Drug-Induced Liver Injury (DILI) Conference XVI
Wednesday-Thursday 23-24 March 2016

How Should Liver Injury and Dysfunction Caused by Drugs Be Measured, Evaluated, and Acted Upon in Clinical Trials?

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Clinical trials in humans exposed to new drugs being developed provide data for the regulatory decisions on approval or non-approval and provide the best information to guide optimal use after marketing by prescribers in treating patients. Speeding and optimizing new drug development during the investigational new drug (IND) period represents the greatest opportunity to shorten time and reduce costs from discovery to approval. There is urgent need to update and revise thinking to consider investigational treatment of patients with pre-existing liver diseases such as chronic viral infection with hepatitis C or B, alcoholic and non-alcoholic steatohepatitis, and other liver disorders. It is also important to recognize hepatocyte adaptation, and to reconsider if controlled rechallenge can be done safely in the carefully controlled environment of clinical trials. This conference will seek comments and proposals from industry, investigators, and regulators on these and other controversial issues that need to be faced, considered, debated, and if possible resolved toward reaching consensus.

Wednesday, 23 March 2016

7:30	*continental breakfast outside the conference room; register*	
8:00	***SESSION I*** **Hepatocyte Adaptation and Possible Rechallenge**	
	Moderators: ***Arie Regev*** *and* ***John Senior***	
8:00	Rechallenge is too dangerous	Christine Hunt
8:20	Maybe it's not	Vid Stanulovic
8:40	It really is too dangerous	Julie Papay
9:00	The isoniazid story, one more time, with implications	John Senior
9:20	Discussion and Debate of Issues	ALL PRESENT
9:50	coffee break	
10:10	Interactions between drug properties and host factors	Ayako Suzuki
10:30	Mechanism of hepatocyte adaptation to chemical injury	Neil Kaplowitz
10:50	New data on adaptive processes	Lily Dara
11:10	Allergic DI++LI from suppression of myeloid cells	Mala Chakraborty
11:30	General DIscussion of Issues,	ALL PRESENT
12:00	lunch break	
1:00	***SESSION II*** **Treating Advanced Liver Disease with Drugs**	
	Moderators: ***Debbie Birnkrant*** *and* ***Mark Avigan***	
1:00	Can study protocols protect patients with liver disease from serious DILI?	John Vierling
1:20	Best use of MELD/CTP scores for baseline and treatment assessment	Patrick Kamath
1:40	Liver function testing to assess treatment effects and predict outcome in HCVLD	Greg Everson
2:00	Acute hepatotoxicity in HCV-cirrhotics treated with direct-acting antiviral agents	Michael Fried
2:20	General DIscussion of Issues	ALL PRESENT
2:50	refreshment break	
3:10	Can we test liver function to assess treatment effects and course of NASH?	Arun Sanyal
3:30	How can we recognize and manage DILI in patients with advanced NASH?	Bob Fontana
3:50	Clinical trial guidelines for DILI in patients which chronic liver disease	Mark Avigan
4:00	Recognizi/ng, assessing managing acute DILI in HCVLD – FDA challenges	Poonam Mishra
4:15	Recognizing, assessing managing acute DILI in NASH – FDA challenges	Ruby Mehta
4:30	General DIscussion of Issues	ALL PRESENT
5:00	*reception: wine and hors d'oeurves; mingle, chat, and relax --- dinner on your own*	

Thursday, 24 March 2016

7:30	*continental breakfast outside the conference room*	
8:00	***SESSION III*** **Immune-mediated DILI Caused by Monoclonal Antibodies (mabs)**	
	Moderators: ***John-Michael Sauer*** *and* ***Jack Uetrecht***	
8:00	Mechanisms of immune tolerance	Amy Rosenberg
8:25	DILI caused by biologics to treat immune-mediated diseases	Herb Bonkovsky
8:50	Inhibition of immune tolerance unmasks DILI potential	Jack Uetrecht
9:15	General Discussion of Issues	ALL PRESENT
9:45	coffee break	
10:00	DILI caused by checkpoint inhibitors and other anti-cancer antibodies	Cyril Konto
10:25	DILI due to immunotherapy targeting immune checkpoints: how to treat?	Arie Regev
10:50	Monoclonal antibody-induced DILI --- a regulatory perspective	Daniel Suzman
11:15	General Discussion of Issues	ALL PRESENT
11:45	lunch break	
12:45	***SESSION IV*** **Hot new breakthrough findings and viewpoints**	
	Moderators: ***Paul Watkins*** *and* ***Gyongyi Szabo***	
12:45	Is the eDISH program the long-sought and best current biomarker for DILI?	John Senior
1:00	Transformative DILI biomarkers – DILIN/SAFE-T collaboration	Rachel Church
1:15	Application of novel biomarkers to assess liver safety in clinical trials	Paul Watkins
1:30	Targeting HMGB1 with antibodies and inhibitory peptides	Dan Antoine
1:45	General Discussion of Issues	ALL PRESENT
2:15	refreshment break	
2:30	Liver disease among infants receiving parenteral nutrition	Katherine Gura
2:45	TAK-875 (fasiglifam) – the real story	Yvonne Dragan
3:00	Modelling drug-induced lipotoxicity	Scott Siler
3:15	NCATS's liver-on-a chip	Lans Tayler
3:30	Role of exosomes in DILI and alcoholic hepatitis	Gyongyi Szabo
3:45	General Discussion of Issues	ALL PRESENT
4:15	adjourn	

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