CARDIAC SAFETY RESEARCH CONSORTIUM CSRC

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AGENDA

Tuesday, May 21, 2024
8:30am - 4:30pm

Margolis Center| 1201 Pennsylvania Ave Suite 500 | Washington, DC 20004

CSRC Think Tank:
Factor XI

TOPIC	Presenter(s)	Time
Welcome and Introductions	Norman Stockbridge (FDA), Dan Bloomfield (Anthos)	**10 mins**
Overview of the CSRC	Jonathan Seltzer (CSRC)	**5 mins**
Session 1: Overview of Factor XI • Moderators: Brandon Atkins (Merck), Aaron Kithcart (Regeneron), Dave Gailani (VUMC)		**70 mins**
1. Factor XI biology & inhibition and preclinical validation • Preclinical Studies/Animal Models • Hemostasis sparing / uncoupling hemostasis and thrombosis	Dave Gailani (VUMC)	15 mins
2. Epidemiology and clinical phenotyping with FXI-deficient individuals	Jean Connors (BWH)	10 mins
3. Human genetic data supporting Factor XI as a target Discuss genetic studies and data.	Lori Morton (Regeneron Genetics Center)	10 mins
4. Novel molecules (with different MOAs) targeting Factor XI; Meta analysis of Ph2 studies (TKR); Biomarkers of activity & Surrogates/ Assays to estimate the PD effects of FXI/FXIa inhibition	Jeff Weitz (McMaster)	20 mins
5. Panel Discussion PANELISTS: Brandon Atkins (moderator); Aaron Kithcart (moderator); Dave Gailani (moderator); Jean Connors; Lori Morton; Jeff Weitz; Erik Tucker; Scott Berkowitz (FDA)		15 mins
BREAK		**10 mins**

Session 2: Factor XI Development Programs • Moderators: Robert Harrington (Weill Cornell), John Strony (JNJ)		**85 mins**
1. Evolution of anticoagulation from warfarin to DOACs to FXI inhibitors	Christian Ruff (TIMI Study Group)	10 mins
2. Potential indications for FXI inhibitors and Phase 3 indications: Industry, Academic and Regulatory Perspectives	Sameer Bansilal (Bayer), Marc Bonaca (CPC Clinical Research)	15 mins
3. What is the potential role of FXI inhibition in:	Jordan Pomeroy (FDA)	30 mins
a. Secondary stroke prevention	Mike Sharma (McMaster)	
b. Atrial fibrillation	Manesh Patel (Duke)	
c. Patient deemed unsuitable for anti-coagulation	Bruce Hug (Anthos)	
d. Renal dysfunction and dialysis	Wolfgang Winkelmayer (Baylor)	
e. AMI	Mike Gibson (BCRI)	
f. Cancer-associated thrombosis	Jeff Weitz (McMaster)	
4. Regulatory Science Perspective: Lessons Learned from DOACs relevant to Factor XI	Jordan Pomeroy (FDA)	10 mins
5. Panel Discussion PANELISTS: Robert Harrington (moderator); John Strony (moderator); Jordan Pomeroy; Mike Sharma; Manesh Patel; Mike Gibson; Robert Giugliano (TIMI); Roxana Mehran (Mount Sinai)		20 mins
BREAK/LUNCH		**30 min**
Session 3: Benefit Risk Safety and Effectiveness **Consensus Endpoints of Interest** • **Moderators:** Norman Stockbridge (FDA), Dan Bloomfield (Anthos)		**105 mins**
1. Patient relevant bleeding: Is minor bleeding on anticoagulants really minor?	Leslie Lake (Nat'l Blood Clot Alliance)	10 mins
2. Patient/Physician Preferences (Academic)	Shelby Reed (Duke)	10 mins
3. Patient/Physician Preferences (Industry)	Bennett Levitan (JNJ)	10 mins

AGENDA CONT.

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4. Benefit/risk assessment in SPAF – integrating stroke prevention and bleeding in a non-inferiority study (Industry perspective)	Elliot Barnathan (JNJ)	10 mins
5. Benefit/risk assessment in SPAF – integrating stroke prevention and bleeding in a non-inferiority study – (Academic perspective)	Mike Gibson (BCRI)	10 mins
6. Considerations in designing benefit-risk analyses involving outcome importance weighting or ranking (FDA perspective)	Leila Lackey (FDA)	10 mins
BREAK		**10 mins**
Session 3 - Panel Discussion: PANELISTS: Norman Stockbridge (moderator); Dan Bloomfield (moderator); Roxana Mehran; Leslie Lake; Shelby Reed; Bennett Levitan; Mike Gibson; Elliot Barnathan; Leila Lackey		45 mins
Session 4: Management of bleeding, procedures, and urgent surgery • **Moderators**: Ricardo Garcia-Sanchez (BMS), Jordan Pomeroy (FDA)		**60 mins**
1. Experience from patients with Factor XI deficiency	Jean Connors (BWH)	10 mins
2. Urgent bleeding management strategies	Jeff Weitz (McMaster)	10 mins
3. Experience with managing urgent surgery with a long-acting FXI inhibitor	Christian Ruff (TIMI)	10 mins
4. Regulatory Perspective – what data are needed?	Jordan Pomeroy (FDA)	10 mins
5. Panel Discussion PANELISTS: Ricardo Garcia-Sanchez (moderator); Jordan Pomeroy (moderator); Jean Connors; Christian Ruff; Jeff Weitz; Jordan Pomeroy; Dan Bloomfield		20 mins
Meeting Summary – Session Moderators and Q&A		**60 mins**