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
- Chagas disease
- Mycetoma
- Malaria
- Paediatric HIV
- Leishmaniasis
- Filarial diseases

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

...from Bench to Bedside

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ISID-SADI 2018 Buenos Aires
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, Governments

2. Catalyse ACCESS
   - Supporting affordable access to all DAAs
   - with Pharma companies, Civil Society organisations, Governments

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

1. **Country/ MoH engagement**
   - Political commitment
   - Resource mobilization
   - Public Health Approach
   - Define patient needs
   - Linkage to care/services
   - Community mobilization
   - HCV disease advocacy
   - HCV treatment literacy

2. **Civil society pledge**
   - National/Regional Priorities
   - Public Health imperative
   - Sustainable Development Goals
   - Policy change
   - Simplification Models of Care
   - Drug Registration
   - Public Health Approach

3. **Payer/Donor commitment**
   - ISID-SADI 2018 Buenos Aires
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

Simplification of antiviral hepatitis C virus therapy to support expanded access in resource-limited settings

Nathan Ford¹, Tracy Swan², Peter Beyer³, Gottfried Hirnschall¹, Philippa Easterbrook¹, Stefan Wiktor¹,*

¹Department of HIV/AIDS, World Health Organization, Geneva, Switzerland; ²Treatment Action Group, New York, USA; ³Department of Essential Medicines and Health Products, World Health Organization, Geneva, Switzerland

Simplified diagnostic monitoring for hepatitis C, in the new era of direct-acting antiviral treatment

Jennifer Cohn⁴, Teri Roberts⁴, Valerianna Amorosa⁵, Maud Lemoine⁶, and Andrew Hill⁷

Expansion of Treatment for Hepatitis C Virus Infection by Task Shifting to Community-Based Nonspecialist Providers: A Nonrandomized Clinical Trial

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Partners engaged with DNDi to implement the HCV strategy

**Donors**
- Malaysia*
- Thailand*

**Other MoHs:**
- Argentina
- Colombia

**Regulatory Authorities**
- UNASUD & ISAGS

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

**FIND**
**PAHO Strategic Fund**
**WHO-PQ & EML**
**Research Partners**
- CRM, PHPT, CRC

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

**MPP**
**UNASUD & ISAGS**
**Regulatory Authorities**

*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
TO ALL OUR
PARTNERS &
DONORS

[Logos of various organizations]