INTRODUCTION

- Nefead is a novel, oral, targeted-release capsule formulation of budesonide, specifically designed to treat IgAN by inhibiting IgA formation in the Peych's patch-rich distal ileum.
- Results from the full 2-year Phase 3 NefIgArd study evidenced an eGFR treatment benefit versus placebo and durable reduction in proteinuria in 9 months of treatment and 15 months of observable follow-up.
- Nefead has received full FDA approval to reduce the loss of kidney function in adults with primary IgAN who are at risk for disease progression, irrespective of proteinuria levels, whereas the EMA indication requires patients to have UPCR ≥1.5 g/g.
- Here, we present the 2-year results for the composite endpoint of time to confirmed 30% eGFR reduction or kidney failure from the NefIgArd study.

METHODS

- The primary endpoint of time-weighted average of eGFR over 2 years showed a difference of 5.05 mL/min/1.73 m² (95% CI 3.24, 7.8; p<0.0001) in favor of Nefead.
- Treatment with Nefead 16 mg/day for 9 months resulted in approximately 50% less deterioration of kidney function versus placebo at 24 months (Figure 2).
- The time to randomization from confirmed 30% eGFR reduction or kidney failure was significantly delayed with Nefead versus placebo.
- Nefead versus placebo treatment effect was similar, irrespective of the handling of rescue medication.
- The rescue medication count as an event: HR 0.51 (95% CI 0.33, 0.79).
- Regardless of rescue medication: HR 0.44 (95% CI 0.27, 0.71).
- The treatment effect of Nefead versus placebo was consistent, irrespective of baseline UPCR category.
- During the 9-month treatment period, Nefead 16 mg/day was well tolerated, with an expected safety profile for a locally acting oral budesonide product.

RESULTS

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CONCLUSIONS

REFERENCES

ABBREVIATIONS

DISCLOSURES

- Nefead has received support for the present study from ChemoCentr; reports institutional grants from Calabiss, ChemoCentr, Ono, Otsuka, Pfizer, Boehringer-Ingelheim, Travere Therapeutics, and ViVor Pharma; and has served on advisory boards for Alnylam, Alexion, AstraZeneca, Bayer, Boehringer-Ingelheim, ChemoCentr, Chiron, Otsuka, and Travere Therapeutics. He has received honoraria from Alexion, AstraZeneca, Biocytum, ChemoCentr, Chiron, Otsuka, Travere Therapeutics, and ViVor Pharma. He has received travel support from Alexion, AstraZeneca, ChemoCentr, Chiron, Otsuka, and Travere Therapeutics. All other authors have no relationships to disclose.

- This work was supported by the Fonds der Chemischen Industrie (FCI). J.B. is a consultant for Calliditas.

- All randomized patients remained blinded and on optimized RAS inhibition

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