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Real-World Study in Progress: Characterization and Clinical Outcomes of Alopecia Areata Patients Treated With Ritlecitinib in a Real-World Cohort (PRESTO)

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DISCLOSURES: This study was funded by Pfizer Inc. C Kindred reports serving on speaker bureaus for Eli Lilly, Sun Pharmaceuticals, and Arcutis; serving on advisory boards for Eli Lilly, Sun Pharmaceuticals, Regeneron, and UCB; is a speaker for UCB, Novartis, Selphyl, and Aerolase; serving on a medical board for Aerolase and Selphyl; serving on the Janssen steering committee and SOC Advisory Board; and is a founding advisor for Xtresse; a web content reviewer for AAD; a consultant for AbbVie; a speaker for Pfizer, Regeneron, and Sanofi; and editor for JNMA and Cutis. T Ito is a clinical trial investigator for AbbVie, Eli Lilly Japan, and Pfizer; serves on advisory boards for Eli Lilly and Pfizer; and is a speaker for Pfizer. W Wu is a clinical trial investigator and speaker for AbbVie, Eli Lilly, and Pfizer. L Asfour is a principal investigator for alopecia areata trials for AbbVie, Sanofi, and Pfizer, and atopic dermatitis trials for Incyte; a consultant for AbbVie and Shark Ninja; a consultant and speaker for L'Oreal; and a speaker for Pfizer. She is President of the British Hair and Nail Society and a member of Alopecia Areata Guidelines Development Group and Therapeutics & Guidelines BAD Subcommittee. V Hebert reports serving on advisory boards and speaker's bureaus for Pfizer, Eli Lilly, and AbbVie. M Sadrarhami, G Gauthier, G Bell, AG Soto, C Martin, and G Schaefer are employees of Pfizer Inc and hold stock or stock options in Pfizer Inc. Support for third-party medical-writing assistance, provided by Nucleus Global, was funded by Pfizer Inc.

BACKGROUND & OBJECTIVE

BACKGROUND

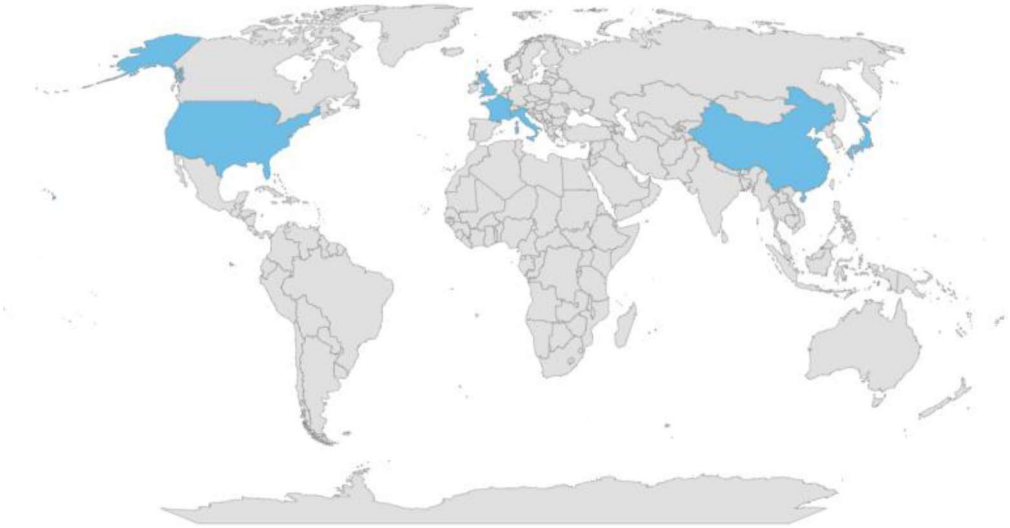
- Alopecia areata (AA) is an autoimmune disease characterized by hair loss on the scalp, face, and/or body
- Ritlecitinib, an oral JAK3/TEC family kinase inhibitor, demonstrated efficacy and safety up to 48 weeks in patients aged ≥12 years with AA in the ALLEGRO phase 2b/3 study (NCT03732807)
- This study led to the approval of ritlecitinib 50 mg once daily for adult and adolescent patients aged ≥12 years with severe AA in the US, Japan, EU, China, and several other countries
- Given the positive results from the ALLEGRO program, there is growing interest in data on patient characteristics and clinical outcomes of ritlecitinib in routine clinical practice

OBJECTIVE

- To present the design of PRESTO (NCT06531109), a non-interventional, real-world study evaluating patient and disease characteristics, treatment patterns, and clinical and patient-reported outcomes among patients with AA who are receiving ritlecitinib

STUDY DESIGN

- The study started on August 7, 2024, and is expected to be completed on March 31, 2028

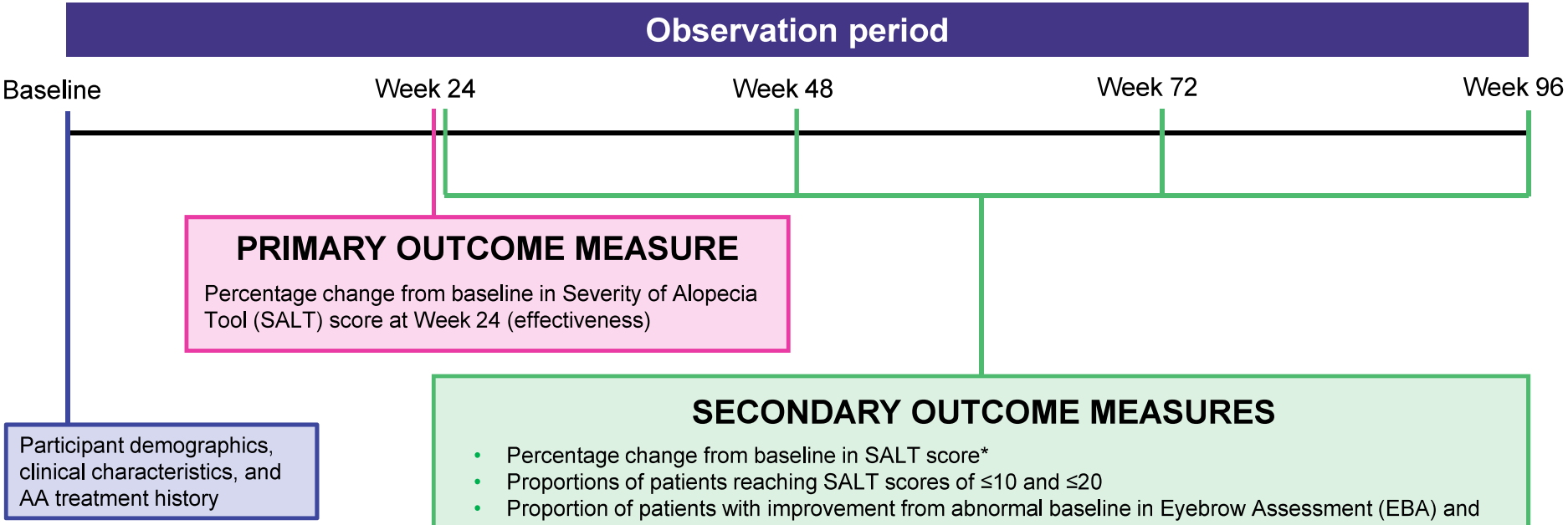


- Participants will be enrolled from the US, Japan, China, France, UK, and Italy
- Participants will receive ritlecitinib prescribed according to the approved product label in real-world practice

- The study population eligible for enrollment includes patients aged ≥12 years diagnosed with AA who receive at least one dose of ritlecitinib and satisfy the inclusion and exclusion criteria:

Inclusion criteria	Exclusion criteria
Age ≥12 years	Diagnosis of other types of alopecia or other diseases that can cause hair loss
Confirmed AA diagnosis	Other scalp diseases that may impact AA assessment or other active systemic diseases that may cause hair loss
Prescribed ritlecitinib	Previous treatment with ritlecitinib or other systemic JAK inhibitors

STUDY DESIGN



*Percentage change from baseline in SALT score is the primary outcome at Week 24 and a secondary outcome at Weeks 48, 72, and 96.

CONCLUSIONS

The PRESTO study will describe real-world ritlecitinib experiences in the treatment of AA, including patient, clinical, and treatment characteristics, as well as clinician- and patient-reported effectiveness and quality of life outcomes