Trajectories For Scalp Hair Regrowth In Patients With Severe Alopecia Areata Treated With Baricitinib

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OBJECTIVE
- This post hoc analysis of integrated data from two Phase 3 trials (BRAVE-AA1 [NCT03570749] and BRAVE-AA2 [NCT03895265]) describes trajectories of clinical response in patients with severe AA treated with baricitinib 2mg or 4mg over 52 weeks.

METHODS
- Study Design: BRAVE-AA1 and BRAVE-AA2
- Baseline AA severity and duration of current episode influence the pattern of clinical response
- Proportion of 4mg-treated patients who achieved a SALT score ≤20 response over 52 weeks in different response pattern subgroups
- Proportion of 2mg-treated patients who achieved a SALT score ≤20 response over 52 weeks in different response pattern subgroups
- Age Parameter
- Asian (%)
- Male (%)
- Female (%)
- White (%)
- Black (%)
- Asian (%)
- European (%)
- Other (%)

KEY RESULTS
- Identification of response patterns based on SALT score percent change from baseline among 4mg-treated patients
- Identification of response patterns based on SALT score percent change from baseline among 2mg-treated patients

CONCLUSIONS
- These analyses revealed three response patterns among patients with severe AA who achieved SALT ≤20 on baricitinib at any point within 52 weeks early gradient baricitinib has demonstrated efficacy for patients with severe AA and has been approved for the treatment of severe AA in various regions including the USA, E.U., and Japan.
- Little is known about the overall pattern of clinical response to treatment of patients with severe AA. Such information will be important to guide health care providers and patients seeking treatment.

REFERENCES
- As reported previously, overall higher response rates were observed with baricitinib 4mg vs 2mg, particularly when considering early and gradual responders.
- 49% and 28% of 4 mg and 2 mg treated patients, respectively, experienced a SALT score ≤20 response (70.6%)
- These analyses revealed three response patterns among patients with severe AA who achieved SALT ≤20 on baricitinib at any point within 52 weeks.
- These findings can help to inform the treatment expectations for scalp hair regrowth in patients with severe AA.
- Longer treatment duration may be needed for some patients to assess the full impact of treatment on scalp hair regrowth.

DISCLOSURES
- All authors serving as a consultant or paid speaker for or participating in clinical trials sponsored by Eli Lilly and Company, Novartis, Johnson & Johnson, Abbvie, Pfizer, Inc, Merck Sharp & Dohme, Inc, Boehringer Ingelheim, Pharma Ltd., Galapagos NV, LEO Pharma, Otsuka Pharmaceutical KK (Japan), Taisho Pharmaceutical Co, and ROHTO Pharmaceutical
- For patients who achieved SALT ≤20, at any point within 52 weeks, a stepwise sequential analysis was performed.
- For each response pattern, the following outcomes were analyzed:
  - Proportion of patients achieving the BRAVE-AM 6 primary endpoint of SALT ≤20 (30% scalp hair loss); and
  - Proportion of patients achieving 50% improvement from baseline in SALT score ≤20 (SALT ≤20):

- The thin blue lines indicate individual patients, the thick blue lines are the smoothing lines using local polynomial regression. The light blue lines indicate the smoothed SALT score percent change from baseline for all patients, the dark blue lines indicate the smoothed SALT score percent change from baseline for each response pattern subgroup.

- Statistical Analyses
  - The full analysis set was used for patients with complete data for all variables used in these analyses.
  - Data were censored after permanent study drug discontinuation or data collected at remote visits due to COVID-19 pandemic.
  - Non-responder imputation was applied to binary endpoints (i.e., SALT ≤20).
  - Proportion of patients achieving 50% improvement from baseline in SALT score (SALT≤20)

- Key Eligibility Criteria
  - Male or female ≥18 years old
  - AA in the 6 months prior to baseline
  - No spontaneous improvement of at least 70% in the bearing area
  - Only patients treated with baricitinib 2mg or 4mg over 52 weeks

- Methods
  - Non-responders were defined as having never reached at least a 30% improvement in SALT score from baseline (SALT0-30) within 52 weeks of treatment.

- Study Design: The full analysis set was used to assess the proportion of patients achieving the CRAVE-AM 6 primary endpoint of SALT ≤20 (30% scalp hair loss); and the proportion of patients achieving 50% improvement from baseline in SALT score ≤20 (SALT ≤20).

- Age, Gender, and Race Parameters
  - Age Parameter
  - Female (%)
  - Male (%)
  - White (%)
  - Black (%)
  - Asian (%)
  - European (%)
  - Other (%)

END OF PAGE 1