Outcomes of Down-Titration in Patients With Severe Scalp Alopecia Areata Treated With Baricitinib: An Update Through Week 152 From BRAVE-AA2

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OBJECTIVE
- To report the Week 152 efficacy results, from the BRAVE-AA2 randomized down-titration sub-study, including recapture data after re-treatment

BACKGROUND
- AA is a common autoimmune disorder marked by non-scarring hair loss that may contribute to significant emotional and psychosocial distress.
- Baricitinib is an oral JAK inhibitor approved for treatment of severe alopecia areata
  - In two randomized, double-blind, placebo-controlled, Phase 3 studies (BRAVE-AA1 [NCT03570749] and BRAVE-AA2 [NCT03899259]), baricitinib 4-mg and 2-mg demonstrated superiority over placebo in hair regrowth after 36 weeks of treatment in adult patients with severe AA
  - BRAVE-AA2 included a randomized down-titration sub-study starting at Week 52 for baricitinib 4-mg responders

AA-alopoea areata; JAK-Janus kinase

Disclosures: B. King has served on advisory boards and is a consultant and/or clinical trial investigator for: Abbvie, Almirall, Almirall Bios, Aereon Pharmaceuticals, Bionx Therapeutics, Bristol Myers Squibb, Concert Pharmaceuticals, Eli Lilly and Company, Horizon Therapeutics, Incyte Corporation, LEO Pharma, Otsuka/Valanis, Pfizer, Regeneron, Sanofi Genzyme, Takeda Biotechnology, and Valeo Bio, and is on speaker's bureau for: Abbvie, Incyte Corporation, LEO Pharma, Pfizer, Regeneron, and Sanofi Genzyme. M. Ohyama has received lecture and advisory fees from: Eli Lilly Japan K.K., Pfizer Japan, Bristol Myers Squibb Japan, Aptive UK, Rofco Pharmaceutical, and Takeda Pharmaceutical, and has received research grants from: Marcho, Shoieido, Advanted Corp, and Sun Pharma Japan; M. Senna has served on advisory boards and is a consultant for: Aereon Pharmaceuticals, Concert Pharmaceuticals, Eli Lilly and Company. J. Shapiro is a consultant or clinical trial investigator for: Pfizer, and is a consultant for: Abbvie and Company. Y. Dutrane, J. Kolodski, G. Yu, C. Liu, and C. Chiasserini are employees and shareholders of: Eli Lilly and Company. S. M. Piraccini has received honoraria from or been a consultant for: Almirall, Eli Lilly and Company, I2DIN, Pfizer, and Vichy Laboratories. Medical writing assistance was provided by Carmen Jaspahuma, PharmD of Eli Lilly and Company.

CONCLUSIONS
- At Week 152, SALT score ≤20 was maintained by 89% of responders who remained on baricitinib 4-mg.
- Among patients who were down-titrated, 59% maintained response through Week 152.
- Overall, 36.6% of patients down-titrated to baricitinib 2-mg met criteria for retreatment with 4mg (20 points or greater worsening in SALT score from Week 52).
- Successful down-titrations were observed more frequently in patients who achieved a stable response from week 36 to 52 and/or those who achieved a depth of response at SALT ≤5 before they were down-titrated.

Successful dose modulation of baricitinib is possible, although more work is needed to optimize the process of down-titration. The timing of down-titration that was prescribed in BRAVE-AA2 may not reflect optimal clinical parameter, results do not suggest that stability and depth of response are important variables to consider.

STUDY DESIGN

Clinical Response (SALT score ≤20) was maintained in patients through Week 152

Pharmacodynamic: Demographics and Baseline Characteristics

RESULTS

Percentage of Patients With Loss of Treatment Benefit (20 points or greater worsening in SALT score from Week 52) Through Week 152

Percentage of SALT Score ≤10 Responders Throughout Week 152

Down-Titration Population: Demographics and Baseline Characteristics

KEY ELIGIBILITY CRITERIA

BRAVE-AA2

- Age ≥18 years to ≤80 years (males) or ≤70 years (females)
- Severe or very severe AA, fulfilling the following criteria:
  - Current episode of AA lasting >6 months to <8 years
  - Hair loss involving ≥50% of the scalp, as measured by SALT score
  - No spontaneous improvement in the 6 months before screening
- Not primarily “diffuse” type of AA
- No concomitant treatments for AA allowed

Down-titration sub-study

- At Week 52, patients treated with baricitinib 4-mg since baseline, who had a SALT score ≤20 (responders) were randomized in a 1:1 ratio to either stay on baricitinib 4-mg or transition to baricitinib 2-mg (randomized down-titration)

- Patients who had AA for 28 years could be enrolled if episodes of regrowth, spontaneous or due to undertreatment, had been observed on the affected areas and were anticipated to continue on a stable dose up to Week 36.

AbbVie; BARI=baricitinib; LOCF= last observation carried forward; SALT=Severity of Alopecia Tool

STUDY ABBREVIATIONS