Analysis of Real-World Adalimumab Biosimilar Clinical Outcomes in the Specialty Pharmacy Setting

Miranda Fortier, PharmD; Amitoj Singh, PharmD; Kyle Miller, PharmD, CSP; Chelsea Hustad, PharmD, CSP;
Robert Topp; Anna Riemer; Avery Usgaard; Kelly Janssens

Lumicera® Health Services

NASP

BACKGROUND

- Adalimumab is an injectable monoclonal antibody indicated for several autoimmune conditions[1] and is a highly prescribed product at Lumicera.
- The adalimumab reference product lost its exclusivity patent in the U.S. in January 2023[2] and since then, ten adalimumab biosimilars have emerged on the market as competitors.[3]
- With lower prices, biosimilars can provide cost savings for patients, pharmacies, and pharmacy benefit managers.[4]
- Although biosimilars must show no clinically meaningful difference in safety, purity, and potency to be approved by the FDA, patients and providers have shown hesitancy to transition.

OBJECTIVES

To provide real-world clinical outcomes of patients prescribed the adalimumab reference product compared to one of the ten FDA approved biosimilars, with the goal of increasing confidence from patients and providers for the effectiveness and safety of biosimilar products.

METHODS

STUDY DESIGN

- Retrospective cohort study using telephonically completed assessments as part of Lumicera's standard workflow.
- The two groups of subjects included patients prescribed the adalimumab reference product and patients prescribed an adalimumab biosimilar product.

SETTING

- Lumicera Health Services is a mail-order specialty pharmacy with integrated delivery network serving over 30,000 patients across the United States.

STUDY PERIOD

- October 1st 2023 to December 31st 2024 (research in progress)

SUBJECTS

- Inclusion Criteria
  - Diagnosis of an FDA-approved indication of adalimumab
  - New to therapy for any adalimumab product
  - Completion of a New Enrollment and Adalimumab – Disease Assessment according to the Patient Management Program at Lumicera
- Exclusion Criteria
  - Less than 18 years of age
  - Pregnancy or breastfeeding
  - Restarting therapy on an adalimumab product
  - Continuing therapy on an adalimumab product
  - Switching between the adalimumab reference product and biosimilar product or between adalimumab biosimilar products

DEMOGRAPHICS AND ENDPOINTS

Endpoints are measured between groups at 3-months post initiation of therapy and 6-months post initiation of therapy

Primary Endpoints

- Difference in patient satisfaction score on a 10-point scale between each group
  - Score of 1 – 3: Not satisfied with product
  - Score of 4 – 6: Neutral satisfaction with product
  - Score of 7 – 10: Highly satisfied with product
- Change in disease state symptoms based on subject self-assessment of current symptoms compared to symptoms 3 months ago with the option to choose one of three categories:
  - Better
  - Stayed the same
  - Worse

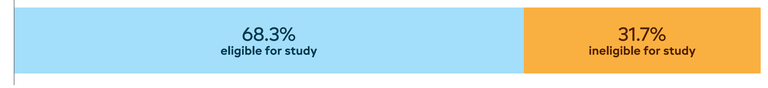
Secondary Endpoints

- Difference in reported side effects between groups
  - Patient response of "yes" or "no" to question of if patients are currently experiencing any side effects related to their medication
  - If response of "yes", responses categorized into the most common side effects reported:
    - Injection site reaction
    - Infection
    - Headache
    - Fatigue
    - Gastrointestinal
    - Other
- Adherence measured by proportion of days covered (PDC) between the following dates:
  - End of three months from therapy start date
  - End of six months from therapy start date
  - Start of month four and end of sixth month from therapy start date

TOTAL NUMBER OF SUBJECTS

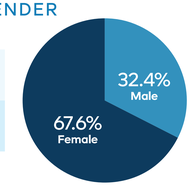
353

ELIGIBILITY & INELIGIBILITY



GENDER

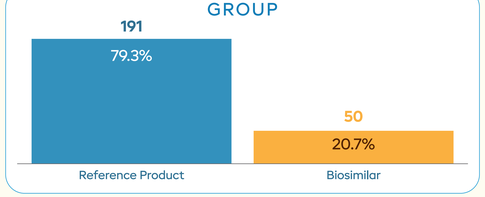
Female	N=163
Male	N=78



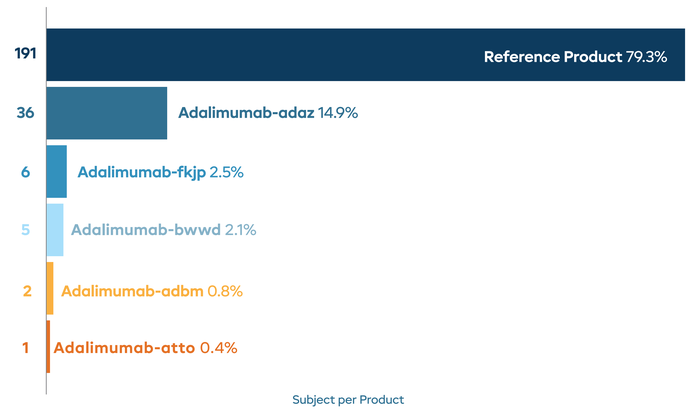
INSURANCE

Commercial	N=112	46.5%
Medicaid	N=106	44%
Medicare	N=23	9.5%

GROUP



PRODUCT



DIAGNOSIS

Ankylosing Spondylitis (AS)	N=22	9.1%
Crohn's Disease (CD)	N=18	7.5%
Hidradenitis Suppurativa (HS)	N=33	13.7%
Juvenile Idiopathic Arthritis (JIA)	N=2	0.8%
Psoriatic Arthritis (PsA)	N=27	11.2%
Plaque Psoriasis (Ps)	N=27	11.2%
Psoriatic Arthritis and Plaque Psoriasis (PsA and Ps)	N=2	0.8%
Rheumatoid Arthritis (RA)	N=95	39.4%
Ulcerative Colitis (UC)	N=13	5.4%
Uveitis (UV)	N=2	0.8%

REFERENCES

1. Humira Prescribing Information Humira. Package Insert. AbbVie Inc.; 2021. Accessed March 14, 2024. https://www.rxabbvie.com/pdf/humira.pdf
2. Volansky R, Stonehill M. Humira exclusivity expires in 2023: Will biosimilar boom benefit patients or industry? 2023. Accessed March 12, 2024.
3. Simple Search Results for: Humira. Purple Book Database of Licensed Biological Products. Accessed July 22, 2024. https://purplebooksearch.fda.gov/results?query=adalimumab&title=Humira.
4. Report: 2023 U.S. generic and Biosimilar Medicines Savings Report. Association for Accessible Medicines. 2023. Accessed July 22, 2024. https://accessiblemeds.org/resources/reports/2023-savings-report.