Early PrEP Implementation in France

Jean-Michel Molina, MD
University of Paris Diderot
Saint-Louis Hospital, Paris, France
The First Steps...

• The ANRS IPERGAY trial of sexual-activity based PrEP was launched in Feb 2012

• This trial was conducted in partnership with the AIDES community group

• 400 participants enrolled in 5 major cities in France (Paris, Lyon, Nice, Nantes, Lille) and Montréal (Canada)
The First Results...

• Following the PROUD press release, the IPERGAY DSMB met the following week

• The DSMB recommended on October 23, 2014 the discontinuation of the placebo arm and that all participants be offered « on demand » PrEP

• The ANRS IPERGAY scientific committee endorsed this recommendation

• ANRS press release on « the early discontinuation of the placebo arm for efficacy »
Mean follow-up of 13 months: 16 pts infected 
14 in placebo arm (incidence: 6.6/100 PY) and 2 in TDF/FTC arm (incidence: 0.9 /100PY)

86% reduction in the incidence of HIV-1
(95%CI:40-98, p=0.0019)
The IPERGAY Open-Label Phase...

- The week following the ANRS press release, open-label TDF/FTC available at all study sites as planned in the protocol and in the informed consent form

- 99% of pts followed in the IPERGAY trial entered this open-label phase + 30 pts being screened

- Since November 2014, nearly 400 pts are followed in this open-label extension

- Preliminary results submitted to CROI 2016

- …but we had to turn down many persons
What Happened Since...

- AIDES has requested a RTU (expanded access program) for TDF/FTC to be used for PrEP
- The ANSM (French FDA) has appointed a group of experts to provide scientific advice...pending
- The French Minister of Health has asked the French group of experts and the National AIDS Council to give recommendations...but not too soon!
- Gilead application to EMA for PrEP....still pending
- WHO new guidelines on PrEP... yesterday!
in The Meantime...

• ECDC has updated his statement on PrEP

• EACS will issue new PrEP guidelines in October 2015

• More and more people are asking how to use PrEP and how to get access to TDF/FTC

• TDF/FTC is being used in the community:
  – False statements to get post-exposure prophylaxis (free)
  – Pill sharing with friends
  – Purchase of TDF/FTC on the internet
Use of Generic Truvada… in Australia

• PrEP not yet approved in Australia

• But can be legally imported for preventative use under personal importation scheme

• Require an Australian-issued prescription.

• Go to www.aidsdrugsonline.net

• Tenvir (Cipla) : 106 Euros for 30 pills
What Can We Do...

- Express frustration....

- Start a new PrEP project with the community and ANRS with the goal of stemming new HIV-infections in Paris
- Start « PrEP » outpatient clinic to provide counseling on PrEP
- Continue lobbying in France, Europe, and International level
- Be ready for PrEP approval and implementation...12/01 ?
Acknowledgments

• The Participants of the ANRS IPERGAY trial
• The Study Staff and Peer-Counselors
• The Trial Scientific Committee
• The DSMB
• The Community Advisory Board
• The ANRS Staff
• INSERM SC10

AnRS
Agence autonome de l’Inserm
AIDES

the CTN
CIHR Canadian HIV Trials Network
BILL & MELINDA GATES FOUNDATION
Fonds de dotation PIERRE BERGÉ
GILEAD