KIDNEW Kidney Implant Development NEtwork Worldwide

International Consortium to develop an Artificial Kidney

Notes from meeting November 9th 2019

Attendees:

- Jeff Ross – Miromatrix
- Jed Dadson – Medtronic
- Fokko Wieringa – Imec
- Ben Fisher – FDA/CDRH
- Carolyn Neuland – FDA/CDRH
- Frank Hurst – FDA/CDRH
- Melissa West – KHI
- Daniel Gossett – NIH/NIDDK
- Celia Witten – FDA/CBER
- Murray Sheldon – FDA/CDRH
- Glenn Bell – FDA/CDRH
- Paul Conway – AAKP
- Glenda Roberts – UW Center for Dialysis Innovation
- Patrick Gee – KHI PFPC
- Nieltje Gedney – Home Dialyzers United
- John Sedor – KidneyX; Cleveland Clinic
- Ray Harris – KHI
- Joseph Bonventre – Brigham and Women's Hospital
- Amy Kerdok – Outset Medical
- Arnold Lande – Northport Navigable Waters Institute
- Victor Gura – Cedars Sinai
- Mandar Gori – AWAK (Singapore)
- Buddy Ratner - UW
- (apologize for not well hearing) ???Claudia Sebric??? – nephrologist, former FDA

Meeting minutes:

The meeting was started by introductions of all attendees following by a brief summary of the purpose of the meeting by Murray and Fokko. Celia mentioned that she wished to obtain a better understanding of the purpose of the meeting and was focused on enabling interactions amongst diverse disciplines.

Fokko then presented a graphical summary of the results from the survey following the first International Consortium meeting in August 2019 (during IDEAS). Full survey results are distributed along with this document.

Industry participation was a main discussion point: One question *"Should the development of an implantable artificial kidney be solely left to industry"* resulted in a clear *"No"* on the survey, but Joe Bonventre mentioned that it is still important to continue to engage industry in this effort. And Victor Gura said that industry is actually getting involved now because the efforts to change the current dialysis approach is becoming "disruptive". Paul Conway stated that our efforts should be to develop a

capacity infrastructure, and to engage more and different companies under KidneyX. Ben Fisher mentioned that this effort seems to be tolerated by current industry, but we don't want industry to simply build a better dialysis machine, disruption indeed is needed. Nieltje stated that as a patient she was interested in new ideas including a "Range of Opportunities" and greater patient choice. And Glenda Roberts said that industry will come to us, if we come up with good ideas, but we need to be clear about our ideas and plans. Jed Danson (Medtronic) said that this should not be left to industry alone, and that we should engage with other regulators around the world to coordinate the feedback and input.
The discussion concluded that reducing the risk for industry is crucial to get them to invest. Presently, the time horizon for an implantable is further away than the traditional investment models can bridge.

Other opportunities: Joe said that we should present our Roadmap at an AIMBE meeting and to obtain input from the AIMBE (American Institute for Medical and Biological Engineering) scholars. Fokko announced that the European Society for Artificial Organs (ESAO) already has agreed to include a KIDNEW session in their upcoming technology congress (London 8 – 12 Sept 2020).

The question of IP issues was raised by Arnold Lande. The importance of proper IP arrangements was generally acknowledged, but no conclusions were suggested. --> Expert advice seems needed.

Patrick mentioned that from his perspective we were heading in the right direction and that we really need to focus on developing an implantable kidney right now! He and Paul Conway suggested that we engage AAKP, which is holding a Global Summit in April 2020 in Washington DC. (https://aakp.org/programs-and-events/global-innovations-in-patient-centered-kidney-care-international-summit/). The group discussed an agreed that, as an action item, we should meet again at the AAKP Global Summit meeting, and that we should at least have begun the development of a definition of what we mean by an implantable artificial kidney by April 2020 for that meeting. Further representative from AAKP should plan on attending the ERA-EDTA Congress in Milan, Italy in June 2020 (https://www.era-edta.org/en/milan2020/) to contribute their voice to a further international consotium meeting, organized by the Dutch Kidney Foundation (DKF) and European Kidney Health Alliance (EKHA, the EU *"twin sister"* of KHI). In addition, we should all attend and meet again at the IDEAS meeting 2020 in Seattle August 30 – September 1. Nieltje concluded that patients are not willing to accept the status quo and they will increase their effort to tell HHS, Congress and others to hear the voice of the patients.

ACTION ITEMS:

- Develop a definition for an implantable artificial kidney by April 2020.
- Plan on attending: AAKP Global Summit in 2020 and hold an International Consortium meeting.
- AAKP and FDA representative to attend ERA-EDTA to communicate with European patients and attend the International Consortium meeting by DKF & EKHA.
- Consider submitting to KIDNEW *technology session* during ESAO 2020 (London, 8 – 12 Sept) https://esao2020.org/
- All attend IDEAS 2020 in Seattle and hold an International Consortium meeting
- Aim to recruit an expert on IP management and anti "patent shelving" in consortia.