Liver Forum Histology Webinar Series

Session 3: The Role of Liver Biopsy as part of Causality Assessment for Suspected DILI in NASH Clinical Trials

Overview: Causality assessment for suspected drug-induced liver injury (DILI) is a major challenge during drug development and becomes a greater challenge when studies are done in patients with NASH who typically enter the trial already with liver blood test elevations.

The role of a liver biopsy in the diagnosis and management of suspected DILI is a subject of ongoing debate. The inherent risks of a liver biopsy must be weighed against the potential useful information to be obtained from evaluation of liver tissue. Histologic results may be nonspecific and often have little impact in establishing the diagnosis of DILI or in changing the clinical assessment; however, histologic evaluation of liver tissue may be helpful in characterizing the pattern, severity, and distribution of hepatic injury, and may have prognostic value.

It is important to have a plan of action and external DILI monitoring committee in place prior to study start, that could promptly assess unexpected or atypical histology found on liver biopsy during a clinical trial.

The goal of Session 3 (Part 1) will be to address:

1. Lessons learned from drug development in liver disease.
2. Understanding the spectrum of histological findings that can be seen in NASH other than inflammation, ballooning, steatosis and fibrosis.
3. Understanding the presentation of interface hepatitis in NASH patients.
4. Best practices for assessment of unexpected or atypical findings found on histology.

Part 1: Lessons Learned from Seladelpar Phase 2b Study

Part 2: The Role of Unplanned Liver Biopsy in DILI Causality Assessment [Date TBD]

Audience Note: Invitation to members of IQ DILI Consortium

Proposed Agenda Part 1
Friday, January 22, 2021
12:00pm-2:00pm ET

Moderator: Melissa Palmer, Gannex Pharma

12:00 PM	**Introduction and Welcome**	*Veronica Miller, Forum for Collaborative Research*
12:05 PM	**Setting the Stage: review of issues and recent data**	*Melissa Palmer, Gannex Pharma*
12:20 PM	**Shared Experience from Drug Development**	*Charles McWherter, CymaBay*
12:40 PM	**Histological Findings of Interest**	*Elizabeth Brunt, Washington University School of Medicine in St. Louis*
12:50 PM	**Panel Discussion:** (includes audience Q&A)	*Arie Regev, Eli Lilly & Company*
		Naga Chalasani, Indiana University
		Zachary Goodman, Inova Fairfax Hospital
		David Kleiner, National Cancer Institute, NIH
		Mark Avigan, U.S. Food and Drug Administration
		Arun Sanyal, Virginia Commonwealth University
1:50 PM	**Wrap Up**	*Melissa Palmer and Arun Sanyal*
2:00 PM	**Adjourn Webinar**	