OPENING REMARKS

Keith Crawford Program Officer, DAIDS Therapeutic Research Program

"We know [LA ARV products] work in resource-limited settings ... Nationality and which hemisphere you live in should not determine how you are able to access these types of treatments"

Dr. Crawford recognized LEAP as a valuable resource for the development of innovative LA therapeutics. He emphasized LEAP's role in helping investigators navigate the challenges of getting products into clinical trials. Citing the effectiveness of LEN and CAB-LA in NIH-supported HIV prevention and treatment trials in Africa (Near 100% protection and 98% virologic suppression), Dr Crawford identified access to LA ARV products as the critical next step. He applauded Charles Flexner and LEAP for sponsoring this forum and expressed optimism that today's discussions will help ensure effective LA treatments are available to everyone who needs them.

Charles Flexner Principle Investigator, LEAP

"We clearly have products that are positioned to radically alter the direction of the HIV epidemic, but ...
We cannot get them to the people who need them most in the parts of the world where this epidemic is still raging"

Dr. Flexner identified the availability of LA ARV formulations as the motivation for today's workshop. For 10 years, LEAP has supported the development of formulations for the prevention and treatment of HIV and related diseases. LA formulations now represent a game-changing approach ***in places where they can be used*** – a Q6m LAI formulation (LEN) is now in the same category as the most effective vaccines, offering near 100% protection from HIV (PURPOSE I). By convening key stakeholders, LEAP aims to find a pathway forward to ensure low-cost LA ARV formulations are available to those who need them and where it is most important. Dr Flexner emphasized the strategic importance of today's workshop content:

- Each plenary session builds on the last. Plenary 1 reviews learnings from low-cost LAI development in other areas; Plenary 2 pivots to LAI ARVs; Plenary 3 & 4 focus on clinical development issues and manufacturing & implementation.
- There are opportunities for rich discussion. Open discussion sessions after Plenary 2 and 3.
- A rapporteur will provide a meeting summary.
- Recordings and summaries will be available at: www.longactinghiv.org.

Special Thanks: Organizing Committee (Andrew Owen, Steve Renard [CELT], Lobna Gaayeb [MPP], Paul Domanico [CHAI], and Kimberly Struble [FDA]); Support Staff (Joe Sharp, Cheryl Westwood [CELT] and Julia Burnett, Matthew Williams [LEAP]); and Rapporteur (Polly Clayden).