BARICITINIB IN THE TREATMENT OF FRONTAL FIBROSING ALOPECIA: MID TRIAL UPDATE

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BACKGROUND

- Frontal fibrosing alopecia (FFA) is an inflammatory cicatricial alopecia primarily affecting post menopausal women[1].
- It is deemed a variant of lichen planopilaris[1].
- The incidence of FFA is unknown but increasing.
- Conventional treatments such as intralesional or topical steroids have been ineffective in halting disease progression[1].
- Several publications have demonstrated JAK/STAT as a potential treatment target in FFA and similar conditions[2,3].

OBJECTIVES

- The primary objective of this study is to assess the efficacy of baricitinib on stopping disease activity and progression of FFA.
- The secondary objective is to evaluate the effect of baricitinib on reported outcomes and clinical assessments at week 12 and 24.

METHODS

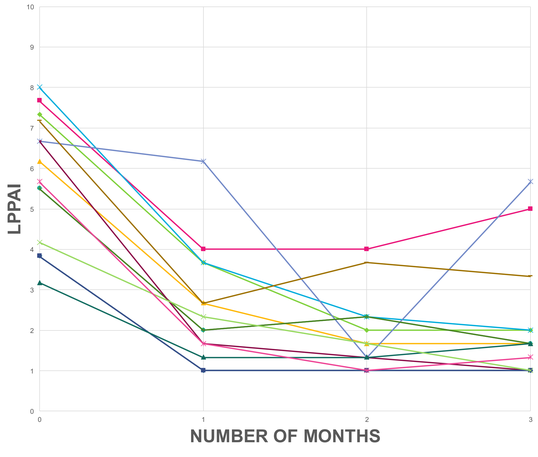
- This is a 36-week open-label study in women >/= 18 years of age who have biopsy proven FFA.
- Subjects were treated with baricitinib 4 mg daily as monotherapy.
- Endpoints include assessment at weeks 12, 24, and 36.
- Week 12 analysis evaluated improvement in the Lichen Planopilaris Activity Index (LPPAI).
- The LPPAI captures patient reported symptoms (pruritus, pain, burning), clinical signs (erythema, perifollicular erythema, scale), and other disease activity measures such as anagen pull and spreading.

RESULTS

- 20 total subjects were screened and five subjects screen failed.
- At time of analysis,13 participants had completed the week 12 visit.
- The patients were all post-menopausal women with biopsy proven FFA and had failed multiple prior therapies.

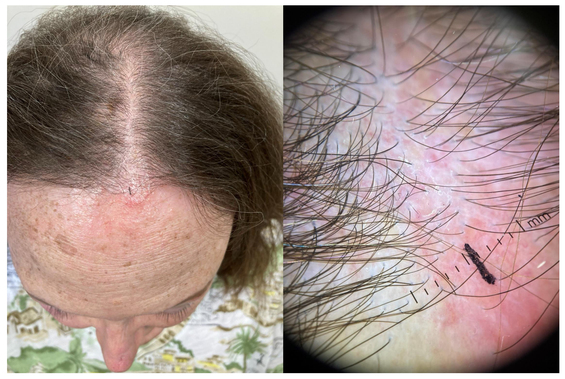
Prior failed therapies	
Subject 1	topical steroids, intralesional steroids, topical and oral minoxidil, hydroxychloroquine, topical tacrolimus, dutasteride, doxycycline, pioglitozone
Subject 2	topical steroids, intralesional steroids, finasteride
Subject 3	topical steroids, intralesional steroids, topical and oral minoxidil, hydroxychloroquine, topical tacrolimus, dutasteride
Subject 4	intralesional steroids, oral minoxidil, hydroxychloroquine, dutasteride, finasteride
Subject 5	topical steroids, oral minoxidil, hydroxychloroquine, topical tacrolimus, dutasteride, doxycycline
Subject 6	topical steroids, intralesional steroids, oral minoxidil, hydroxychloroquine, dutasteride
Subject 7	topical steroids, topical minoxidil, hydroxychloroquine, topical tacrolimus, dutasteride, finasteride, doxycycline
Subject 8	oral minoxidil, hydroxychloroquine, topical tacrolimus, doxycycline
Subject 9	topical minoxidil, hydroxychloroquine, topical tacrolimus, dutasteride, finasteride, doxycycline, spironolactone, laser cap, topical tofacitinib
Subject 10	topical steroids, intralesional steroids, topical and oral minoxidil
Subject 11	topical steroids, oral minoxidil
Subject 12	topical steroids, oral minoxidil, hydroxychloroquine, pimecrolimus, doxycycline, mycophenolate mofetil
Subject 13	topical steroids, intralesional steroids, topical and oral minoxidil, hydroxychloroquine, topical tacrolimus, finasteride

- From screening to week 12 the average **LPPAI** for all the participants decreased from **6.18** to **2.26 (-3.92)** which was statistically significant ($p<0.05$).

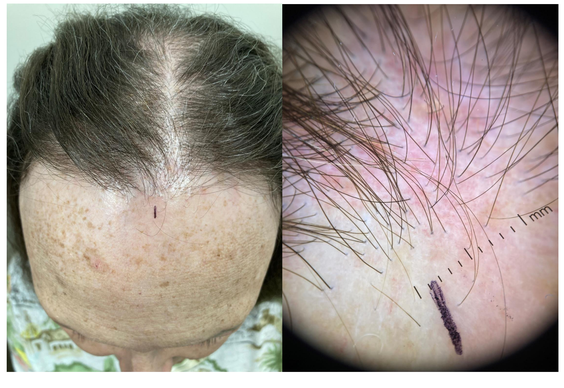


RESULTS

- The patient reported outcome for scalp hair growth (**PRO Scalp**) increased from **0.85** to **2.38 (+1.54)** on average during the same time ($p<0.05$).
- The patient reported outcome for eyebrow growth (**PRO eyebrow**) showed no difference during this time.
- The **visual analogue scale (VAS) pruritis score** decreased on average from **4.38** to **3.46 (-0.92)** but this was not statistically significant ($p>0.05$).



*Gross and dermatoscopic view of a subject's frontal scalp at **screening** with significant perifollicular erythema and scale.*



*Gross and dermatoscopic view of a subject's frontal scalp at **month three** with significant improvement in perifollicular erythema and scale.*

CONCLUSIONS

- After 12 weeks of therapy, baricitinib shows potential as an effective monotherapy for FFA.
- While patient perception of eyebrow hair growth did not change in this short time, perception of scalp hair growth improved as well as symptoms of itch.
- Clinical improvement in disease was apparent based on LPPAI which accounts for patient symptoms as well as measurable differences in multiple features of FFA including erythema, perifollicular erythema, and perifollicular scale.
- More time will be needed to assess for hair growth or disease remission.

REFERENCES

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