort of psoriatic patients (0.2%) is similar to that seen in the general population (0.31%) in Italy. However, the course of the disease was mild in most patients. Biological therapies may likely lessen 'cytokine storm' of COVID-19, which sometimes lead to multiple organ failure, ARDS, and death.

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KEYWORDS
COVID-19; psoriasis; biological therapy; dermatology; sars-CoV-2

1. Introduction

The first Italian case of COVID-19 was confirmed in the Lombardy Region on 20 February 2020; the number of cases grew rapidly, reaching 187,327 cases by 22 April and continuing to grow worldwide [1,2]. Early data suggested that age, smoking and preexisting comorbidities, such as diabetes mellitus, cardiovascular disease, arterial hypertension, and obstructive lung diseases, are associated with severe courses of COVID-19, and death [3].

A UK study including over 17 million patients assisted by the National Health Service, showed that hospitalized patients with rheumatoid arthritis, systemic lupus erythematosus or psoriasis had a 1.23 (range 1.12–1.35) hazard ratio for in-hospital COVID-19 death, independent of other risk factors [4].

Chronic immune-mediated inflammatory diseases like psoriasis, atopic dermatitis, or inflammatory bowel disease are associated with multiple comorbidities that are also associated with severe courses of COVID-19. These diseases are characterized by innate and adaptive immune dysregulation, which is targeted by immunomodulatory therapies [5].

Although the safety profile of biologic agents is generally better than that observed with traditional immunosuppressive therapies, there is concern that treatment with these agents might increase the risk of viral infections and upper tract respiratory infections [6]. The Italian Society of Dermatology – SIDeMaST – encouraged psoriatic patients to continue their current systemic treatment and to discuss any discontinuation or interruption with their dermatologist on a case-by-case basis [7].

Factors that should be considered when deciding to continue biologics include the severity of psoriasis or psoriatic arthritis, as well as underlying COVID-19 risk factors such as old age, cardiovascular disease, hypertension, lung disease, diabetes, concomitant immunosuppressive medications and the risk of exposure to the SARS-COV-2 virus based on geographical location, occupation, and living situation [8,9].

To date, there is neither an agreement nor a study sustaining the impact of continuing or stopping biologics in psoriatic patients during the COVID-19 pandemic [10–16]. Furthermore, data on the epidemiology of COVID-19 disease in patients treated with biological drugs are very scarce[8].

The PSO-BIO-COVID [17] is a multicentre observational study, supported by the Italian Society of Dermatology-SIDeMaST, that aims to evaluate the prevalence and severity of COVID-19 in psoriatic patients treated with biologic agents during the first phase of the emergency and to report the clinical outcomes of patients who had contact with SARS-CoV-2 infection cases.

2. Patients and Methods

Patients with moderate-to-severe chronic plaque psoriasis undergoing treatment with any biologic agent (anti-TNF-α, anti-IL-17, anti-IL-12/23 and anti-IL-23) were included in the PSO-BIO -COVID registry. Patients ≥18 years of age who received at least one dose of a biologic prior to 22 February 2020 had the criteria to be included in this study. Patients with confirmed COVID-19 (COVID-19 patients) were defined as those with a positive SARS-CoV-2 test (i.e. patients who tested positive for SARS-CoV-2 on real-time reverse transcriptase–polymerase chain reaction [RT-PCR] testing of a nasopharyngeal and/or oropharyngeal swab). Individuals who had been in contact with SARS-CoV-2 positive subjects and were under quarantine or active health surveillance were defined as 'SARS- CoV-2 suspected patients.' Data from patients with confirmed COVID-19 and SARS- CoV-2 suspected patients between 22 February and 22 April 2020 were

gathered in a standardized data-collection system following remote visits, or via e-mail.

All patients were asked about socio-demographic variables (i.e. sex, age, work activity), geographic (based on residential address) information, current smoking status, body mass index, and baseline comorbidities. Symptoms and clinical outcomes of COVID-19 patients were monitored from February 20 until 22 April 2020, corresponding to the first 2 months of the emergency phase.

The biological drugs used for treatment by these patients were also recorded.

The study was approved by the National Ethical Committee for COVID-19-related studies at INMI Lazzaro Spallanzani IRCCS, with the Dermatology Department-Fondazione Policlinico Tor Vergata as coordinating center.

Frequencies and percentages were used for descriptive analyses. Continuous variables were summarized as means ± standard deviation. No formal statistical comparisons were performed, mainly due to the small number of patients with confirmed SARS-CoV-2 infection.

Treatments were analyzed by clustering biologics into therapeutic classes: TNF-α inhibitors (adalimumab, etanercept, infliximab), IL-17 inhibitors (brodalumab, ixekizumab, secukinumab), IL-12/23 inhibitor (ustekinumab), and IL-23 inhibitors (guselkumab, risankizumab, tildrakizumab).

3. Results

As of 22 February 2020, there were 12,807 psoriatic patients on biologic therapy for psoriasis who met inclusion criteria, from 33 Italian dermatological centers. Twenty-six patients (0.2%) had a confirmed diagnosis of COVID-19, with differences in the Italian territorial areas, 0.38% in the North, 0.09% in the Center and 0.08% in the South of the country. Fifteen of 26 (57.7%) COVID-19 patients were males, with a mean age of 54.0 years (range: 22–83 years). The average BMI was 31.4 kg/m2 and the proportion of smokers was 19.2%. One-third of patients were health-care professionals (Table 1). The most common comorbidities of COVID-19 patients were hypertension (15%) and obesity (11%) (Table 2). All patients showed COVID-19 clinical symptoms; fever was present in 16 patients and cough was reported by 19% of cases. Seven patients had pneumonia (four with fever and dyspnea and three with fever, cough, and dyspnea).

Eleven of 26 patients were hospitalized. Their mean age was 63.5 years and they had many underlying comorbidities including hypertension (5.45%), diabetes (4.31%), chronic renal insufficiency (1.9%) and cardiovascular disease (1.9%). Two patients died due to acute respiratory distress syndrome (ARDS) or multiple organ dysfunction; the first patient was an 83-year-old man treated with TNF-α inhibitor and affected by multiple comorbidities (hypertension, hyperlipidemia, obesity, diabetes mellitus, and chronic obstructive pulmonary disease (COPD)) the second patient was a 77-year-old man, with cardiovascular disease, under IL-12/23 inhibitor.

Nineteen (73%) of 26 COVID-19 patients recovered by the end of the observation period while five patients (19%) had mild symptoms (Table 2).

At the time of COVID-19 diagnosis, the duration of biologic therapies ranged from 5.0 ± 0.9 months for IL-23 to 65.0 ± 43.4 months for IL-12/23; therapy was discontinued by 20 (76%) patients, while 6 patients never interrupted the treatment. Seven out of 20 (27%) COVID-19 patients restarted their therapy at the end of the study period (Table 2).

Moreover, we found 125 SARS- CoV-2 suspected patients (1.0%). The average age of these patients was 50.3 years (range 23–84 years) and 62% were male; their mean BMI was 25.6 kg/m2 and the proportion of smokers was 32.0% (Table 1). Forty-four of 125 patients were asymptomatic. Fever and cough were the most common symptoms occurring in 66/125 (53%) and 33/125 (26%) patients, respectively; three patients presented pneumonia and one of them was hospitalized; 97 (78%) patients fully recovered. Eighty-nine (71%) discontinued their biologic therapy and 51% (n = 64) re-started the same treatment at the final date of follow-up (Table 3).

4. Discussion

COVID-19 is a novel infectious disease caused by SARS-CoV-2, with a wide-ranging disease course. Italy is the European country that was hit first and has faced the first wave of infection of the pandemic out of China. In fact, from the organizational health perspective, the Italian government adopted extraordinary measures to limit viral transmission and to allocate resources to medical and intensive care units. From their side, Italian physicians have taken rapid actions to guarantee the best continuity of care, and to contain the transmission of infected cases among patients with inflammatory chronic diseases, promoting remote visit. Moreover, the first concern of physicians caring for patients with inflammatory disease was the potential increased risk of SARS-CoV-2 infection or the risk of developing a serious form of infection.

The impact of SARS-CoV-2 infection in patients with moderate-to-severe psoriasis under biological treatment is currently unclear. Here we have presented data of prevalence of COVID-19 in a large cohort of Italian psoriatic patients in the emergency phase. Comorbidities, risk factors, clinical characteristics, and outcomes in 26 COVID-19 patients and 125 SARS-CoV-2 suspected patients were also reported. Data about 12,807 patients undergoing treatment with any biologic treatment for moderate-to-severe psoriasis were collected from 33 dermatologic centers that were highly representative of the referral Italian centers for the treatment of psoriasis and of the distribution of COVID-19 in Italy. Indeed, areas like Bergamo or Milan, with more than 20,000 confirmed diagnoses of COVID-19, to Cagliari and Palermo with less than 500 cases were included in the study in the emergency phase (22 February-22 April 2020) [18].

During the first 2 months of the lockdown, SARS-CoV-2 infection was confirmed in 26/12,807 (0.2%) of psoriatic patients. The small number of cases does not allow any conclusions to be reached about differences in geographic distribution, but the prevalence of confirmed COVID-19 observed in our cohort is consistent with that seen (0.31%) in the COVID-19 patients in

Table 1. Baseline Characteristics of COVID-19 patients and SARS- CoV-2 suspected patients *.

		Anti TNF-a	Anti IL-17	Anti IL 12/23	Anti IL-23	Total	Anti TNF-a	Anti IL-17	Anti IL-12/23	Anti IL-23	Total
Number of patients included in the study		5033	4300	2638	836	12,807	5033	4300	2638	836	12,807
		COVID-19 patients (n, % of total patients)					**SARS- CoV-2 suspected patients (n, % of total patients)**				
Patients §		6 (0.1%)	10 (0.2%)	6 (0.2%)	4 (0.5%)	26 (0.2%)	53 (1.1%)	41 (1.0%)	24 (0.9%)	7 (0.8%)	125 (1.0%)
Age (years) Range		57.2 (16.4) 41–83	53.0(12.2) 35–72	52.3(20.0) 52–93	54.0 (15.7) 32–54	54.0(14.8) 22–83	57.0(13.9) 23–84	45.2(11.8) 28–75	44.8(10.6) 29–67	48.1(19.2) 24–78	50.3(14.1) 23–84
Sex (males)		3 (50%)	6 (60.0%)	4 (66.7%)	2 (50.0%)	15 (57.7%)	34 (64.2%)	32 (78.0%)	14 (58.3%)	4 (57.1%)	84 (67.2%)
BMI (kg/m2)		35.3 (8.7)	34.4 (8.5)	25.3 (3.5)	27.2 (2.6)	31.4 (8.0)	26.1 (4.4)	25.5 (3.7)	24.8 (3.4)	25.1 (3.5)	25.6 (3.9)
Smoker (number)		2 (33.3%)	3 (30.0%)	0	0	5 (19.2%)	16 (30.2%)	12 (29.3%)	9 (37.5%)	3 (42.9%)	40 (32.0%)
Work activity	Physician, Nurse, Other HCP	2 (33.3%)	5 (50.0%)	1 (16.7%)	0	8 (30.8%)	7 (13.2%)	1 (2.4%)	3 (12.5%)	0	11 (8.8%)
	Home worker	0	0	0	0	0	5 (9.4%)	0	0	0	5 (4.0%)
	Craftsman	0	1 (10.0%)	0	2 (50.0%)	3 (11.5%)	2 (3.8%)	5 (12.2%)	0	1 (14.3%)	8 (6.4%)
	Clerk	0	0	2 (33.3%)	1 (25.0%)	3 (11.5%)	10 (18.9%)	12 (29.3%)	8 (33.3%)	1 (14.3%)	31 (24.8%)
	Professional driver	0	1 (10.0%)	0	0	1 (3.8%)	0	0	0	1 (14.3%)	1 (0.8%)
	Student	0	0	1 (16.7%)	0	1 (3.8%)	1 (1.9%)	0	0	1 (14.3%)	2 (1.6%)
	Factory worker	0	0	0	0	0	7 (13.2%)	6 (14.6%)	1 (4.2%)	0	14 (11.2%)
	Military	0	0	0	0	0	1 (1.9%)	1 (2.4%)	0	0	2 (1.6%)
	Retailer	0	1 (10.0%)	0	0	1 (3.8%)	6 (11.3%)	9 (22.0%)	7 (29.2%)	0	22 (17.6%)
	Retired	2 (33.3%)	2 (20.0%)	0	1 (25.0%)	5 (19.2%)	13 (24.5%)	4 (9.8%)	2 (8.3%)	1 (14.3%)	20 (16.0%)
	Unemployed	0	0	1 (16.7%)	0	1 (3.8%)	1 (1.9%)	0	1 (4.2%)	1 (14.3%)	3 (2.4%)
	Other	2 (33.3%)	0	1 (16.7%)	0	3 (11.5%)	0	3 (7.3%)	2 (8.3%)	1 (14.3%)	6 (4.8%)

*Data are means (SD) or numbers (%); § = percentages are calculated based on the total number of patients; Anti TNF-α (adalimumab, etanercept, infliximab); Anti IL-17 (brodalumab, ixekizumab, secukinumab); Anti IL-12/23 (ustekinumab); Anti IL-23 (guselkumab, risankizumab, tildrakizumab).

Table 2. Clinical characteristics and outcomes of COVID-19 patients*.

	Anti TNF-α	Anti IL-17	Anti IL-12/23	Anti IL23	Total
Number of patients included in the study	5033	4300	2638	836	12,807
	Patients with confirmed COVID-19 (n, % of total patients)				
COVID-19 Patients §	6 (0.1%)	10 (0.2%)	6 (0.2%)	4 (0.5%)	26 (0.2%)
Joint involvement	3 (50%)	3 (30%)	1 (17%)	1 (25%)	8 (31%)
Co-morbidities					
Hypertension	2 (33%)	1 (10%)	1 (17%)	0	4 (15%)
Obesity	2 (33%)	1 (10%)	0	0	3 (11%)
Diabetes	0	0	1 (17%)	0	1 (4%)
Other	1 (17%)	0	0	1 (25%)	2 (8%)
None	0	4 (40%)	3 (50%)	1 (25%)	8 (31%)
Duration of therapy with the biologic (months)	29.9 (26.5)	20.8 (12.1)	65.0 (43.4)	5.0 (0.9)	30.7 (31.6)
Comedication	0	0	0	1 (25%)	1 (4%)
Biologic therapy discontinued	5 (83%)	8 (80%)	3 (50%)	4(100%)	20 (76%)
Hospitalized	2 (33%)	3 (30%)	4 (66%)	2 (50%)	11 (42%)
Outcome					
Recovered	5 (83%)	7 (70%)	5 (83%)	2 (50%)	19 (73%)
Sequelae	0	1 (10%)	0	2 (50%)	3 (12%)
Death	1 (17%)	0	1 (17%)	0	2 (8%)
Unknown/Pending	1 (17%)	4 (40%)	1 (17%)	1 (25%)	6 (23%)
Biologic therapy restarted	2 (33%)	3 (30%)	1 (17%)	1 (25%)	7 (27%)
COVID-19 symptoms and complications					
Fever	4 (67%)	7 (70%)	3 (50%)	2(50%)	16 (62%)
Anosmia/Ageusia	2 (33%)	2 (20%)	2 33%)	1 (25%)	7 (27%)
Cough	2 (33%)	0	3 (50%)	0	5 (19%)
Dyspnea	0	1 (10%)	1 (10%)	0	2 (8%)
Pneumonia	2 (33%)	2 (20%)	2 (33%)	1 (25%)	7 (27%)
Gastrointestinal disorder	2 (33%)	0	1 (17%)	0	3 (11%)
Other	0	3 (30%)	0	0	3 (11%)

*Data are means (SD) or numbers (%)

Notes: (§) percentages are calculated based on the total number of patients; TNF-α (adalimumab, etanercept, infliximab); IL-17 (brodalumab, ixekizumab, secukinumab); IL-12/23 (ustekinumab); IL-23 (guselkumab, risankizumab, tildrakizumab).

Table 3. Clinical characteristics and outcomes of SARS- CoV-2 suspected patients*.

		Anti TNF-a	Anti IL-17	Anti IL-12/23	Anti IL-23	Total
Number of patients included in the study		5033	4300	2638	836	12,807
		Patients suspected cases (n, % of total patients)				
SARS- CoV-2 suspected patients §		53 (1.1%)	41 (1.0%)	24 (0.9%)	7 (0.8%)	125 (1.0%)
Joint involvement		23 (43%)	5 (12%)	1 (4%)	2 (29%)	31 (25%)
Co-morbidities	Hypertension	8 (15%)	8 (19%)	5 (21%)	1 (14%)	22 (18%)
	Obesity	2 (4%)	0	0	0	2 (2%)
	Diabetes	2 (4%)	0	0	0	2 (2%)
	Other	3 (6%)	1 (2%)	0	0	4 (3%)
	None	15 (28%)	11 (27%)	4 (17%)	4 (57%)	34 (27%)
Duration of therapy with the biologic (months)		36.7 (30.1)	26.5 (10.0)	42.4 (13.6)	6.2 (2.6)	32.8 (22.9)
Comedication		8 (15%)	1 (2%)	1 (4%)	0	10 (8%)
Biologic therapy disconinued		37 (70%)	28 (68%)	19 (79%)	5 (71%)	89 (71%)
Hospitalized		0	0	1 (4%)	0	1 (0.8/%)
Outcome	Recovered	37 (70%)	35 (85%)	19 (80%)	6 (86%)	97 (78%)
	Sequelae	2 (4%)	0	0	0	2 (2%)
	Death	0	0	0	0	0
	Unknown/Pending	14 (26%)	6 (15%)	5 (21%)	1 (14%)	26 (21%)
Biologic therapy restarted		20 (38%)	25 (61%)	17 (71%)	2 (29%)	64 (51%)
COVID-19-like symptoms and complications	Fever	24 (45%)	27 (66%)	10 (42%)	5 (71%)	66 (53%)
	Cough	14 (26%)	11 (27%)	5 (21%)	3 (43%)	33 (26%)
	Dyspnea	2 (4%)	0	0	0	2 (2%)
	Anosmia/Ageusia	6 (11%)	2 (5%)	0	2 (29%)	10 (8%)
	Pneumonia	1 (2%)	0	2 (8%)	0	3 (2%)
	Gastrointestinal disorder	5 (9%)	4 (10%)	1 (4%)	0	10 (8%)
	Other	0	1 (2%)	0	0	1 (1%)

Notes: (§) percentages are calculated based on the total number of patients; TNF-α (adalimumab, etanercept, infliximab); IL-17 (brodalumab, ixekizumab, secukinumab); IL-12/23 (ustekinumab); IL-23 (guselkumab, risankizumab, tildrakizumab).

Italy according to the Italian Institute of Health [19]. Thereby no increased risk of SARS-CoV-2 infection appears to be associated to the use of biologic therapies. The observed comorbidities (hypertension, other cardiovascular diseases, dyslipidemia, obesity, diabetes, and COPD) in our patients are in line with data reported in COVID-19 positive Italian population [19]. Consistent

with recent reports, the major risk factors include old age, male sex, and the presence of comorbidities as observed in more than two-thirds of patients with COVID-19 [18]. Among our cohort of 26 COVID-19 patients, 11 were hospitalized and 2 died (Case Fatality Rate 7.7%), while up to 22 April 2020, as reported by the Italian Institute of Health and Ministry of Health, 15.7% of SARS-CoV-2 patients required hospitalization and 25,085 SARS-CoV-2 patients had died (Case Fatality Rate 13.4%) [1,2]. Outcomes of COVID-19 pandemic seem to be determined by the extent of imbalances in the host immune system. The primary immune response is positive and leads to viral clearance in the majority of cases. However, for reasons still not clear, the secondary immune response ('cytokine storm'), maybe exaggerated and challenge tissue integrity, sometimes leading to multiple organ failure, ARDS, and increased risk of mortality [20]. It cannot be ruled out that biological therapies may likely reduce 'cytokine storm' in which excessive amounts of pro-inflammatory cytokines are produced. A low degree of morbidity, severe disease, and mortality was registered in our psoriatic patients treated with biological therapies. Our data revealed a low prevalence of COVID-19 among patients with psoriasis that was consistent with data in the general population in Italy. It is conceivable that the number of patients who actually had COVID-19 was higher than we estimated due to the difficulty of patients with high-risk exposure/close contact obtaining a swab in the first months of pandemic. Notably, however, all our patients with confirmed or highly suspicious COVID-19 had a mild course of the infection, and there was no evidence for an increased risk of hospital admission or death from COVID-19 in our psoriatic patient's cohort compared with general population.

5. Conclusion

These findings suggest that the use of biologics is not associated with higher risk of SARS-COV2 infection or with worse COVID-19 outcomes. Our results may help to optimize the management of psoriatic patients during the ongoing pandemic and to support dermatologists in encouraging patients to continue their treatment.

Author contributions

MT, MG, AC, LB, KP were involved in the conception and design of the study; MT, MG, AC, LB, KP, PQ, GF, PG, AVM, CP, AC, AP, SP, FB, GA, FR, LS, GM, FL, MTR, MRB, CF, PR, PA, MCF, PP, PS, SPN, SG, AC, SPC, GR, FP, AO, ML, IZ and PSO-BIO-COVID study group recruited patients and data acquisition; MG, MT, LB, AC, KP were involved in the analysis and interpretation of the data; all authors contributed to drafting the paper/revising it critically for intellectual content and approved the final version of the manuscript to be published.

Declaration of interest

L Bianchi reports personal fees from speaker and as consultant for Abbvie, Novartis, Janssen-Cilag, Pfizer, UCB, and Leo-Pharma, outside the submitted work. SP Cannavò has served as speaker or board member for Abbvie, Celgene, Eli-Lilly, Leo Pharma, Janssen, Novartis, Sanofi-Genzyme. A Chiricozzi served as advisory board member and consultant and has received fees and speaker's honoraria or has participated in clinical trials for Abbvie, Almirall, Biogen, Fresenius Kabi, Leo Pharma, Lilly, Janssen, Novartis, Sanofi Genzyme, and UCB-Pharma. A Conti served as advisory board member and consultant, and has received fees and speaker's honoraria or has participated in clinical trials for Abbvie, Leo Pharma, Eli Lilly, Novartis, UCB-Pharma, Pfizer, Sandoz, Celgene, Biogen and Janssen Cilag. MC Fargnoli has served on advisory boards, received honoraria for lectures and research grants from Almirall, Abbvie, Galderma, Leo Pharma, Mylan, Medac Pharma, Celgene, Pierre Fabre, UCB, Eli Lilly, Pfizer, Janssen, Novartis, Sanofi-Genzyme, Roche, Sunpharma, and MSD. P Gisondi has been a consultant and/or speaker for Abbvie, Almirall, Celgene, Janssen, Leo-pharma, Eli Lilly, Novartis, Pfizer, Sandoz, UCB. K Peris reports personal fees for advisory board meeting from Almirall, AbbVie, Biogen, Janssen, Eli Lilly, Celgene, Galderma, Leo Pharma, Novartis, Pierre Fabre, Sanofi, Sandoz, and Sun Pharma outside the conduct of the work. S Piaserico has been a consultant and/or speaker for Abbvie, Almirall, Celgene, Janssen, Leo-pharma, Eli Lilly, Merck Sharp & Dohme, Novartis, Pfizer, Sandoz, and UCB. I Zalaudek has been a consultant and/or speaker for Novartis, Celgene, Amgen. The authors have no other relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript apart from those disclosed.

IRB approval status

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