OBEXELIMAB, A B CELL INHIBITOR, IN IGG4-RELATED DISEASE, INCLUDING PATIENTS WITH PANCREATOBILIARY INVOLVEMENT: RESULTS FROM THE PHASE 3 INDIGO TRIAL

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In the Phase 3 INDIGO trial, weekly subcutaneous obexelimab reduced IgG4-related disease flare risk by 56% versus placebo (HR 0.443, p=0.0005) in 194 patients, including nearly half with pancreatobiliary involvement.

KEY POINTS

- Flares occurred in 26.8% of obexelimab-treated patients versus 54.6% on placebo through 52 weeks.
- All four key secondary endpoints were met, including time to first investigator-determined flare (p=0.0001), number of flares (p=0.0008), complete remission (p=0.0049), and cumulative glucocorticoid rescue therapy (p=0.0042).
- Obexelimab is a humanized bifunctional monoclonal antibody inhibiting B lineage cells via co-engagement of CD19 and FcγRIIb, without effector cell-mediated depletion.
- Approximately half of enrolled patients had pancreatobiliary involvement at baseline (pancreatic 46.9%, biliary 28.4%), making results directly relevant to the pancreatobiliary community.
- The drug was well tolerated with no new safety signals.
- Patients initiated standardized glucocorticoid therapy (20–60 mg/day prednisone equivalent) with 8-week taper to discontinuation before randomization to obexelimab 250 mg or placebo weekly for 52 weeks.

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