E0400: Treatment Patterns of an Adalimumab Biosimilar (ABP 501) Among Patients with Inflammatory Bowel Disease: An Observational Study Using German Pharmacy Claims Database

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INTRODUCTION

- A biosimilar is a biological product that is highly similar to the reference product (RP) and has no clinically meaningful differences from the RP in terms of safety, purity, and potency.[1]
- ABP 501 (AMGEVITA®) was the first approved adalimumab biosimilar by the EMA and the FDA and has been marketed in the EU since 2018.
- Real-world evidence from European countries on treatment patterns of ABP 501 can provide valuable data ahead of US market entry, particularly for patients with inflammatory bowel disease (IBD), an indication approved on the basis of extrapolation.

OBJECTIVES

- To evaluate real-world treatment patterns of ABP 501 among patients with IBD using the IQVIA German pharmacy claims database.

METHODS

- This was a retrospective cohort analysis using data collected from the IQVIA pharmacy claims (LRx) database – a longitudinal database that gathers data from pharmacy chains, independent pharmacies, or coding centers with a broad national coverage of ~84% of German statutory health insurance patients.
- Inclusion criteria:
  - ≥18 years of age
  - Diagnosis* with IBD
  - Initiated on ABP 501 between October 2018 and March 2020
  - Had ≥365 days of continuous observation both pre- and post-initiation of ABP 501

*Imputed using the machine learning models developed based on the patients' treatment histories, the models were trained and validated on the IQVIA electronic medical records database.

- Outcome measures
  - Treatment persistence using Kaplan-Meier analysis with a permissible treatment gap of up to 120 days
  - Initial switching patterns among patients who switched from ABP 501 to other advanced therapies
- Outcome analyses
  - Outcome measures were analyzed stratified by prior use of adalimumab (ADA) products (including ADA RP and ADA biosimilars) during baseline (12 months before the initiation of ABP 501): 1) ADA-naïve patients: no prior use of ADA products during baseline; and 2) Switchers: previously exposed to ADA products during baseline
  - This study was designed as a descriptive analysis. No *a priori* hypotheses were tested and no statistical comparisons were conducted between groups.

RESULTS

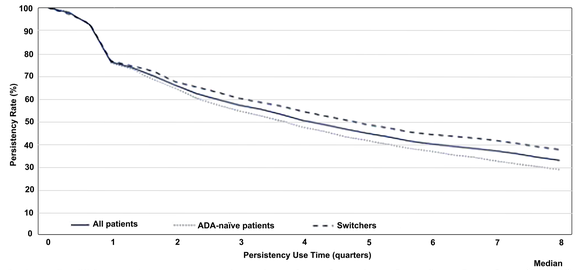
- 3,362 patients with IBD were included in the analysis, comprising 54% (n=1,828) ADA-naïve patients and 46% (n=1,534) Switchers.
- Overall, mean age was 41 years, 49% were women, most were treated primarily in an office-based clinical setting (85%) and by gastroenterologists (73%).
- Prior use of glucocorticoids (54% vs. 27%), immunosuppressive drugs (25% vs. 15%), non-ADA TNF inhibitors (TNFi[s]) (10% vs. 3%), and non-TNFi biologics (5% vs. 1%) at baseline was more common for ADA-naïve patients than Switchers.

Table 1. Baseline patient characteristics, stratified by prior exposure to an ADA RP or a biosimilar

	All Patients	ADA-naïve patients[a]	Switchers[b]
Patient count	3,362	1,828	1,534[c]
Age in years, mean (SD)	40.9 (14.4)	40.1 (14.2)	41.9 (14.7)
Sex, n(%)			
Female	1,637 (48.7)	887 (48.5)	750 (48.9)
Male	1,280 (38.1)	716 (39.2)	564 (36.8)
Unknown	445 (13.2)	225 (12.3)	220 (14.3)
Treating specialty, n(%)			
Dermatologist	2 (0.1)	1 (0.1)	1 (0.1)
Gastroenterologist	2,468 (73.4)	1,346 (73.6)	1,122 (73.1)
Rheumatologist	98 (2.9)	46 (2.5)	52 (3.4)
Unknown	794 (23.6)	435 (23.8)	359 (23.4)
Treatment setting, n(%)			
Hospital-based	506 (15.1)	284 (15.5)	222 (14.5)
Office-based	2,856 (85.0)	1,544 (84.5)	1,312 (85.5)
Prior treatment at baseline[d], n(%)			
Non-steroidal anti-inflammatory drugs (NSAIDs)	566 (16.8)	323 (17.7)	243 (15.8)
Glucocorticoids	1,410 (41.9)	994 (54.4)	416 (27.1)
Immunosuppressive drugs	678 (20.2)	453 (24.8)	225 (14.7)
Tumor necrosis factor inhibitor (TNFi; excluding adalimumab)	225 (6.7)	184 (10.1)	41 (2.7)
Other biologics (excluding TNFi)	104 (3.1)	88 (4.8)	16 (1.0)
Janus kinase inhibitor (JAKi)	12 (0.4)	12 (0.7)	0 (0.0)
Concomitant treatment, n (%)			
NSAIDs	443 (13.2)	216 (11.8)	227 (14.8)
Glucocorticoids	812 (24.2)	522 (28.6)	290 (18.9)
Immunosuppressive drugs	327 (9.7)	187 (10.2)	140 (9.1)

[a]ADA-naïve patients were those with no previous use of adalimumab products (including RP and other adalimumab biosimilars) within 12 months prior to ABP 501 initiation; Switchers were patients who were previously treated with RP or other adalimumab biosimilars within 12 months prior to ABP 501 initiation. The two categories are mutually exclusive.
[b]n=1,297 were switched to ABP 501 from RP and n=237 were switched from other adalimumab biosimilars.
[c]n=445 patients had missing information on gender.
[d]Categories are not mutually exclusive. Patients were possibly treated with more than 1 category of drugs during baseline.

Figure 1. Persistence of ABP 501 among patients with IBD, stratified by ADA-naive patients vs. Switchers



Persistency Rate (%) (in quarters)	0	1	2	3	4	5	6	7	8	Median (in months) (95% CI)
1) All patients (n=3,362)	100.0	75.9	65.7	56.8	50.1	44.4	39.8	36.6	32.5	12.1 (11.3-13.0)
2) ADA-naïve patients (n=1,828)	100.0	75.5	64.3	54.2	46.9	41.2	36.3	32.3	28.3	10.9 (9.8-11.6)
3) Switchers (n=1,534)	100.0	76.4	67.3	60.0	54.0	48.3	43.9	41.4	37.2	14.1 (12.7-15.3)

- Median persistence of ABP 501 was 12.1 (95% CI: 11.3 – 13.0) months, with numerically higher persistence being observed in Switchers (14.1 months, 95% CI: 12.7 – 15.3) than ADA-naïve patients (10.9 months, 95% CI: 9.8 – 11.6) (**Figure 1**).
- 22.7% (n=763) of all patients switched from ABP 501 to other advanced therapies within 12 months of ABP 501 initiation, most frequently to non-TNFi biological therapies (9.3% of all patients) followed by switching to the RP (6.6% of all patients).
- Switching patterns among those patients who discontinued ABP 501 due to switching to another advanced therapy (n=763) varied between naïve patients and Switchers. Among patients who switched, naïve patients most often switched to non-TNFi biologics and Switchers most often switched to RP.

Table 2. Switch Rates and Patterns During the First 12 Months after ABP 501 Initiation

	All Patients	ADA-naïve patients	Switchers
Patient count	3,362	1,828	1,534
Total switched patients, n (%)	763 (22.7)	374 (20.5)	389 (25.4)
Initial switching patterns post ABP 501, n (%)			
ADA reference product	221 (29.0)	38 (10.2)	183 (47.0)[a]
Other ADA biosimilar	126 (16.5)	35 (9.4)	91 (23.4)[b]
TNFi (excluding ADA)	74 (9.7)	57 (15.2)	17 (4.4)
Biologics (excluding TNFi), n(%)	314 (41.2)	220 (58.8)	94 (24.2)
IL1 inhibitor	1 (0.1)	1 (0.3)	0 (0.0)
IL12/23 inhibitor	168 (22.0)	110 (29.4)	58 (14.9)
IL17 inhibitor	2 (0.3)	0 (0.0)	2 (0.5)
IL6 inhibitors	1 (0.1)	0 (0.0)	1 (0.3)
Integrin antagonists	142 (18.6)	109 (29.1)	33 (8.5)
JAKi	28 (3.7)	24 (6.4)	4 (1.0)

ADA, adalimumab; IL, interleukin; JAKi, Janus kinase inhibitor; TNFi, tumor necrosis factor inhibitor. ABP 501 = AMGEVITA (adalimumab)
[a]n=165 and n=18 previously treated with RP and ADA biosimilars at baseline, respectively
[b]n=65 and n=26 previously treated with RP and ADA biosimilars at baseline, respectively

CONCLUSIONS

- Our findings suggested an overall low switch rate to RP among patients receiving ABP 501 for treating IBD.
- Higher treatment persistence was observed in Switchers than ADA-naïve patients.
- Reasons for switching were not captured in this database. The differences in switching patterns between naïve patients and Switchers are unknown but it may indicate nocebo effect as Switchers are more commonly switched back to RP. Future studies are needed to understand the differences in switching patterns between ADA-naïve patients and Switchers.

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REFERENCE

1. FDA Guidance for Industry Scientific Considerations in Demonstrating Biosimilarity to a Reference Product. April 2015. Available at https://www.fda.gov/media/82647/download.

DISCLOSURES

- Ran Jin, James O'Kelley and Greg Kricorian are employees and/or stockholders of Amgen Inc.
- Silvia Kruppert, Marc Hammer and Florian Scholz are/were employees of Real World Solutions, IQVIA Germany.
- Data collection was independently undertaken by IQVIA Real World Solutions. The analysis described here used data from the IQVIA LRx which is a wholly owned IQVIA product. Amgen is one of multiple subscribers to the LRx.