Hepatitis C

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X Congress of the SEMTSI
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An estimated 70 million individuals are infected with HCV (viremic), a prevalence of ~1% in 2016.
The first-ever Global Strategy on Viral Hepatitis, 2016-2021

AIM: to test 90% and treat 80% of people with HCV by 2030, however in 2015…

Only 20% of all HCV infections were diagnosed

~ 1.75 million people were newly infected with HCV in 2015 and only 1.1 million people had started treatment in 2015
<table>
<thead>
<tr>
<th>API/Original manufacturer</th>
<th>US FDA</th>
<th>EMA</th>
<th>Pan genotypic</th>
<th>Patents (1st &amp; last expiration date)</th>
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</thead>
<tbody>
<tr>
<td>sofosbuvir-Gilead</td>
<td>12-2013</td>
<td>1-2014</td>
<td>Combined</td>
<td>✓ (2024-2032)</td>
</tr>
<tr>
<td>simeprevir-Janssen</td>
<td>11-2013</td>
<td>5-2014</td>
<td>No</td>
<td>✓ (2026-2032)</td>
</tr>
<tr>
<td>sofosbuvir+ledipasvir-Gilead</td>
<td>10-2014</td>
<td>11-2014</td>
<td>No</td>
<td>✓ (2030-2034)</td>
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<tr>
<td>ombitasvir+paritaprevir+dasabuvir+ritonavir-AbbVie</td>
<td>12-2014</td>
<td>1-2015</td>
<td>No</td>
<td>✓ (2030-2034)</td>
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<tr>
<td>daclatasvir-BMS</td>
<td>07-2015</td>
<td>8-2014</td>
<td>Combined</td>
<td>✓ (2027-2033)</td>
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<tr>
<td>sofosbuvir+velpatasvir-Gilead</td>
<td>06-2016</td>
<td>7-2016</td>
<td>Yes</td>
<td>✓ (2031-2034)</td>
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<tr>
<td>elbasvir +grazoprevir-Merck</td>
<td>01-2016</td>
<td>7-2016</td>
<td>No</td>
<td>✓ (2032-2035)</td>
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<tr>
<td>sofosbuvir+velpatasvir+voxilaprevir-Gilead</td>
<td>07-2017</td>
<td>6-2017</td>
<td>Yes</td>
<td>✓ (2031-2034)</td>
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<tr>
<td>glecaprevir/pibrentasvir-AbbVie</td>
<td>08-2017</td>
<td>7-2017</td>
<td>Yes</td>
<td>✓ (2031-2034)</td>
</tr>
</tbody>
</table>
Malaysia & Thailand added to Gilead Voluntary Licensing by Sep 2017…at which prices?
Access to HCV Treatments and IP barriers
Hepatitis C: Problem statement

RATIONING TREATMENT

- Minimal Disease
- F0-F1 patients
- F2 patients
- F3 patients
- F4 patients

20-30 million people

70 to 130 million people

Severe Disease

Liver Fibrosis

Minimal Disease
April 2016, launch DNDi-HCV program
Rationing of the most expensive treatments has also become reality in the richer countries.
HCV Public health challenges in the short to middle term

- Urgent need of simplified models to Dx & Treat HCV, including decentralization, task shifting and community involvement

- 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
HCV: Rapidly evolving pipeline

FIGURE 14.
OVERVIEW OF HCV MEDICINES ON THE MARKET AND IN THE PIPELINE (PHASES II & III)

Preclinical → Phase 1 → Phase 2 → Phase 3 → Approved

ravidasvir (PPI-668)

odalesvir (ACH-3102)
ruzasvir (MK-8408)

sovaprevir
MK-3682
AL-335
SCY-635***

danoprevir
daclatasvir
elbasvir
ledipasvir
ombitasvir
pibrentasvir
velpatasvir
asunaprevir
boceprevir*
glecaprevir
grazoprevir
paritaprevir
simeprevir
telaprevir*
vapireviral
voxilaprevir

* Boceprevir and telaprevir are no longer recommended by WHO
** Marketed only in Japan
*** unclear, may have been discontinued

Source: Unitaid.
The DNDi-HCV public health approach

DNDi HCV Strategy

1. Regional R&D
   - Complete development of ravidasvir 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 Public Health approach and reduction of Access barriers

2. Support Affordable Access
   - Political commitment & accountability
   - Policy change for the sustainable adoption of test & treat with DAAs
   - Promote access to affordable, safe, quality and efficacious DAA’s
   - Address regulatory and intellectual property barriers for access to HCV diagnostics & medicines
   - Need of simplified test & treat HCV models of care, scalable to different countries
DNDi-HCV Strategic Objectives

• Develop new, affordable, pan-genotypic TT for Public Health Approach on HCV

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

• Improve access (IP, regulatory, pricing, etc.) and affordability to HCV TT in countries
Focus on key countries to influence regions

- Clinical Studies RDV + SOF
- Pharmacovigilance Studies RDV + SOF
DNDi HCV program & field work with partners

- **Cambodia**
  - Test & Treat simplify; decentralization & DAAs scale-up

- **Egypt**
  - Clinical Study (Pharco) (G4)

- **South Africa**
  - Clinical Study (DNDi) (G5)

- **Thailand**
  - Clinical Study (DNDi) (G1,2,3 & 6)

- **Argentina**
  - Registration Study (local partner)

- **Malaysia**
  - Clinical Study (DNDi) (G3, 2 & 6)

- **Ukraine**
  - Clinical Study (DNDi/MSF) (G1)

**Countries included in Gilead License**

**Countries excluded from Gilead License**

**LATAM countries, Advocacy Actions**
Outline of RDV clinical program

First submission
- Pan-genotypic submission (SRA)
- Special populations
- Expanded access

- Designed to meet SRA requirements and secure early access to treatment through expanded access programs

- PYRAMID
- Malaysia / Thailand Stage 1
- Malaysia / Thailand Stage 2
- South Africa
- Egypt Adolescents
- Egypt Easy-to-Treat
- Ukraine PLWH/PWID
- Malaysia ALD/ARD
- Cambodia ALD
- Malaysia Cohort Study
- Cambodia Cohort Study
- Argentina CT

DNDi
Drugs for Neglected Diseases Initiative
RVD must be used in combination with sofosbuvir (relevance of Sof IP landscape)
Partners engaged with DNDi to implement the HCV strategy

MoHs: Malaysia, Thai, CBD, Ukraine, Egypt, and South Africa

WHO, PQ & EML, Global Fund ERP

Research partners: CRM, Chiang Mai & Cairo Univ

IP partners: South Centre & MdM

MSF & DNDi OCP, OCG, SAMU, EPICE NTRE & ACCESS CAMPAIGN

FIND

Generic manufacturers for DAA supply

Regulatory authorities: Malaysia, Thai, CBD, Ukraine, Egypt & South Africa

CSOs & patient groups: C+, TWN, MAC, MTAAG+, TTAG, OZONE, TreatAsia, Ukr Net
THANK YOU
TO ALL OUR
PARTNERS &
DONORS

MEDECINS SAN FRONTIERES

THE STARR FOUNDATION

DNDi
Drugs for Neglected Diseases initiative