Hepatitis C

Dr. Graciela Diap-MD, Access HCV
18th International Congress on Infectious Diseases (ICID) - XIII Congreso SADI
Buenos Aires, Argentina
March 1-4, 2018
Origins of DNDi

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?’

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
Responding to the Needs of Neglected Patients

DNDi’s PRIORITY: Neglected Patients

- Hepatitis C
- Sleeping sickness
- Mycetoma
- Chagas disease
- Malaria
- Paediatric HIV
- Leishmaniasis
- Filarial diseases

...from Bench to Bedside

Global Antibiotic R&D Partnership
A joint WHO/DNDi initiative

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DNDi-HCV strategic objectives:

- Develop new, affordable, pan-genotypic TT for HCV
- Simplify HCV test & treat strategies and develop innovative models of care to support scale up
- Improve access (IP, regulatory, pricing, etc.) and affordability of HCV TT in countries
DNDi Hepatitis C Strategy: 3 pillars

1. **Accelerate R&D**
   - Accelerating the development of promising drug candidates
   - With Pharma companies
   - With Governments

2. **Catalyse ACCESS**
   - Supporting affordable access to all DAAs
   - With Pharma companies
   - With Civil Society organizations
   - With Governments

3. **Simplify TREATMENT STRATEGIES**
   - Working with health providers to scale – up treatment
   - With Primary healthcare doctors
   - With Non Governmental Organizations

**DNDi**

**Pharma companies**

**Governments**

**ISID-SADI 2018 Buenos Aires**
Ravidasvir: Towards a pan-genotypic treatment

- DNDi’s pipeline analysis identified ravidasvir (RDV), an NS5A inhibitor drug candidate with pan-genotypic potential

- **DNDi obtains licence** to RDV from Presidio (US): development, manufacture and distribution in LATAM, SEA and Africa

- **DNDi is developing RDV** with Pharco (Egypt): Pharco is also producer of generic SOF (no patent in Egypt)

- **DNDi partnership in Malaysia**: with Pharco and Pharmaniaga (Malaysia): manufacture and supply of RDV and supply of SOF

- **New - DNDi collaboration with InSud Pharma, Laboratorio Elea (Argentina) and Pharco**: Register, manufacture, distribute RDV + SOF in Argentina + LATAM
Develop new, affordable, pan-genotypic TT for HCV

Effectiveness of ravidasvir plus sofosbuvir in interferon-naïve and treated patients with chronic hepatitis C genotype-4

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Develop new, affordable, pan-genotypic TT for HCV
Ravidasvir License Territory
Develop new, affordable, pan-genotypic TT for HCV
Study design in Malaysia & Thailand

Sofosbuvir Plus Ravidasvir for the Treatment of HCV Chronic Infection

ClinicalTrials.gov Identifier: NCT02961426

Open Label Phase II/III, Multicenter, Trial to Assess the Efficacy, Safety, Tolerance, and Pharmacokinetics of Sofosbuvir Plus Ravidasvir in HCV (+/- HIV) Chronically Infected Adults With no or Compensated Cirrhosis in Thailand and Malaysia
2017: Starting clinical trial of Ravidasvir & Sofosbuvir for the treatment of HCV chronic infection in 2 countries

- **4 sites in Thailand**
  - Starting date: 2017
  - In partnership with the government

- **6 sites in Malaysia**
  - Starting date: 2017
  - Co-sponsored by the Ministry of Health

- 300 Patients recruited
Accelerating the development of promising drug candidates

- Complete development of ravidasvir for use with sofosbuvir as pan-genotypic treatment for HCV
- Registration of ravidasvir in priority countries willing to adopt a Public Health strategy
- Contribution to develop local and regional strategies to promote a Public Health approach and reduction of Access barriers
Catalysing affordable access to all DAAs

- Raise **political commitment** & accountability
- Encourage **policy change** for the sustainable adoption of test & treat with DAAs
- Promote **access to affordable**, safe, quality and efficacious DAAs
- Address **regulatory and intellectual property** barriers for access to HCV diagnostics & medicines
Partners catalysing affordable access to DAAs
RDV as a Public Health Tool

Country/ MoH engagement
- Political commitment
- Resource mobilization
- Public Health Approach

Civil society pledge
- Define patient needs
- Linkage to care/services
- Community mobilization
- HCV disease advocacy
- HCV treatment literacy

Payer/Donor commitment
- National/Regional Priorities
- Public Health imperative
- Sustainable Development Goals

Policymaker/ Regulators undertaking
- Policy change
- Simplification Models of Care
- Drug Registration
- Public Health Approach
Developing innovative models of care to support scale-up

- Efforts to *decentralize* from central hospitals to the primary healthcare level and to peripheral health Centres
- To develop *task-shifting* which would reduce reliance on doctors and other highly qualified medical personnel,
- To *boost community involvement* to support uptake and acceptance
Simplify HCV test & treat strategies and develop innovative models of care to support scale up.
Partners engaged with DNDi to implement the HCV strategy

**CSOs, Patient groups and NGOs:** MSF*, South Centre*, C+, TWN, MTAAG+, MAC, TTAG, Ozone, Ifarma, DPN+, CoNE Manipur, MdM, TreatAsia

**UNITAID & other donors**

**MoHs:** Malaysia* & Thailand*

**Other MoHs:** Argentina, Colombia

**Regulatory Authorities**

**UNASUD & ISAGS**

**FIND***

**MPP**

**PAHO Strategic Fund**

**WHO-PQ & EML**

**Research Partners*** CRM, PHPT, CRC

**Presidio***
Regional Generic Malaysia*
Regional Generic LATAM*
Generic suppliers SOF/DCV Pharco*

**Research Partners*** CRM, PHPT, CRC

*agreements signed
Future developments with Ravidasvir

- Ukraine (MSF): special populations, expanded access from big cohorts
- Egypt (Pharco): G4 adults + data from adolescents
- Thailand Clinical Study: ongoing
- Cambodia (MSF): special populations, expanded access from big cohorts
- Malaysia Clinical Study: ongoing
- LATAM: additional data to support wider Regional Uptake
- South Africa: G5 data
THANK YOU
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MALAYSIA

THE STARR FOUNDATION

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