



8th Paris Hepatitis Conference

Paris, 12th January 2015

How to improve access to therapy? Around the World table.

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The EPA C Questionnaire-based Survey of HCV Italy 2014

- 63 out of 353 Centers throughout Italy participated
- 33,433 patients were involved, 56% genotype 1
- 2,875 (15%) genotype 1 were eligible to triple therapy, 35% underwent therapy

- Combining these figures with NHS registries of identification of HCV disease (016)
the predicted number of known HCV patients are:
 - 220-250,000 Monoinfected attending liver Centers
 - 30,000 HIV co-infected attending ID Centers
 - 25,000 Inmates
 - 70,000 Under the care of GPs and legal migrants

Overall 375,000

HCV Treatment with Second Wave DAAs in Italy

Reimbursement by NHS

SOF since December 5, 2014

SMV, DCV and Harvoni pending

Patients eligible to SOF/RBV therapy

1. CPT A and B cirrhosis and HCC CR to resection or ablation not listed to LT
 2. Recurrent HCV post LT METAVIR \geq F3 or FHC
 3. Chronic hepatitis with cryo syndrome or NHL
 4. Chronic hepatitis METAVIR \geq F3
 5. Cirrhosis listed to LT MELD $<$ 25 or HCC within Milan criteria (2 months wait)
 6. Chronic hepatitis F \geq 2 in organ transplanted (any)
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Expanded Access and Compassionate Use of Second Wave DAAs

AbbVie compassionate (ABT-450-R/ombitasvir + Dasabuvir) HCV-1

(AIFA since 27th October 2014 by name with Ethical Committee approval)

1. CPT A cirrhosis without comorbidities who are intollerant/ineligible to PR
2. Chronic hepatitis METAVIR \geq F3 non responder to PR
3. Recurrent HCV post LT METAVIR F0-F2 or FHC
4. Chronic hepatitis with cryo syndrome or NHL

Named Patients/Compassionate DCV and SMV

Nominal forms to be filled in to have Pharma approval

“[...] Compassionate use should be reserved for patients without viable treatment options that cannot wait for novel treatments to become available and in a medical condition supporting potential use of simeprevir/daclatasvir in combination with other HCV therapy [...]”.

Expanded Access and Compassionate Use of Second Wave DAAs

AbbVie compassionate (ABT-450-R/ombitasvir + Dasabuvir) in HCV-1

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- 1.CPT A cirrhosis without comorbidities who are intollerant/ineligible to PR
- 2.Chronic hepatitis METAVIR \geq F3 non responder to PR
- 3.Recurrent HCV post LT METAVIR F0-F2 or FHC
- 4.Chronic hepatitis with cryo syndrome or NHL

Named Patients/Compassionate DCV

- 1.Patients having a serious or life-threatening condition impacting life expectancy
 - 2.No comparable or satisfactory alternative treatment options
 - 3.Currently available treatment options exhausted
 - 4.No clinical trials available
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Expanded Access and Compassionate Use of Second Wave DAAs

Named Patients/Compassionate SMV

Ineligible/contraindicated to IFN

1. Genotype 1 and 4
2. CPT A and B compensated cirrhosis (METAVIR F4) or extrahepatic HCV manifestation
3. Access to SOF or DCV
4. Immediate need for antiviral treatment

Genotype 4

1. CPT A cirrhosis (METAVIR F4) or extrahepatic HCV manifestation
 2. Eligible to PegIFN and RBV
 3. HCV treatment experienced
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Expanded Access and Compassionate Use of Second Wave DAAs

AbbVie Topaz 2 (ABT-450-R/ombitasvir + Dasabuvir ± RBV) in HCV-1

Phase 3b Study

1. Any stage of compensated liver disease
2. Either naive or IFN-experienced patients

SOF compassionate

STOP on 15th December 2014

1. Recurrent HCV post LT METAVIR \geq F2 or FHC
 2. Decompensated cirrhosis listed to LT MELD $<$ 25
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