UAB Pathway to Clinical Xenotransplantation WorkshopUniversity of Alabama at Birmingham, March 21-22, 2019

Thursday March 21, 2019 Morning

8.00-8.05am: Welcome (Herb Chen/Devin Eckhoff)

8.05-8.10am: Welcome (Leo Buhler, President of the IXA)

8.10-8.50am: Taking Xenotransplantation into the Clinic - A Personal View

(Joe Tector) Presentation 30 minutes; Discussion 10 minutes

8.50-9.35am: Xenotransplantation in Nonhuman Primates – the Present Position (Moderator: Joe Tector)

Kidney xenotransplantation
Cardiac xenotransplantation
Discussion 15 minutes

(David Cooper) 15 minutes (Christopher McGregor) 15 minutes

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9.35-10.00am: Coffee break

10.00-12.30pm: Donor Genetic Engineering and Regulatory and Potential Infectious Risk Considerations (Moderator: Joe Tector)

- **10.00-10.40am:** Genetic-engineering techniques for donor pigs and regulatory implications (David Ayares) Presentation 30 minutes; Discussion 10 minutes
- **10.40-11.20am:** Organ-source pig health status and potential infectious risks (Jay Fishman) Presentation 30 minutes; Discussion 10 minutes
- **11.20-12.00noon:** Histocompatibility testing for xenotransplantation (Matt Tector) Presentation 30 minutes; Discussion 10 minutes
- 12.00-12.30pm: Round Table Discussion

Panel members: David Ayares, Leo Buhler, Jay Fishman, Matt Tector

12.30-1.15pm: Luncheon break

Thursday March 21, 2019 Afternoon

- 1.15-5.00pm: Antibody-Mediated Allotransplant Rejection: Lessons for Xenotransplantation (Moderator: Guerard Byrne)
- **1.15-1.55pm:** Antibody-mediated allograft rejection in nonhuman primate models (Stuart Knechtle) Presentation 30 minutes; Discussion 10 minutes
- **1.55-2.35pm:** Prevention and treatment of clinical antibody-mediated allograft rejection (Robert Montgomery) Presentation 30 minutes; Discussion 10 minutes
- **2.35-3.15pm**: Chronic antibody-mediated allograft rejection (Stanley Jordan) Presentation 30 minutes; Discussion 10 minutes

3.15-3.30pm: Coffee break

- **3.30-4.10pm:** ABO-incompatible pediatric heart transplantation (Lori West). Presentation 30 minutes; Discussion 10 minutes
- 4.10-5.00pm: Round Table Discussion

Panel Members: Stanley Jordan, Stuart Knechtle, Robert Montgomery, Lori West

5.00pm: ADJOURN

6.30-8.30pm: RECEPTION

Friday March 22, 2019 Morning

8.00-10.20am: Patient Evaluation and Selection for First Clinical Trials (Moderator: David Cooper)

8.00-9.20am: Evaluation and selection of the first patients

Kidney(Jayme Locke)20 minutesHeart(Christopher McGregor)20 minutesPediatric heart(James Kirklin)20 minutesInfection risks(Jay Fishman)20 minutes

9.20-10.20am: Round Table Discussion

Panel Members: Leo Buhler, Jay Fishman, Robert Gaston, Stanley Jordan, James Kirklin, Stuart Knechtle, Jayme Locke, Christopher McGregor, Robert Montgomery, Lori West

10.20-10.40am: Coffee break

10.40am-12.20pm: Regulatory and Economic Aspects of Clinical Trials of Xenotransplantation (Moderator: Chris McGregor)

- **10.20-10.40am:** Addressing regulatory requirements for the organ-source pig (Karl Kraebber) Presentation 20 minutes
- **10.40-11.00am:** The US FDA perspective (TBD) Presentation 20 minutes
- **11.00-11.20am:** Payer view of xenotransplantation (Jon Friedman) Presentation 20 minutes

11.20-12.00noon: Round Table Discussion:

Panel Members: Jay Fishman, Jon Friedman, Karl Kraebber, FDA presenter, Zac Dorsey, Ron Evans, Martha Tankersley (all UABMC)

12.noon-1.00pm: Box Lunch and Discussion – What has the workshop achieved? (Moderator: Joe Tector)

1.00-1.15pm: Closing remarks (Chen/Eckhoff)

1.15pm: ADJOURN