Chronic hepatitis C
Building access into drug development: DNDi strategy
Isabelle Andrieux-Meyer from Drugs for Neglected Diseases initiative works with Médecins Sans Frontières, Pharco, Presidio, Chemo, people living with HCV, people living with drugs, people living with HIV, and the governments of Thailand, Malaysia, Argentina, to develop affordable DAAs.
Responding to the Needs of Patients Suffering from Neglected Diseases...

- Malaria
- Leishmaniasis
- Paediatric HIV
- Sleeping Sickness (HAT)
- Chagas Disease
- Filaria
6 New Treatments Developed Since 2007

- Easy to Use
- Affordable
- Field-Adapted
- Non-Patented
Treatment progresses

- According to the World Health Organization, viral hepatitis (HCV) caused 1.34 million deaths in 2015, an increase of 22% since 2000. (WHO, 2017)
- Without diagnosis and treatment to halt transmission, this number will continue to grow.
- Despite a simple, safe, and effective cure, and global commitments to eliminate HCV as a public health threat by 2030, most HCV positive people have not been diagnosed and cannot access treatment.
- In 2015, only 7.4% of HCV positive people (or 1.1 million people) have started treatment
- 81% of PLW HCV reside in low and middle income countries.
DNDi HCV Program:

• DNDi’s Regional R&D strategy: Developing a DAA combination treatment
  – that will be as effective as the currently recommended treatment
  – but affordable
  – and available in a very large number of countries
  – combined with a very simple strategy of screening and diagnosis
  – in order to implement a public health approach

• DNDi’s Support Affordable Access strategy is based on
  – the use of drugs that have been developed to late stage but won’t be taken further, due to the lack of a profitable market;
  – the use of different options to overcome price barriers, a combination of, e.g. favourable voluntary licensing, volume price negotiations, patent oppositions, TRIPs flexibilities
A pan-genotypic treatment for less than $300

- DNDi, Pharco and Presidio agreement to test combination of sofosbuvir + ravidasvir
- Partnership with Malaysia and Thailand to conduct Phase II/III multicentre study (900 patients)
- Using innovative licensing agreement or TRIPS flexibilities
An innovative licensing agreement for ravidasvir that covers a very large territory.

- Presidio granted non-exclusive license to DNDi
- DNDi has option to take non-exclusive license after March 2018 if no exclusive license by Presidio
- Pre-existing exclusive license by Presidio to other partners
- No license required/no patent claims filed or granted
In 2015, 71 million (62 million – 79 million) individuals had viremic HCV infections with an overall prevalence of 1.0% (0.8%- 1.1%).

Source: Polaris Observatory (http://www.polarisobservatory.com/)
Phase 2/3 efficacy, safety and pharmacokinetics trial of SOF-RDV for the treatment of HCV chronic infection

HCV antibody positive  
HCV RNA positive

SOF+RDV 12 Weeks
F0-3
Fibroscan F4 y/n

SOF+RDV 24 Weeks

N = 600 evaluable subjects for primary endpoint analysis plus up to 150 in PWUD exploratory strata

Enrollment pause and interim analysis planned after enrollment of the first 300 evaluable subjects
STORM-C : aspirations & benefits

• In support of the goal of universal access to DAAs, MSF, Access Campaign, and DNDi, with Pharco and Chemo as industrial partners, are working together to develop new chemical entities independent from big pharma companies.

• This project will bring treatments to stringent regulatory authority approval standards and registration at large scale, and make them available at an affordable price, including in MICs excluded from access programs, and eventually in HICs.
STORM-C: aspirations & benefits

- The primary and immediate benefit of this project will be **reduced morbidity and mortality** in MSF projects and DNDi studies, with an estimated 12,000 direct beneficiaries cured of HCV over the three years of the project in **Cambodia, Malaysia, South Africa, Thailand, Vietnam, Argentina and Ukraine**.

- An additional approximate 30,000 patients will be treated through the larger MSF and DNDi projects, through the UNITAID HCV co-infections grant and the UNITAID FIND partnership notably.
Outline of clinical program

First submission
- PYRAMID
- Malaysia / Thailand Stage 1

Pan-genotypic submission (SRA)
- Malaysia / Thailand Stage 2
- Vietnam
- South Africa

Special populations
- Egypt Adolescents
- Egypt Easy-to-Treat
- Ukraine PLWH/PWID

Expanded access
- Malaysia ALD/ARD
- Cambodia ALD

- Malaysia Cohort Study
- Cambodia Cohort Study
- Argentina CT
There is an urgent need ...
Remerciements

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- All patients and Civil Society Groups
- Governments of Thaïland, Malaysia.
- PHPT Team
- DNDi Team