

Lessons Learned from the Seladelpar Phase 2b Study

Melissa Palmer, MD

Liver Forum

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Disclosures

- CMO Gannex Pharma, a wholly owned subsidiary of Ascletis

Seladelpar

- PPAR-delta agonist
- Nov '19 Termination Phase 2 NASH and PSC / Hold Phase 3 PBC
- “Planned, blinded histological assessments of the first tranche of liver biopsies in the trial revealed atypical histological findings, including histology characterized as an interface hepatitis presentation, with or without biliary injury”
- Asymptomatic, improved or stable liver blood tests
- Findings were also unexpected based on pre-clinical and clinical experience





Histology?



- Interface hepatitis
- Piecemeal necrosis
- Process of inflammation and erosion of the hepatic parenchyma leading to a disappearance of the interface between the lobule and portal tracts
- Autoimmunity
- AIH/NASH?
- AIH - DILI?



DILI

- DILI with normal or unchanged ATs?
- AI DILI?
- External DILI safety committee

Clinical Development Operational



- Eligibility criteria?
- Baseline biopsy reporting?
- How many pathologists?
- Glass Slide or digital?
- Tranche/real time?
- Scrambling?
- Paired biopsies evaluation versus PBO at EOT?

