Early Real-World Experience with Abrilada within the Canadian Patient Population

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OBJECTIVES

- The goal of this study was to describe the experience of patients on ADL-afzb, including demographics, previous biologic use, persistence, and adherence.
- Results were compared to the reference adalimumab (D2E7, “ADL-Ref”) and other adalimumab biosimilars (ABP501, SB5, FKB327, GP2017, MSB11022, AVT02 and CT-P17)

CONCLUSIONS

- Our findings suggest high persistence and adherence rates for patients receiving adalimumab-afzb in a real-world setting.
- Further studies are needed to determine the persistence and adherence of adalimumab biosimilars over an extended duration.

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BACKGROUND

- Adalimumab, a biologic therapy, effectively treats various immune diseases by inhibiting tumor necrosis factor-alpha (TNF-α)[1]. It binds to TNF-α, a pro-inflammatory cytokine, modulates the immune response and reduces inflammation.
- Adalimumab was first marketed in Canada in 2004[2]. Since the expiry of market exclusivity protection, several biosimilars have been approved, including Abrilada™ (ADL-afzb).
- ADL-afzb has been approved as an adalimumab biosimilar in Canada for a broad range of conditions including rheumatoid arthritis, psoriatic arthritis, ulcerative colitis and Crohn’s disease[3].
- As part of post-registration efforts, it is important to gather additional real-world data to enhance our understanding of ADL-afzb in clinical practice.

METHODS

Study design and data sources

- This retrospective cohort study utilized longitudinal claims data from IQVIA Canada’s Private Drug Plan (PDP) and Ontario Drug Benefit databases (ODB).
- Patients initiating adalimumab from March 1, 2022 to October 31, 2022 were indexed in analysis groups based on their first claim (1- ADL-afzb, 2-ADL-Ref, 3-Other adalimumab biosimilars) and were followed for 6 months (**Figure 1**).
- Patients were excluded if they did not meet the minimum drug plan activity in the 12-month lookback and 3-month look forward period.

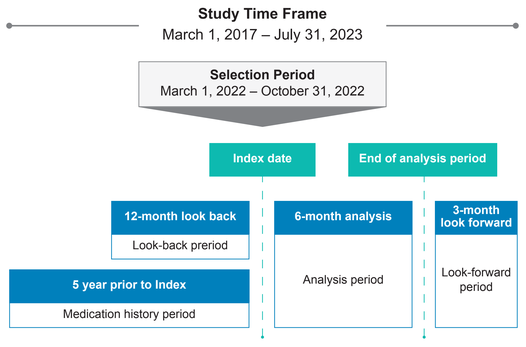
Previous medication use

- Patients were considered biologic or targeted synthetic disease-modifying antirheumatic drugs (tsDMARDs) experienced if they had at least one claim for a biologic or tsDMARDs product in the 5-years medication history period.
- Patients were considered adalimumab-experienced if they had ≥1 claim for adalimumab (other than their index product) in the 12-month lookback period.

Measures of persistence and adherence

- Log-rank test and Kaplan-Meier curves were used to assess persistence.
- Adherence was estimated using proportion of days covered (PDC).

Figure 1: Study design and key time periods



Notes: Patients initiating adalimumab in the 8-month selection period were included in the analysis. The date of the first claim was the index date and determined the patient’s analysis group.

RESULTS

Demographics and previous medication use

- 5,874 patients were included; with 657 indexed on ADL-afzb, 693 on ADL-Ref and 4,524 on other adalimumab biosimilars (**Table 1**).
- The average patient age was 47.1 for ADL-afzb, 49.4 for ADL-Ref and 50.5 for other adalimumab biosimilars. Patients were mostly female for all three groups (52.1-55.7%) and most came from the PDP database (76.0%-84.3%).
- Biologic or tsDMARDs experience (other than adalimumab) was 11.6% in ADL-afzb, 12.0% in ADL-Ref and 14.0% in other adalimumab biosimilars. 71.4% of ADL-afzb, 1.3% of ADL-Ref and 52.6% other adalimumab biosimilars patients were adalimumab-experienced.

Table 1: Patient demographic information and treatment characteristics[1]

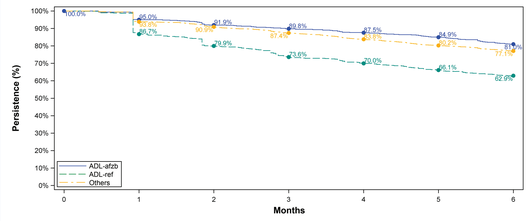
		Index groups		
Patient Characteristics	**Characteristic Category**	**ADL-afzb**	**ADL-Ref**	**Other adalimumab biosimilars**
Total	Total, n (%)	657 (100%)	693 (100%)	4,524 (100%)
Data Source	PDP, n (%)	554 (84.3%)	527 (76.0%)	3,700 (81.8%)
	ODB , n (%)	103 (15.7%)	166 (24.0%)	824 (18.2%)
Age (years)	Mean (SD)	47.1 (15.1)	49.4 (15.2)	50.5 (15.2)
	Median (IQR)	47 (22)	51 (24)	51 (21)
Gender	Female, n (%)	363 (55.3%)	361 (52.1%)	2,519 (55.7%)
	Male, n (%)	291* (44.3%)	329* (47.5%)	1,990 (44.0%)
	Unknown, n (%)	<6* (0.5%)	<6* (0.4%)	15 (0.3%)
Biologic or tsDMARDs Experience	Not Experienced, n (%)	581 (88.4%)	610 (88.0%)	3,889 (86.0%)
	Experienced, n (%)	76 (11.6%)	83 (12.0%)	635 (14.0%)
Adalimumab Experience	Not Experienced, n (%)	188 (28.6%)	684 (98.7%)	2,145 (47.4%)
	Experienced, n (%)	469 (71.4%)	9 (1.3%)	2,379 (52.6%)

Notes: Age is determined at index date. All values with a count of less than 6 patients were masked as <6* according to privacy rules. Where applicable, secondary suppression was used to avoid back calculation of a small value. PDP: IQVIA Canada’s Private Drug Plan database, ODB: Ontario Drug Benefit database, tsDMARDs: targeted synthetic disease-modifying antirheumatic drugs.

Persistence

- The average time to discontinuation was 163.1 days for ADL-afzb, 140.1 days for ADL-Ref and 158.7 days for other adalimumab biosimilars.
- Persistence at 6 months was not significantly different between ADL-afzb (81.0%) and other adalimumab biosimilars (77.1%) (p-value=0.6, adjusted relative to 0.05 using Sidak’s method for three comparisons), but lower for ADL-Ref (62.9%) (**Figure 2**).

Figure 2: Kaplan-Meier chart of persistence rates between index groups[1]

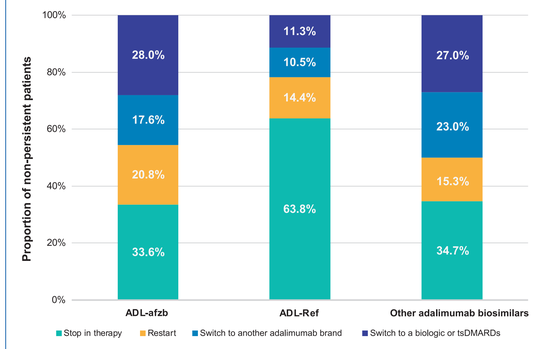


Strata Comparison		Chi-Square	p-Values	
Index group	**Index group**		**Raw**	**Siak**
Abrilada	Humira	68.3	<.0001	<.0001
Abrilada	Other biosimilars	1.2	0.3	0.6
Humira	Other biosimilars	49.7	<.0001	<.0001

Notes: Persistence was measured by the duration from index to discontinuation of therapy, defined as a gap in therapy of 90 days or more, a switch to another advanced therapy or a switch to different adalimumab brand. Log-rank test was used for comparing survival distributions between index groups.

- The most common reason for discontinuation among patients who are not persistent was a stop in therapy for all three groups, with 33.6% of ADL-afzb, 63.8% of ADL-Ref and 34.7% of others adalimumab biosimilars non-persistent patients stopping therapy (**Figure 3**).

Figure 3: Reason for discontinuation among non-persistent patients at 6 months[1]

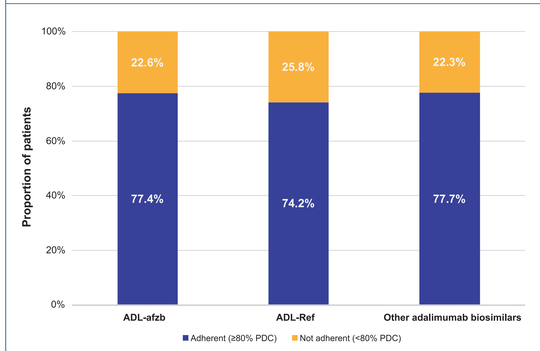


Notes: Stop in therapy is defined as patients who discontinue index medication but do not initiate another adalimumab brand or a biologic or tsDMARDs medication. Restart is defined as patients who discontinue index medication and initiate the same medication again. Switch to another adalimumab brand is defined as patients who discontinue index medication and initiate an adalimumab brand other than index medication. Switch to a biologic or tsDMARDs is defined as patients who discontinue index medication and initiate another type of biologic or tsDMARDs medication.

Adherence

- The average adherence during the first 6 months of therapy was 88.2% for ADL-afzb compared to 85.5% and 87.7% for ADL-Ref and other adalimumab biosimilars respectively.
- The proportion of adherent patients (≥80% PDC) was 77.4% for ADL-afzb, 74.2% for ADL-Ref and 77.7% for other adalimumab biosimilars (**Figure 4**).

Figure 4: Patient adherence to treatment[1]



Notes: The PDC is defined as the ratio of days in which a person has medication available over the period of interest (6 months after index date or until discontinuation). Patients who score ≥80% PDC were considered adherent. Patients with <2 claims in the analysis period are excluded from adherence calculations.
PDC: Proportion of days covered.

References

1. Ellis, C. R. & Azmat, C. E. Adalimumab. in StatPearls (StatPearls Publishing, Treasure Island (FL), 2024).
2. Health Canada. Product Information - Humira. (2022) - https://pdf.hres.ca/dpd_pm/00067414.PDF
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Disclosures

[1-2]Employee of Pfizer Inc; [3]Employee of Pfizer Canada Inc; [4]Employee of IQVIA Solutions Canada Inc; [5]Employee of Pfizer Ltd

Pfizer sponsored the study; contributed to the design; participated in the analysis and interpretation of the data; in writing, reviewing and approval of the final version

1 Data source: IQVIA Canada Private Drug Plan (PDP) Claims Database and Ontario Drug Benefit (ODB) Claims Database (March 1, 2017 - July 31, 2022)