Hepatitis C Strategy
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DNDi
Drugs for Neglected Diseases initiative
**DNDi Origins**

**1999**
- First meeting to describe the lack of R&D for neglected diseases
- MSF commits the Nobel Peace Prize money to the DND Working Group
- JAMA article: ‘Access to essential drugs in poor countries - A Lost Battle?’
- ‘Fatal Imbalance’

**July 2003**
- Creation of DNDi
- Founding partners:
  - Institut Pasteur, France
  - Indian Council of Medical Research, India
  - Kenya Medical Research Institute, Kenya
  - Médecins Sans Frontières
  - Ministry of Health, Malaysia
  - Oswaldo Cruz Foundation/Fiocruz, Brazil
  - WHO – TDR (Special Programme for Research and Training in Tropical Diseases) as a permanent observer
How it works:

With Public and Private Funding

Conducts research with:
- Biotechnology & Pharmaceutical Industries
- Universities
- Public Research Institutions
- Ministries of Health

Not for profit R&D organization that delivers, through an innovative model, new and affordable medicines

For neglected patients
To develop and deliver treatments
DNDi’s success is only possible through innovative partnerships

Over 160 partnerships worldwide

CRITERIA FOR SUCCESS
- Share the same vision
- Mutual understanding
- Involvement throughout the whole process
7 new treatments available and up to 16 new chemical entities in the pipeline

**HAT**
- **Screening**: SCYX-1330682, SCYX-1608210 oxaborole
- **Pre-clinical**: Acoziborole

**Leishmaniasis**
- **Screening**: Leish H2L
- **Pre-clinical**: DNDI-5421, DNDI-5610 oxaborole, Amino pyrazoles, CGH VL Series 1
- **Phase Ia/PoC**: Fexinidazole
- **Phase IIb/III**: NECT Nifurtimox-Eflornithine Combination Therapy

**Chagas**
- **Screening**: Chagas H2L
- **Pre-clinical**: GSK3186899, GSK3494245
- **Phase IIb/III**: Benzimidazole Paediatric Dosage Form

**Filaria**
- **Screening**: Macro Filaricide 3
- **Biomarkers**: ABBV-4083, TylaMac

**Pediatric HIV**
- **Screening**: Two ‘4-in-1’ LPV/r/ABC/3TC
- **Development**: LPV/r pellets with dual NRTI

**HCV**
- **Screening**: Ravidasvir/Sofosbuvir

**Mycetoma**
- **Screening**: Fosravuconazole

New Chemical Entity (NCE); Fexinidazole (for HAT, VL, and Chagas disease) = 1 NCE; Fosravuconazole = 1NCE
71 million people worldwide living with hepatitis C (HCV) infection in 2015

- Only 20% diagnosed
- Only 7% treated

- Infected, diagnosed but not treated
- Diagnosed and treated
- Infected, neither diagnosed nor treated

1.75 million adults
New infections with HCV in 2015

1.1 million people
Treated in 2015

~ 400,000 deaths
a year mainly by cirrhosis / hepatocellular carcinoma
Patents and restrictive license agreements affect prices significantly

SOFOSBUVIR (SOF)+ DACLATASVIR (DCV) prices

- USA: US$74,000 to 147,000
- EU: US$47,500 to 56,000
- Malaysia: US$6,212 to 71,000
- LATAM: US$40,000 to 52,000
- Cambodia: US$900
- Egypt: US$370
- India: US$180
- Cambodia: US$108
Hepatitis C: Problem statement

RATIONING TREATMENT

20-30 million people
70 to 130 million people

Minimal Disease
Liver Fibrosis
Severe Disease

F0-F1 patients
F2 patients
F3 patients
F4 patients
Rationing of the most expensive treatments has also become reality in the richer countries.
HCV Public Health Challenges

• Urgent need of simplified models to Diagnostic & Treat. HCV

• Wide availability of affordable, easy-to-use, all-oral pan-genotypic regimens that can enable a public health approach

• Overcome IP & regulatory barriers to expand access to HCV treatment for all
DNDi Hep C Strategy:
Contribute to HCV Elimination by 2030

DNDi’s HCV project aims to deliver safe, efficacious, pangenotypic, affordable, and easy-to-use DAAs combos, that will be optimal for public health use.
April 2016, launch DNDi-HCV program

Hepatitis C treatment for under $300 coming soon

Drugs for Neglected Diseases initiative says drug successfully tested in Egypt could be available within 16-24 months.

Hépatite C : un traitement à moins de 300 dollars à l’étude

Un essai clinique va débuter en Thaïlande et en Malaisie pour tester une nouvelle combinaison thérapeutique à prix abordable.

La mayoría de los afectados por la enfermedad vive en los países más pobres, donde los precios actuales son imposibles de assimir

La iniciativa para el Desarrollo de Medicamentos para Enfermedades Olvidadas (DNDi) ha llegado a un acuerdo con el laboratorio egiptio Phenco para desarrollar un tratamiento de la hepatitis C que costará 300 dólares (unos 265 euros) al
Abundant Hep C portfolio… but several candidates abandoned
Ravidasvir license territory, March 2016
Focus on key countries to influence regions

- Clinical Studies RDV + SOF
- Pharmacovigilance Studies RDV + SOF
• Develop new, affordable, pan-genotypic DAA for Public Health Approach on HCV

• Simplify HCV test & treat strategies and develop pilot innovative models of care to support scale up

• Advocate for improved access (IP, regulatory, pricing, etc.) and affordability to HCV DAAs in countries
DNDi HCV programme & field work with partners

Countries included in voluntary license programmes:
- Egypt clinical study (Pharco) (G4)
- Ukraine clinical study (DNDi-MSF) (G1)
- Malaysia Clinical Study (DNDi) (G1, 2, 3 & 6)
- Thailand clinical study (DNDi) (G1, 2, 3 & 6)
- South Africa Clinical Study (DNDi) (G5)

Countries excluded from voluntary license programs:
- South Africa
RVD must be used in combination with sofosbuvir (relevance of Sof IP landscape)
Partners engaged with DNDi to implement the HCV strategy include:

- MoHs: Malaysia* & Thailand*
- MoHs: Ukrayne, Egypt and SA
- Regulatory Authorities
- UNASUR & ISAGS
- Presidio* Pharco* Regional Generic Malaysia*
- Generic suppliers SOF/DCV
- South Centre, CSOs, Patient groups and NGO
- FIND*
- MPP
- PAHO Strategic Fund
- WHO-PQ, GF & EML
- MSF*
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THANK YOU
TO ALL OUR
PARTNERS &
DONORS

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