Real-World Ritlecitinib Treatment of Severe Alopecia Areata (AA) in the US: Patient Characteristics and Physician Satisfaction

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BACKGROUND

- Alopecia areata (AA) is an autoimmune disease characterized patchy or complete nonscarring hair loss on the scalp, with or without additional loss of facial and/or body hair[1]
  - AA is associated with considerable psychosocial burden and negative impacts on patient's health-related quality of life (HRQoL)[2,3]
- Ritlecitinib, a selective, dual inhibitor of JAK3/TEC family kinases, demonstrated efficacy and safety in the pivotal ALLEGRO phase 2b/3 trial in adults and adolescents
- In June 2023, ritlecitinib 50 mg daily was approved to treat adults and adolescents with severe AA[4]
- As approved kinase inhibitor treatments for AA are relatively new, limited data exist describing how dermatologists are integrating them into real-world clinical practice, or the impact of such treatments on patients

OBJECTIVE

- To describe characteristics, treatment history, treatment satisfaction, and treatment success among adult patients with severe/very severe AA who were treated with ritlecitinib in the United States, further stratified by time on ritlecitinib, and by patients who were initiated on ritlecitinib within 2 months of the survey

METHODS

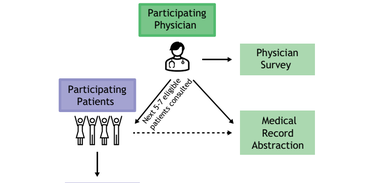
STUDY DESIGN

- A secondary database analysis was performed using data from the Adelphi Real World AA II US Disease Specific Programme™ (DSP) - a cross-sectional survey with retrospective data collection from US dermatologists and their patients with AA in a real-world setting
  - The DSP was conducted between November, 2023, and June, 2024, and collected de-identified data from patient medical records (**Figure 1**)
  - Data included patient demographics, clinical characteristics, treatment history and satisfaction, and AA impact

Study population

- Adults ≥18 years diagnosed with physician-assessed severe/very severe AA in the US and receiving ritlecitinib at the time of the survey **(Figure 1)**

Figure 1. Study design



Patient Inclusion Criteria:
- ≥ 18 years old
- Was not involved in a clinical trial
- Diagnosed with AA

Patient Inclusion Criteria:
- Dermatologist involved in AA treatment management
- Minimum workload of ≥7 adults with AA (≥1 mild, 3 moderate, and 3 severe/very severe)

AA, alopecia areata.

Statistical analysis

- Descriptive statistics were reported for each objective, for the overall cohort sample (patients receiving ritlecitinib) and each subgroup
- Subgroups include:
  - Ritlecitinib treatment duration (<3 months, 3-6 months, ≥7 months)
  - Patients who were initiated on ritlecitinib within 2 months of the survey (recently initiated)

RESULTS

Patient demographics & clinical characteristics

- The overall cohort included 123 adults with a mean (SD) age of 37.1 (11.5) years, 57% being male, 79% being white, and 88% having commercial insurance **(Table 1)**
- Of these 123 patients, 26 recently initiated ritlecitinib

Table 1 . Demographics of patients receiving ritlecitinib

Characteristic	All patients receiving ritlecitinib (N=123)	Recently initiated ritlecitinib (n=26)
Age in years, mean (SD)	37.1 (11.5)	34 (11.9)
Male, n (%)	70 (57)	9 (35)
Race, n (%)		
White	97 (79)	22 (85)
Black	20 (16)	2 (8)
Other	9 (8)	-
Hispanic, n (%)	14 (1)	5 (19)
Employment status, n (%)		
Working full/part time	96 (78)	19 (73)
Student	12 (10)	6 (23)
Unemployed	7 (6)	-
Other/unknown	8 (7)	1 (4)
Health insurance type, n (%)		
Commercial insurance	108 (88)	25 (96)
Medicaid or medicare	10 (9)	1 (4)
Other	3 (3)	-

- Overall mean (SD) disease duration, reported among 84 patients, was 2.1 (3.0) years **(Table 2)**
- Patients had a mean (SD) percentage of scalp hair loss (SHL) of 71.1% (18.5) at ritlecitinib initiation (n=93) and 60.9% (24.2) at the time of the survey (n=104) (**Table 2**)
- For the overall cohort (N=123), 73% reported worsening AA at ritlecitinib initiation; at the time of the survey, 89% reported improving/stable AA (**Table 2**)

Table 2 . Clinical characteristics of patients receiving ritlecitinib

Characteristic	Patients receiving ritlecitinib	
Disease duration	n=84	
Mean (SD)	2.1 (3.0)	
Assessment Period:	**At ritlecitinib initiation**	**At time of survey**
% SHL	N=93	n=104
Mean (SD)	71.1 (18.5)	60.9 (24.2)
Hair regrowth status, n (%)	N=123*	N=123
Improving	1 (1)	51 (41)
Stable	29 (24)	59 (48)
Worsening	90 (73)	13 (11)
Don't know	3 (2)	0 (0)
Quality of hair regrowth, n (%)	-	n=79
Fine (sometimes referred to as fuzzy)	-	41 (52)
Strong	-	38 (48)
Patient has experienced hair regrowth in the past, n (%)	-	N=123
Yes	-	19 (15)

SHL, scalp hair loss.
*Disease status immediately prior to ritlecitinib initiation.

Treatment overview

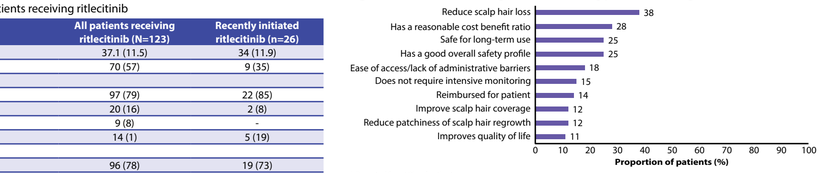
- The top physician-reported treatment goals included reducing hair loss (94%), improving quality of life (41%), and achieving long-term control (32%) **(Figure 2)**

Figure 2. Treatment goals* among patients receiving ritlecitinib (N=123)

* Reported for ≥10% of patients.

- Among patients with physician-reported reasons for selecting ritlecitinib, the most common factors were its ability to reduce scalp hair loss (38%), reasonable cost-benefit ratio (28%), good overall safety profile (25%), and safe for long-term use (25%) **(Figure 3)**

Figure 3. Reasons for selecting ritlecitinib* among patients receiving ritlecitinib (n=113)



* Reported for ≥10% of patients.

- Among those with treatment line data (n=102), a mean (SD) of 1.8 (0.9) lines of treatments (LoT) were reported; ritlecitinib was the first LoT for 46% of these patients (**Table 3**)
- Ritlecitinib treatment duration, measured from the start of ritlecitinib to the date of the survey , varied among those with known treatment duration (n=111): <3 months, 33%; 3-6 months, 41%; ≥7 months, 25% **(Table 3)**
- Among those treated with prior AA therapies (n=60), 18% received another JAK inhibitor before initiating ritlecitinib **(Table 3)**

Table 3. Treatment characteristics

Characteristic	Patients receiving ritlecitinib
Current regimen, n (%)	N=123
Ritlecitinib monotherapy	103 (84)
Combination therapy	20 (16)
Intralesional injected corticosteroid (e.g. triamcinolone crystals)	12 (10)
Topical corticosteroid	7 (6)
Oral corticosteroid	4 (3)
Total number of treatment lines	n=102
Mean (SD)	1.8 (0.9)
Ritlecitinib received as, n (%)	n=102
First line	47 (4)
Second line	35 (34)
Third line or later	20 (20)
Duration of ritlecitinib at time of survey, n (%)	n=111
Months, mean (SD)	4.8 (3.2)
<3 months	37 (33)
3-6 months	46 (41)
7-9 months	15 (13)
9-12 months	9 (8)
12+ months	4 (4)
Last treatment received prior to ritlecitinib initiation, n (%)	n=60
Topical corticosteroid	20 (33)
Intralesional injected corticosteroid (e.g. triamcinolone crystals)	18 (30)
Oral corticosteroid	11 (1)
Oral or topical JAKi	11 (18)
Systemic IM	9 (15)
IV injected corticosteroid	4 (7)
Topical IM	3 (5)
Other	7 (12)

IM, immunomodulator; IV, intravenous; JAKi, Janus kinase inhibitor.

- Proportions of patients with hair regrowth increased with treatment duration (<3 months [n=37], 49%; 3-6 months [n=40], 72%; ≥7 months [n=34], 82%; **Table 4)**

Table 4. Clinical characteristics by duration of ritlecitinib treatment among patients receiving ritlecitinib

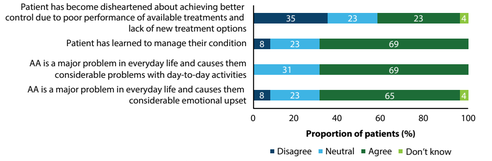
Characteristic, n (%)	Patients receiving ritlecitinib*			
Assessment Period:	**Overall cohort with known date of treatment initiation (n=111)**	**<3 months (n=37)**	**3-6 months (n=40)**	**≥7 months (n=34)**
Hair is currently regrowing, n (%)	n=111	n=37	n=40	n=34
Yes	75 (68)	18 (49)	29 (72)	28 (82)
No	33 (30)	17 (46)	10 (25)	6 (18)
Don't know	3 (3)	2 (5)	1 (2)	-
Body region with hair regrowth at time of survey, n (%)	n=80	n=18	n=29	n=28
Scalp	79 (99)	18 (100)	29 (100)	28 (100)
Eyebrow	12 (15)	4 (22)	5 (17)	3 (11)
Facial (beard or mustache)	8 (10)	1 (6)	2 (7)	4 (14)
Eyelash	7 (9)	2 (11)	2 (7)	3 (11)
Body (arms, legs, chest)	7 (9)	2 (11)	2 (7)	3 (11)
Public area	2 (2)	-	-	1 (4)
Percentage scalp hair regrowth at time of survey	n=71	n=16	n=28	n=27
Mean (SD)	30.4 (27.4)	19.7 (15.4)	21.9 (19.0)	45.6 (33.4)
Quality of hair regrowth, n (%)	n=75	n=18	n=29	n=28
Fine (sometimes referred to as fuzzy)	37 (49)	13 (72)	14 (48)	10 (36)
Strong	38 (51)	5 (28)	15 (52)	18 (64)

*Receiving ritlecitinib and had a known date of ritlecitinib initiation.

Psychosocial burden among recent ritlecitinib initiators

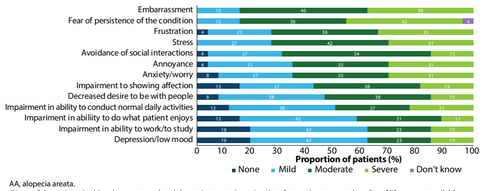
- Among the subset of patients who recently initiated ritlecitinib (n=26), dermatologists reported 69% learned to cope with their AA prior to starting ritlecitinib **(Figure 4)**; however, 85%, 73%, and 65% still reported moderate/severe embarrassment, frustration, and anxiety due to their AA, respectively **(Figure 5)**

Figure 4 . Physician-reported HRQoL among patients with AA who were initiated on ritlecitinib within 2 months of the survey (n=26)



AA, alopecia areata; HRQoL, health-related quality of life.

Figure 5. Physician assessment of impact of AA among patients who were initiated on ritlecitinib within 2 months of the survey (n=26)*

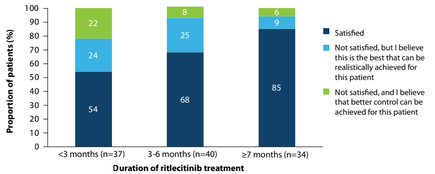


AA, alopecia areata.
*None of the patients in this subgroup completed the patient questionnaire, therefore patient-reported quality of life was not available.

Physician-reported treatment satisfaction and success

- The proportion of patients with physician-reported satisfaction with their patient's AA control was 54% (n=37), 68% (n=40), and 85% (n=34) after <3, 3-6, and ≥7 months of ritlecitinib, respectively **(Figure 6)**

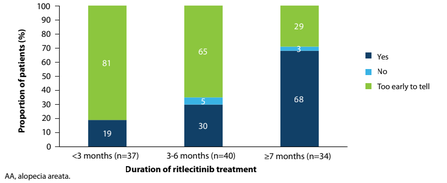
Figure 6. Physician-reported satisfaction with current control of patient's AA



AA, alopecia areata.

- Physicians reported ritlecitinib treatment as a success for 68% of their patients in the ≥7-month group (n=34), but felt it was still too early to tell if it was a successful treatment for 29% of patients **(Figure 7)**

Figure 7. Physician perception: considers the treatment regimen to be a success



AA, alopecia areata.

LIMITATIONS

- Physicians provided data on consecutively consulting patients meeting the eligibility criteria, thus reducing the chance of selection bias; however, generalizability of the study results to the wider patient population may be impacted as follows:
  - Participants from the AA DSP did not constitute a true random sample and participation was influenced by the willingness to complete the record forms
  - The patient sample may have been more severely affected by their disease and/or treatment due to their consulting nature and patients who consulted more frequently were more likely to be included in the patient sample
  - Study data are self-reported by participants as no independent verification was possible due to the nature of the DSP methodology
  - As patients currently on treatment may be more likely to feel satisfied with their therapy (i.e., did not discontinue due to lack of efficacy), satisfaction results cannot be generalized

CONCLUSIONS

- Despite many patients coping with AA, dermatologists reported substantial emotional and daily life impacts among patients due to their severe/very severe AA before initiating ritlecitinib
- Ritlecitinib was chosen for efficacy, safety profile, and cost-benefit ratio
- Hair regrowth, physician satisfaction, and perceived treatment success increased with treatment duration
- While selection bias should be considered, results indicate the importance of sustained treatment for the management of patient expectations

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DISCLOSURES

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