Panel Discussion Questions (1 / 2)

- When evaluating screening histology are all abnormal histologic changes reported or only NAS score and fibrosis grade?
- What is the spectrum of histologic findings that can be seen in NASH other than inflammation, ballooning, steatosis, and fibrosis?
- What does “interface hepatitis” look like histologically in a patient with NASH versus what is usually associated with this term such as in AIH?
- Should liver biopsies be “paired” when assessing EOS histology?
- If unexpected histologic lesions are identified in EOS liver biopsy, what are the next steps on the part of the 1. Pathologist 2. Sponsor 3. Investigator 4. FDA?
- Is it sufficient to compare to the histology from the placebo arm instead of comparing to baseline histology?
- Can histologic DILI be seen in the setting of normal/near normal liver-related blood tests?
- Can interface hepatitis be seen in the setting of normal or near normal liver-related blood tests?

Panel Discussion Questions (2 / 2)

- How many pathologists should evaluate screening and EOS histologic slides in a NASH clinical trial?
- Should EOS histology be evaluated as soon as possible or is it sufficient to wait until all patients or a predetermined number of patients have completed the trial?
- What/how many members should make up an external DILI monitoring committee/ when to set up/ blinded/ unblinded members prior to study start – Who should be on the committee? – pathologist /clinical development/ statistician/ DILI expert?
- The eligibility for the phase 2 seladelpar trial was consistent with other phase 2 NASH trials. However, this begs the question: how did this patient population differ? and if not different - why were these histologic findings found in this trial and not in other NASH trials? Are these findings now being reported, or found, more often in NASH trials now that there is increased sensitivity to finding/reporting this expanded spectrum that can be seen in NASH?