

Worldwide Clinical and Real-World Exposure to Baricitinib

Ruth Ann Vleugels¹, Brittany Craiglow²,
Arash Mostaghimi¹, Elise Olsen³,
Angelina Sontag⁴, Karen Denning⁴,
Najwa Somani⁴, Maria Hordinsky⁵

¹Brigham and Women’s Hospital, Boston, USA, ²Yale School of Medicine, New Haven, USA, ³Duke Dermatology Clinic, Durham, USA, ⁴Eli Lilly and Company, Indianapolis, USA, ⁵University of Minnesota, Minneapolis, USA

Sponsored by Eli Lilly and Company under license from Incyte Corporation

OBJECTIVE

- To report the worldwide real-world and clinical trial exposure to baricitinib across a range of diseases, ages, and racial backgrounds

CONCLUSIONS

- Over 14,600 patients have received baricitinib in clinical trials and an estimated >1.8 million patients have received baricitinib in the real-world setting
 - As the average daily dose and length of therapy may vary over time, real-world exposures are only an estimate of the total number of patients receiving baricitinib
- Baricitinib use in 59 completed and ongoing clinical trials spans a variety of populations and disease states
 - 4870 patients with dermatologic conditions
 - 2941 patients who were Asian or Black
 - 866 patients aged <1 month to <18 years (including an ongoing AD study¹, but not an ongoing AA study²)
- The exposure data in this analysis provide a view of the ages, indications, and racial populations in which baricitinib has been studied over time in clinical trials. It also provides a view of the populations in which baricitinib has been used in the real-world setting



Scan the QR code for a list of all Lilly content presented at the congress.
Other company and product names are trademarks of their respective owners.

BACKGROUND

- Baricitinib, an oral selective JAK inhibitor, is approved in many geographies for adults with rheumatoid arthritis or alopecia areata, and for patients as young as 2 years of age with atopic dermatitis or juvenile idiopathic arthritis
- Baricitinib is also approved in the United States for hospitalized patients with COVID-19 infection

ANALYSIS SETS

Real-World Exposure^a

- Latest data cut-off to January 31, 2024
- Estimates based on:
 - Total mg sold
 - Average daily dose
 - Average length of therapy

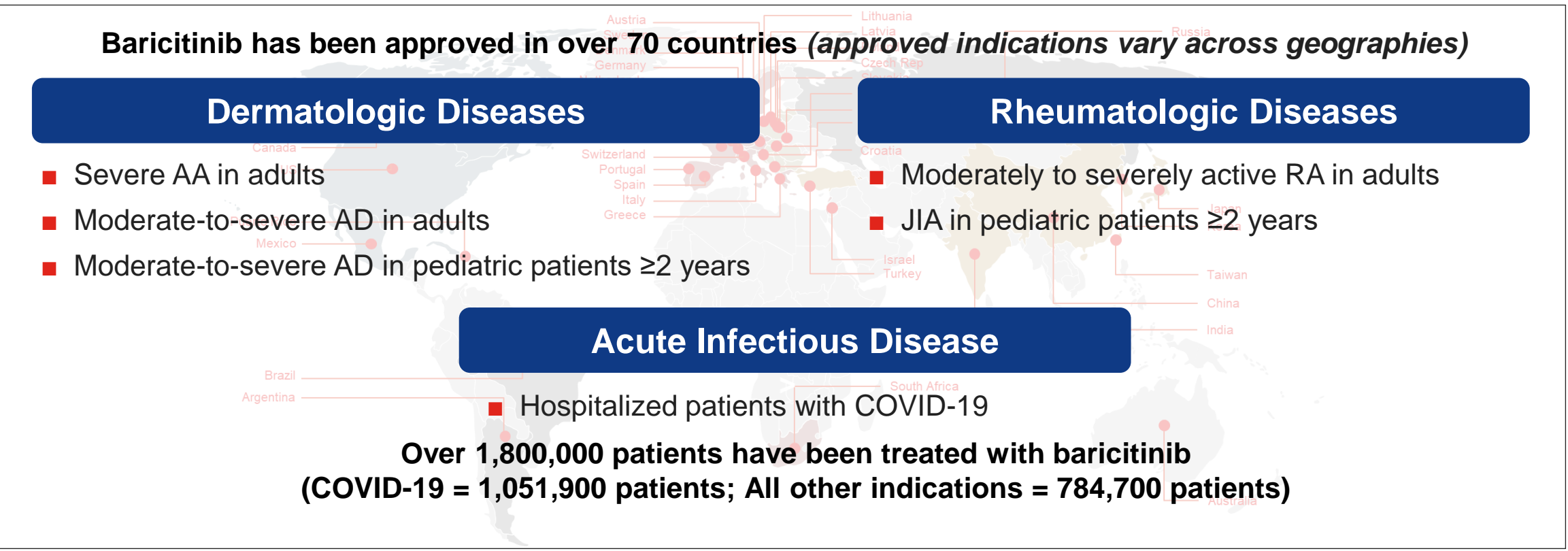
Clinical Trial Exposure

- Latest data cut-off to February 13, 2024
- Includes data for both ongoing and completed trials

^aEstimates were calculated based on total milligrams sold, average daily dose, and average length of therapy as reported to regulatory agencies through the cumulative timeframe ending January 31, 2024.

KEY RESULT

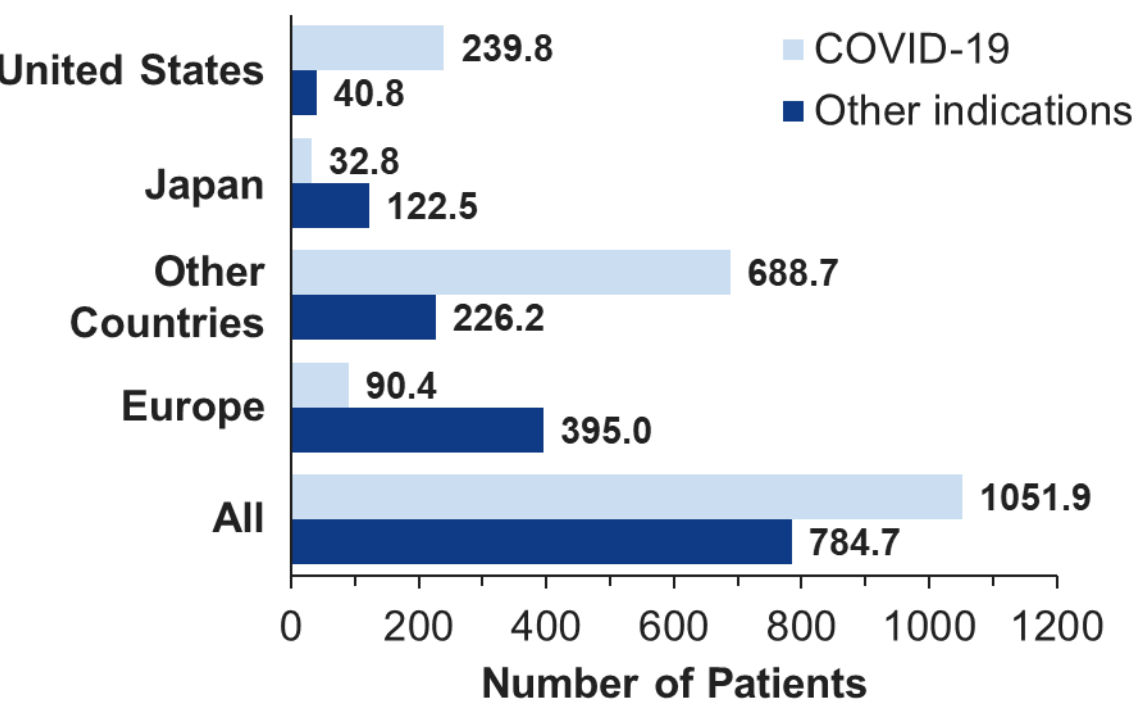
Baricitinib Real-World Experience



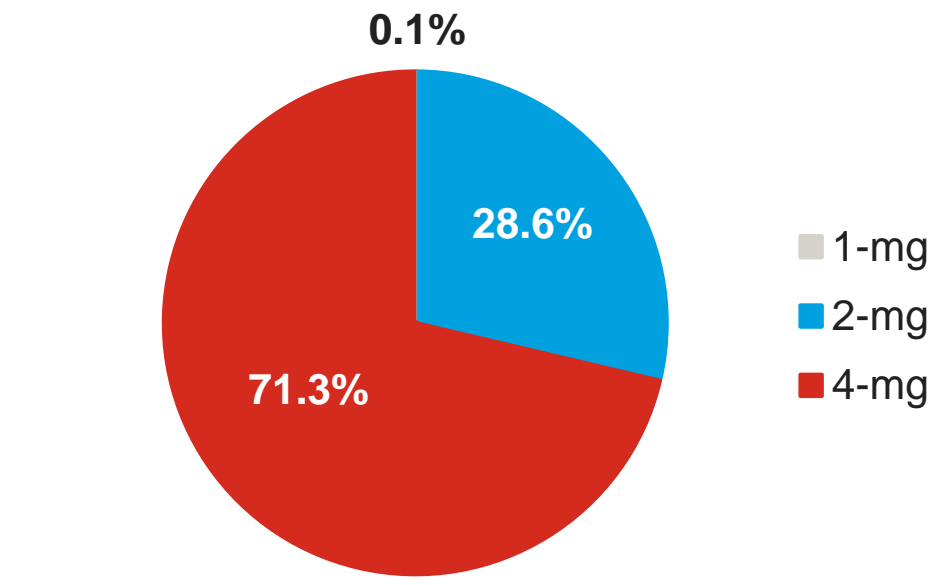
Notes: The patient exposure estimates represent potential exposure to baricitinib and do not indicate efficacy or safety. Estimates were calculated based on total milligrams sold, average daily dose, and average length of therapy as reported to regulatory agencies through the cumulative timeframe ending January 31, 2024. As average daily dose and length of therapy may vary over time, exposure estimates may not represent the actual number of patients who have received baricitinib. Data on file, Eli Lilly and Company.

Baricitinib Real-World Estimates (N=1,836,600)

Patient Exposure: Geography^a (,000)



Patient Exposure: Dose^b



^aTotals may not sum due to independent rounding; ^bOf these estimated patient exposures, 57.3% were for COVID-19 with the remaining for all other indications combined.

Reference: 1. Wollenberg A, et al. Poster presented at: EADV 2023. Poster P0499. 2. <https://clinicaltrials.gov/search?term=NCT05723198>. Accessed September 2024

Abbreviations: AA=alopecia areata; AD=atopic dermatitis; BARI=baricitinib; COVID-19=coronavirus 2019; JAK=Janus kinase; JIA=juvenile idiopathic arthritis; RA=rheumatoid arthritis

Disclosures: R. Vleugels is a consultant for: AbbVie, AstraZeneca, Eli Lilly and Company, and Priovant Therapeutics; B. Craiglow has received fees and/or honoraria from: AbbVie, Arcutis, BiologicsMD, Dermavant, Eli Lilly and Company, GlaxoSmithKline, Incyte Corporation, LEO Pharma, Pfizer, Regeneron, Sanofi Genzyme, Sun Pharma; A. Mostaghimi has been a consultant for: AbbVie, Concert Pharmaceuticals, Digital Diagnostics, Eli Lilly and Company, and Pfizer; E. Olsen has been an advisory board member for: Eli Lilly and Company; and has been a consultant for: Kintor Pharmaceutical, Pfizer, and Taisho Pharmaceutical; A. Sontag, K. Denning, and N. Somani are employees and shareholders of: Eli Lilly and Company; M. Hordinsky has received grants from: AnaptysBio, Arcutis, ASLAN Pharmaceuticals, Concert Pharmaceuticals, Eli Lilly and Company, National Alopecia Areata Foundation, Pfizer, RegenLab, and Technoderma Medicines; has received honoraria and has been consultant/advisory board member for: AbbVie, Almirall, Eli Lilly and Company; and has been an *UpToDate* Section Editor on: Hair Medical writing assistance was provided by Serina Stretton, PhD, CMPP, of ProScribe – Envision Pharma Group, and was funded by Eli Lilly and Company

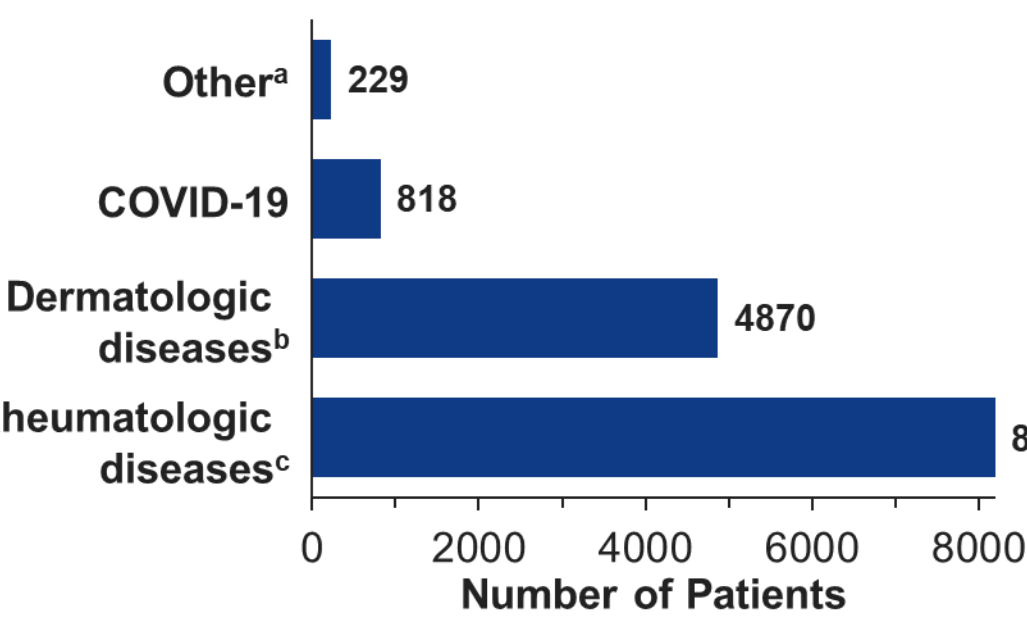
Baricitinib Clinical Trial Experience

Clinical Trial Participants Across 59 Clinical Trials, Completed and Ongoing Since June 2008

All trial participants	17,665
All trial participants receiving BARI	14,660 ^a
Patients	14,112
Healthy volunteers	548

^aParticipants allocated to treatment regimens that may have included more than 1 of BARI, placebo, and comparator were counted in each applicable treatment category. For trials that remained blinded to the study team at the time of this report, the number of participants is estimated based upon the study randomization scheme.

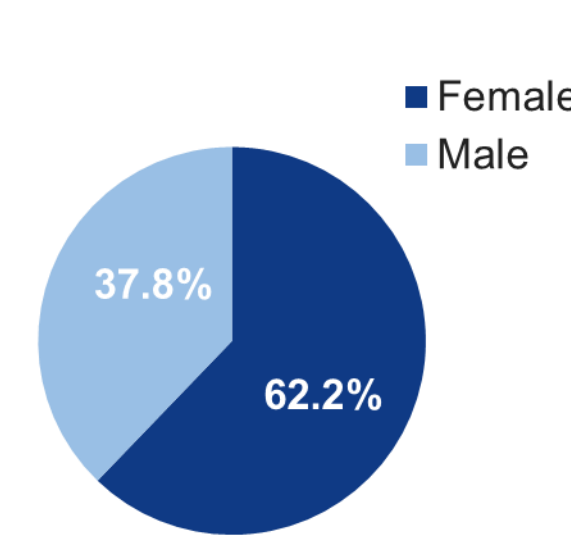
Completed and Ongoing Clinical Trials Patient Exposure: Indication (N=14,112)



^aIncludes patients with rare autoimmune syndromes expected to benefit from JAK inhibition (compassionate-use treatment program) (n=71) and patients with biliary cholangitis (n=1), renal impairment (n=36), diabetic kidney disease (n=103), hepatic dysfunction (n=8), and autoimmune type I interferonopathies (n=10); ^bIncludes plaque psoriasis (n=256), atopic dermatitis (n=3050), and alopecia areata (n=1564); ^cIncludes rheumatoid arthritis (n=6242), systemic lupus erythematosus (n=1662), and juvenile idiopathic arthritis (n=291).

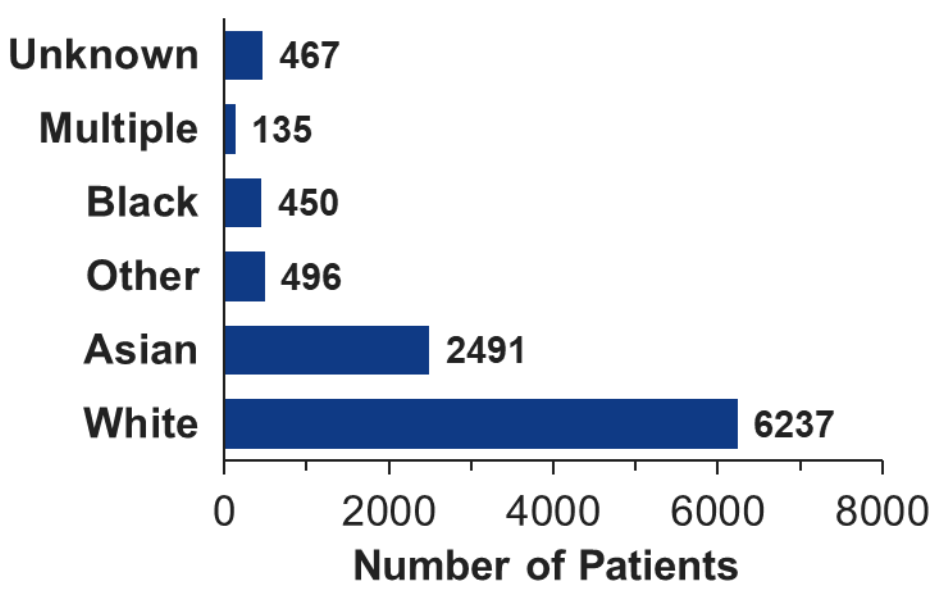
Baricitinib Completed Clinical Trials (N=10,276)

Patient Exposure: Sex

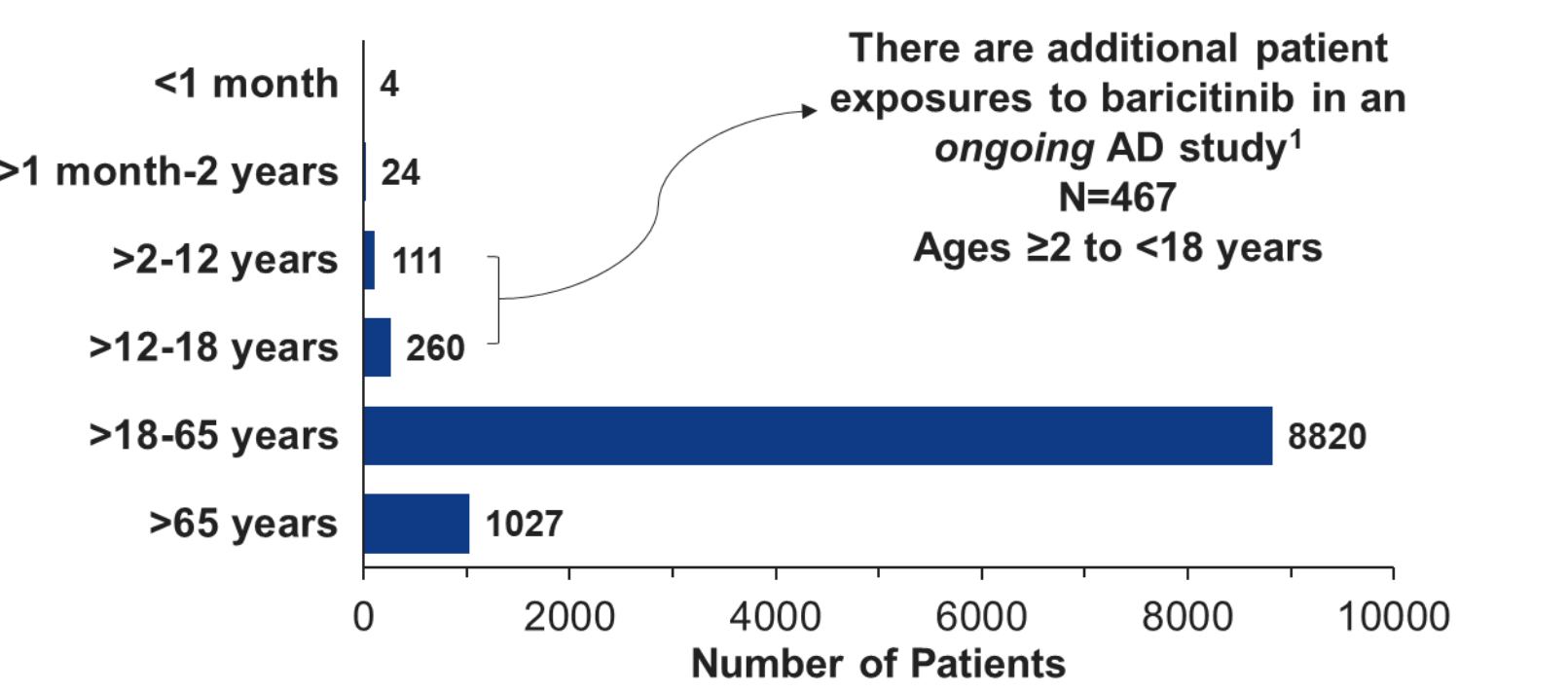


Note: Data are presented for all completed studies through February 13, 2024.

Patient Exposure: Race



Patient Exposure^a: Age



^aData are presented for all completed studies through February 13, 2024; 30 patients (16 female, 14 male) had unknown data for age.