Deuruxolitinib Data Looks Good at Week 52

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Response Data for Deuruxolitinib Looks Good at Week 52

Deuruxolitinib is a Janus kinase (JAK) 1 and JAK2 inhibitor. It has been studied in the THRIVE-AA1 and THRIVE-AA2 clinical trials. In these studies, adult patients with AA were randomized to 8 mg BID and 12 mg BID doses vs placebo. At 24 weeks, about 30 % of patients using deuruxolitinib 8 mg twice daily achieved good regrowth. In other words, they met the typical AA study endpoint that denotes good regrowth (ie SALT score less than 20).

Concerns were raised in 2023 with deuruxolitinib at the 12 mg twice daily dose. Blood clots in patients receiving these doses caused the FDA to pause clinical trials of deuruxolitinib. We've discussed these issues in the past and a link to prior articles is here:



Week 52 Data show 60 % of patients Meet SALT M<20 Endpoint

New data that was presented at a recent meeting of the <u>European Academy of</u> <u>Dermatology and Venereology</u> showed that an even greater number of patients achieve the SALT 20 endpoint by week 52 compared to week 24. Dr King presented week 52 data as part of the company's open label study. Here, patients received either 8 mg BID or 12 mg BID oral deuruxolitinib. After 52 weeks of cumulative dosing, 63.6% of patients in the 8 mg BID group achieved a SALT score less than 20. This was similar (62.1%) in the 12 mg BID group.

Comments and Discussion

This is exciting data. It would appear that deuruxolitinib is effective in treating advanced AA. It's a bit surprising that the 12 mg BID dosing and 8 mg BID dosing produce similar clinical outcomes. That's not a dose response we typically see with our other JAK inhibitors. In

other words, for most other JAK inhibitors, higher doses of the drug bring better results.

The time draws near that various regulatory bodies around the world will need to consider approving deuruxolitinib. I'd be surprised if any dose other than the 8 mg dose goes up for consideration. Personally, what's left for me as a hair specialist is:

1) to closely follow over time if the safety of deuruxolitinib is the same as other JAKs,

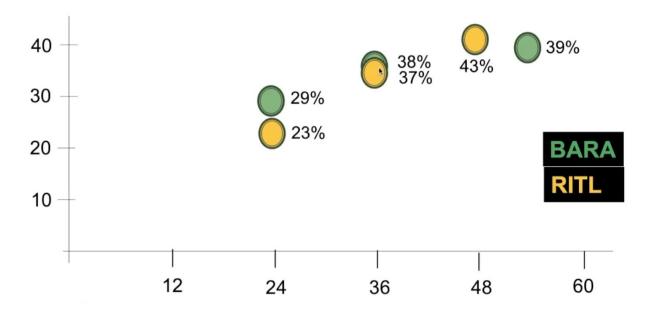
2) to follow if deuruxolotinib is truly more effective than other JAKs or just as effective at 8 mg BID dosing over 2, 3 and 5 years of observation

and

3) what will be the final cost of this drug.

How does the 52 week Deuruxolitinib data compare to 52 weeks data for Baricitinib and Ritlecitinib?

The graph below shows the proportion of patients using baricitinib and ritlecitinib that achieve reasonably good regrowth (SALT <20) and includes data up to 1 year. It shows the proportion of patient who achieve 80 % regrowth (ie SALT less than 20). If 60 % of those treated with 8 mg BID deuroxolitinib achieve a SALT less than 20 that would put deuruxolitinib as a top performing JAK inhibitor - at least at week 52. I hope to review all the data at some point - everything on the table. Long term studies of safety as well as effectiveness are key for all JAK inhibitors but especially JAKs that have already been issued warnings in their trials. Similar to all JAK inhibitors, we'll need to follow deuruxolitinib long term data on blood clots, cancer, heart disease and infections.



REFERENCE

ABSTRACT 6743 - https://eadv.org/wp-content/uploads/scientific-abstracts/EADV-congress-2023/Hair-and-nail-disorders.pdf

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