

# High sustained virological response rates using generic direct antiviral treatment for Hepatitis C

## REDEMPTION-1

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**LB03**

# A Global Tragedy

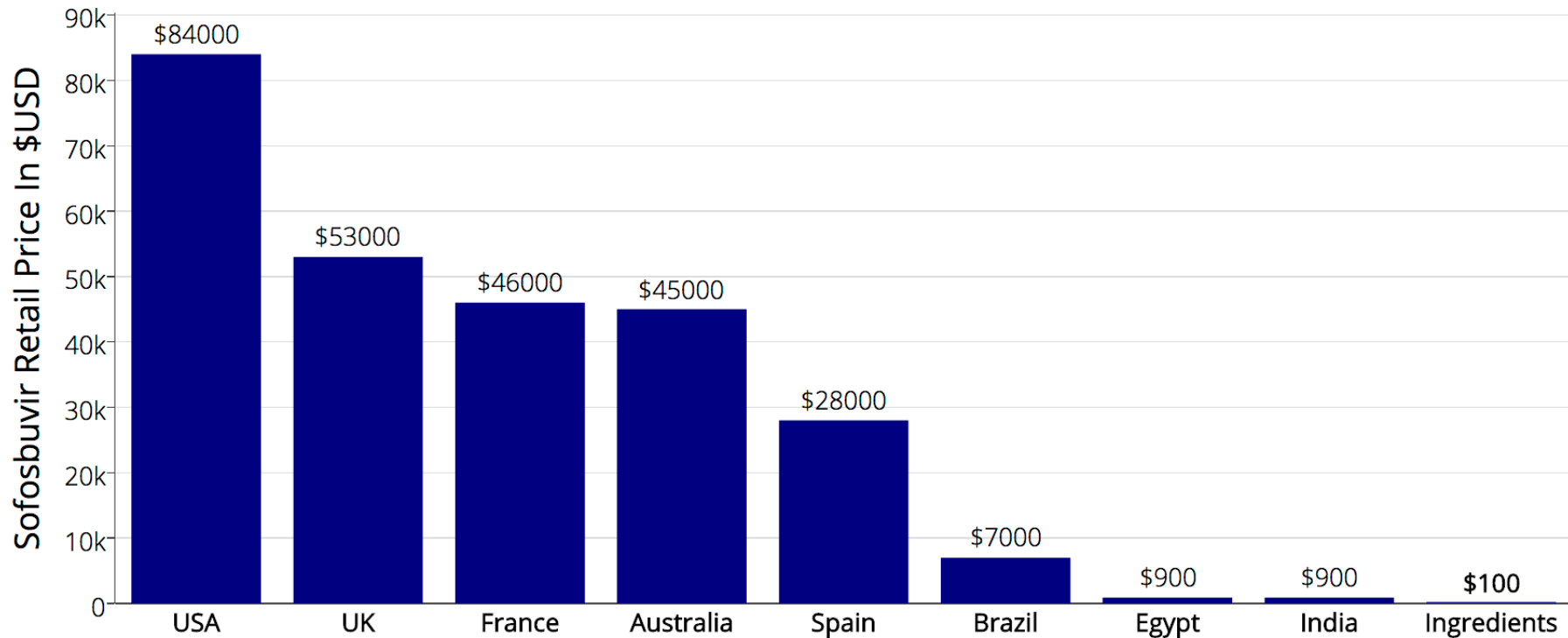
- In a breakthrough that rivals the invention of penicillin drugs called Direct Acting Antivirals (DAAs), which cure the Hepatitis C Virus (HCV) with minimal side effects and a 95% success rate, have reached the market
- Together with HIV, HBV, TB and Malaria, HCV is one of the 5 major causes of infectious disease death worldwide
- Tragically this new cure is not being deployed:
  - We have 150,000,000 infected with HCV worldwide<sup>1</sup>, and
  - We have 500,000 deaths from HCV annually<sup>1</sup>, but
  - We have only 500,000 patients treated for HCV with DAAs annually<sup>2,3</sup>

1. <http://www.who.int/mediacentre/factsheets/fs164/en/>

2. [http://www.unitaid.eu/images/marketdynamics/publications/Hepatitis\\_C\\_Medicines\\_Technology\\_and\\_Market\\_Landscape\\_Update.pdf](http://www.unitaid.eu/images/marketdynamics/publications/Hepatitis_C_Medicines_Technology_and_Market_Landscape_Update.pdf)

3. <http://www.bidnesstc.com/59228-gilead-sciences-inc-abbvie-inc-finally-see-growth-in-hcv-prescription-volum/>

# The Deployment Problem Is Price



# Background

- The high prices of these new medications prevent patient access to highly effective HCV treatment
- Generic versions of the DAAs sofosbuvir, ledipasvir, daclatasvir are being mass produced for 1% of the current US retail price<sup>1</sup>
- Under the laws of Australia<sup>2</sup>, the UK<sup>3</sup>, and many other countries, individuals have the right to import a three month supply of medication, for their personal use

1. [Hill A. Minimum Costs for Producing Hepatitis C Direct-Acting Antivirals. Clin Inf Dis. 2014](#)

2. <https://www.tga.gov.au/personal-importation-scheme>

3. <https://www.gov.uk/government/organisations/hm-revenue-customs>

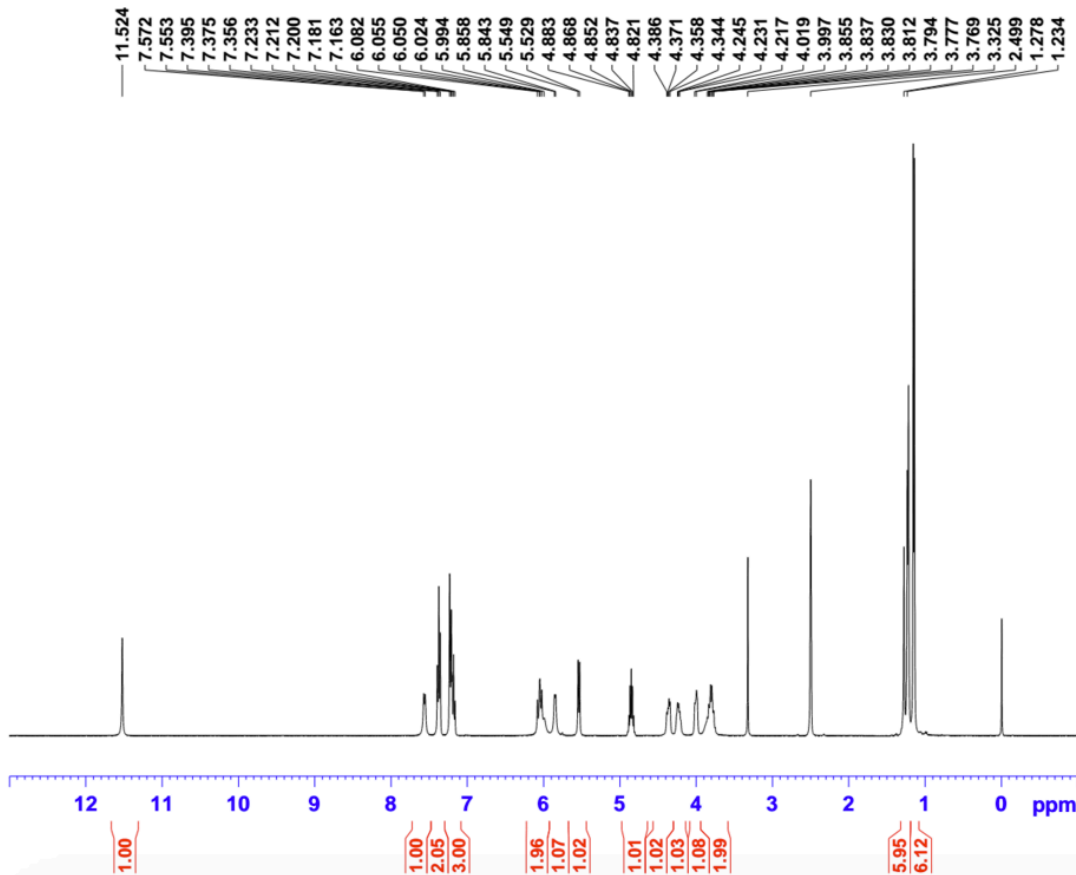
# The Legal Basis Of Personal Importation

- Patents provision monopoly rights, however...
- Article 60 of TRIPS - De Minimis Imports – states:
  - *Members may exclude from the application of the above provisions small quantities of goods of a non-commercial nature contained in travellers' personal luggage or sent in small consignments*
- In line with Article 60 most countries allow some form of personal medication importation
- <http://fixhepc.com/> helps patients access medication and discuss their treatment online

# Methods

- Generic DAAs were first evaluated for quality using HPLC, NMR and Mass Spectrometry
- Consecutive patients enrolled via the [fixhepc.com](http://fixhepc.com) website and were assisted in making a personal importation of affordably priced medication
- Patients were assessed pre-treatment, during treatment, and then for SVR (cure) following treatment using the [gp2u.com.au](http://gp2u.com.au) Telemedicine platform
- The objective of this analysis was to assess the safety and effectiveness of the generic medications legally imported by patients

# Sofosbuvir NMR



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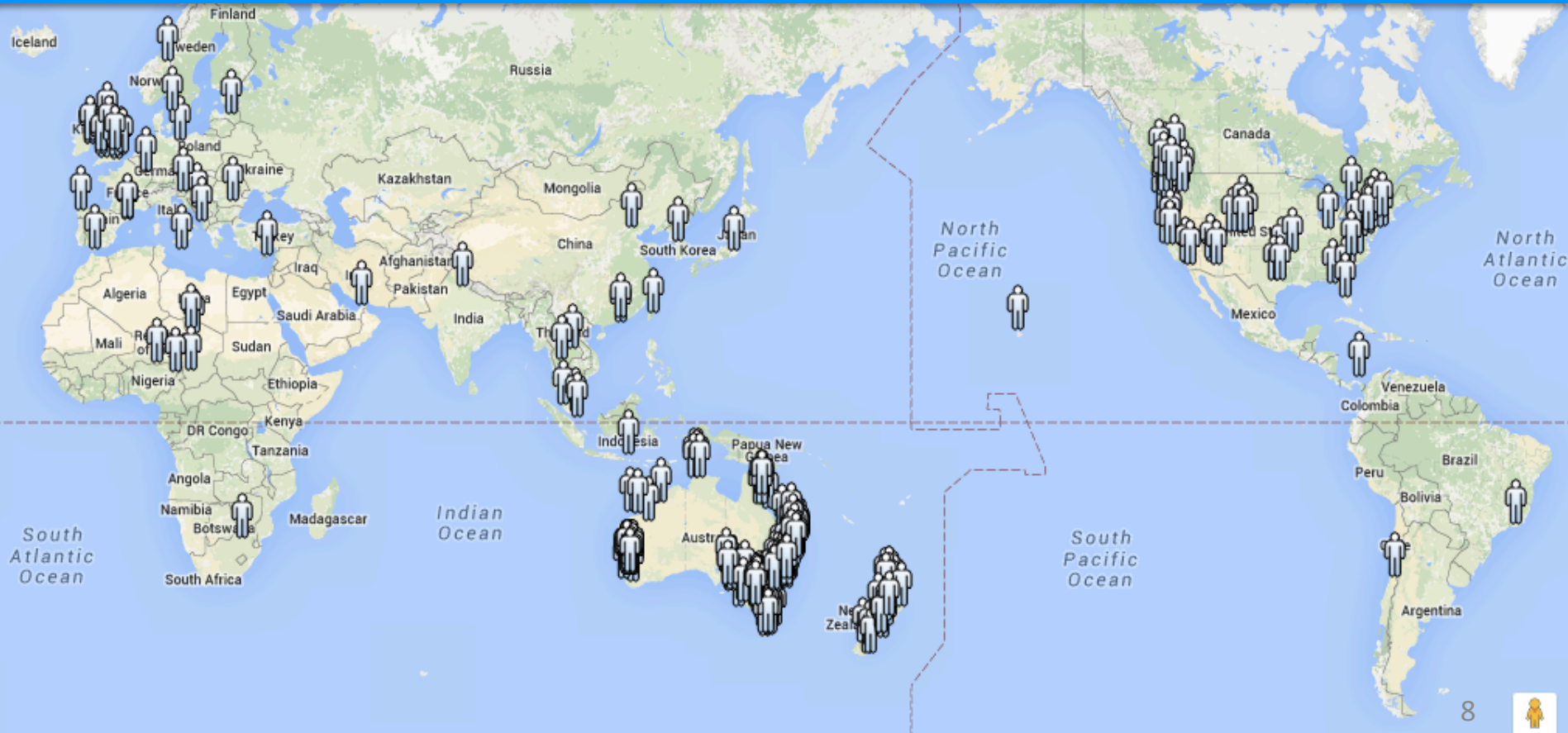
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RG        86.75
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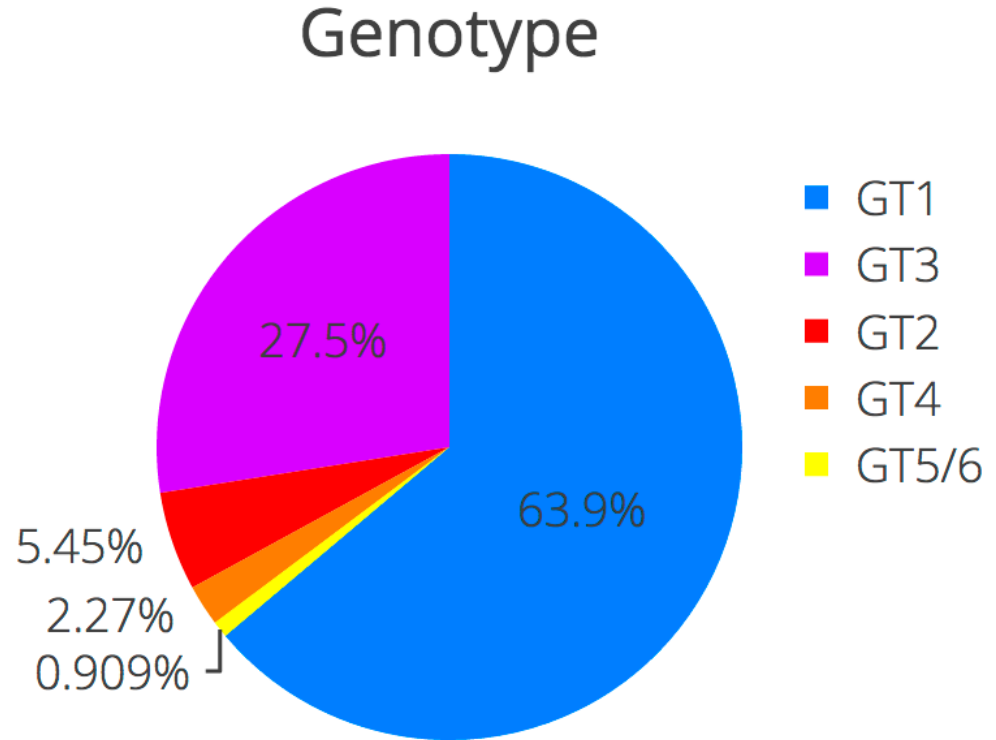
# Over 400 Patients Worldwide Enrolled



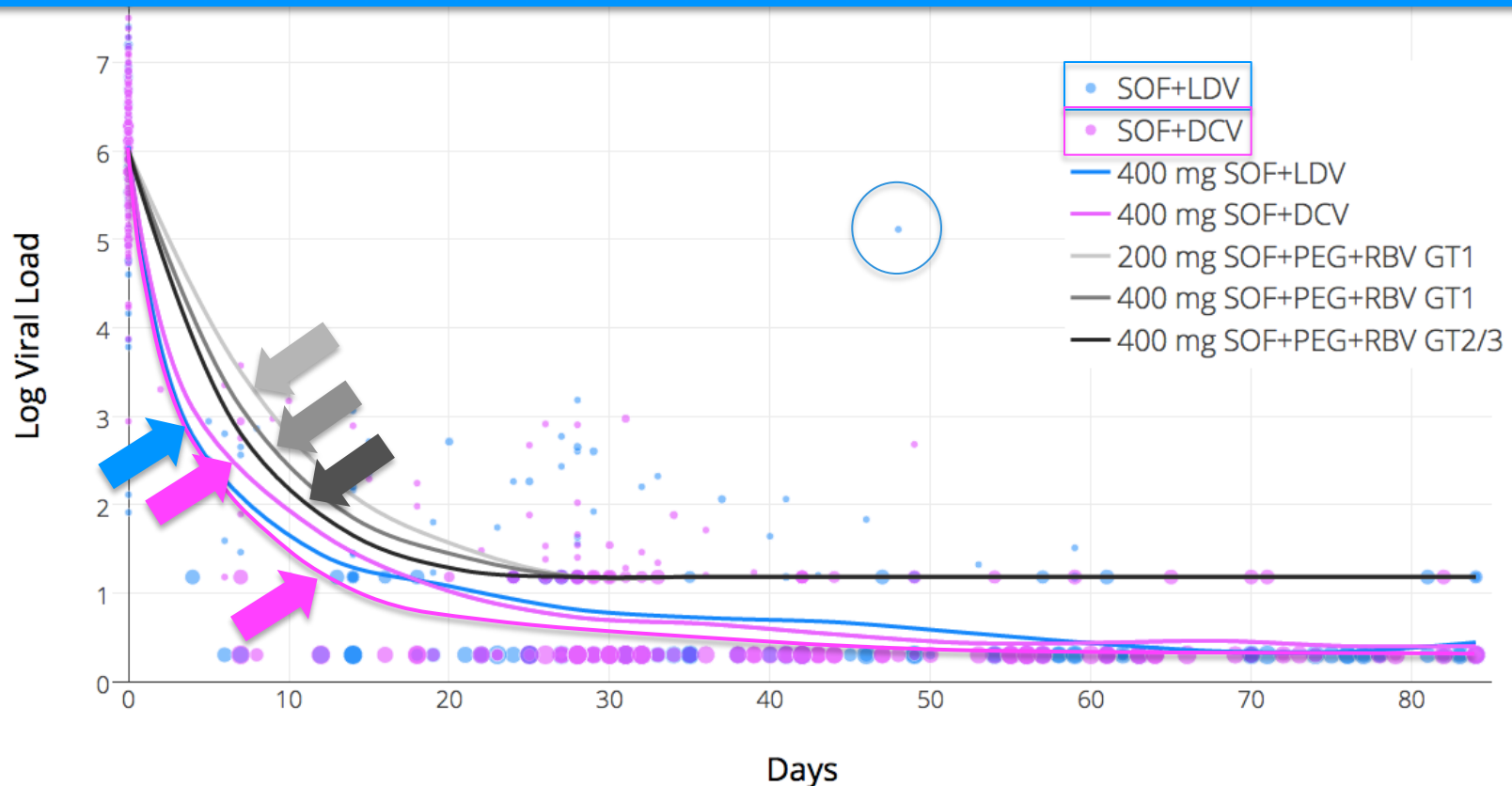


# Baseline Characteristics

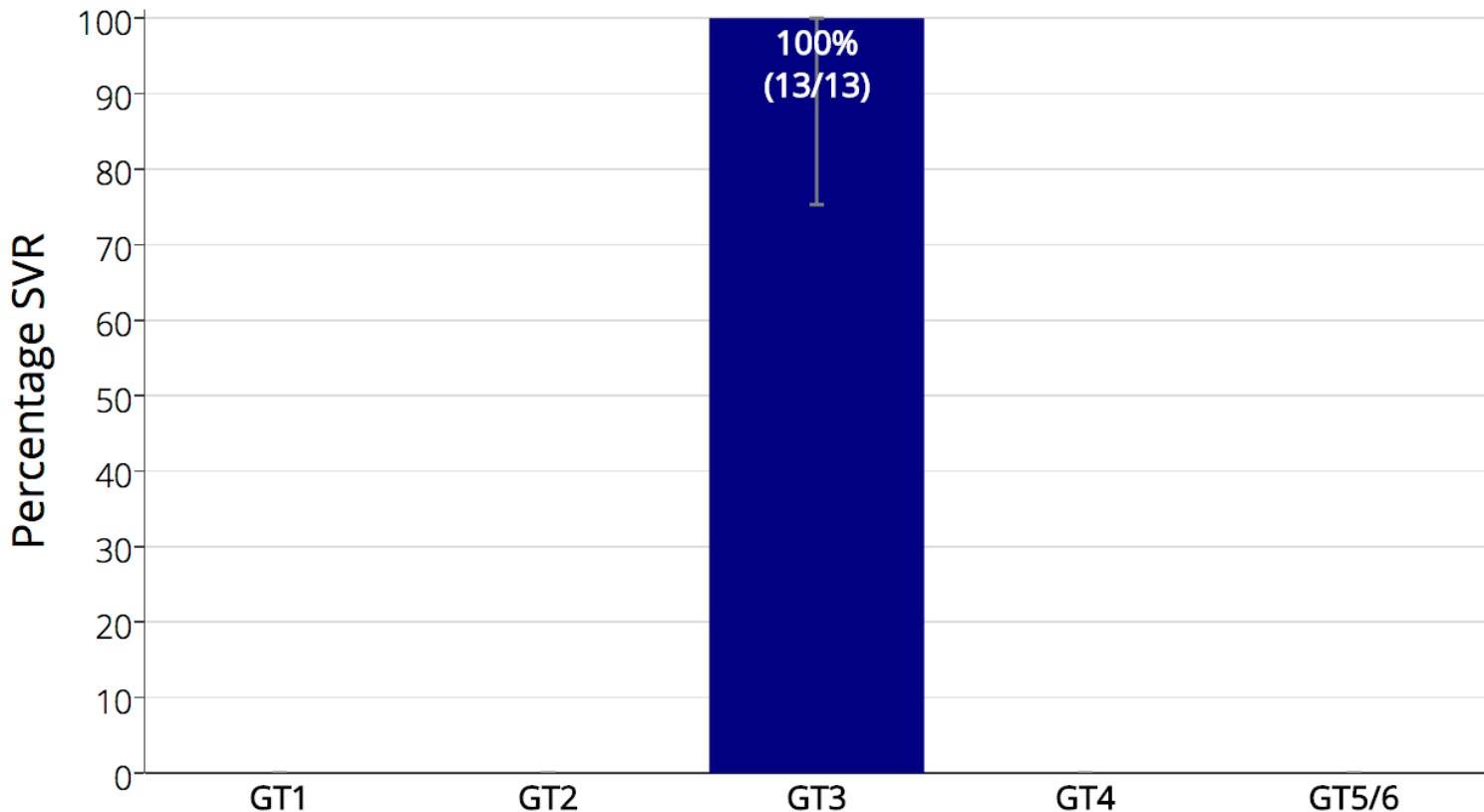
n	448
SOF+RBV	0.9% (4/448)
SOF+LDV	45.8% (205/448)
SOF+LDV+RBV	4.7% (21/448)
SOF+DCV	42.6% (191/448)
SOF+DCV+RBV	6.0% (27/448)
Naïve	51.6%
Cirrhosis	31.3%
Male	54.2%
Mean Age	54.4 years
Mean HCV RNA	6.46 log IU/ml 2878793 IU/ml



# Viral Response REDEMPTION-1 vs Published

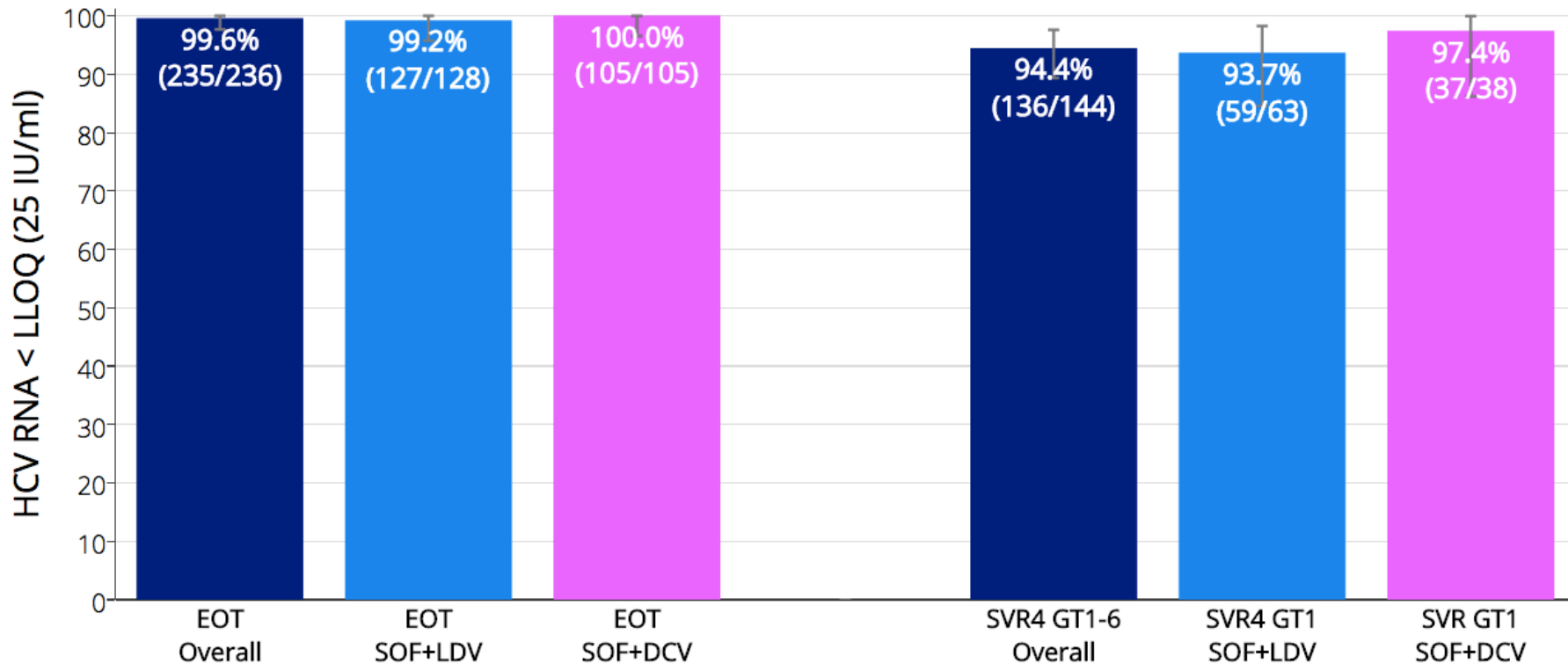


# SOF+LDV+RBV for GT3? (Ed Gane 2015<sup>1</sup>)

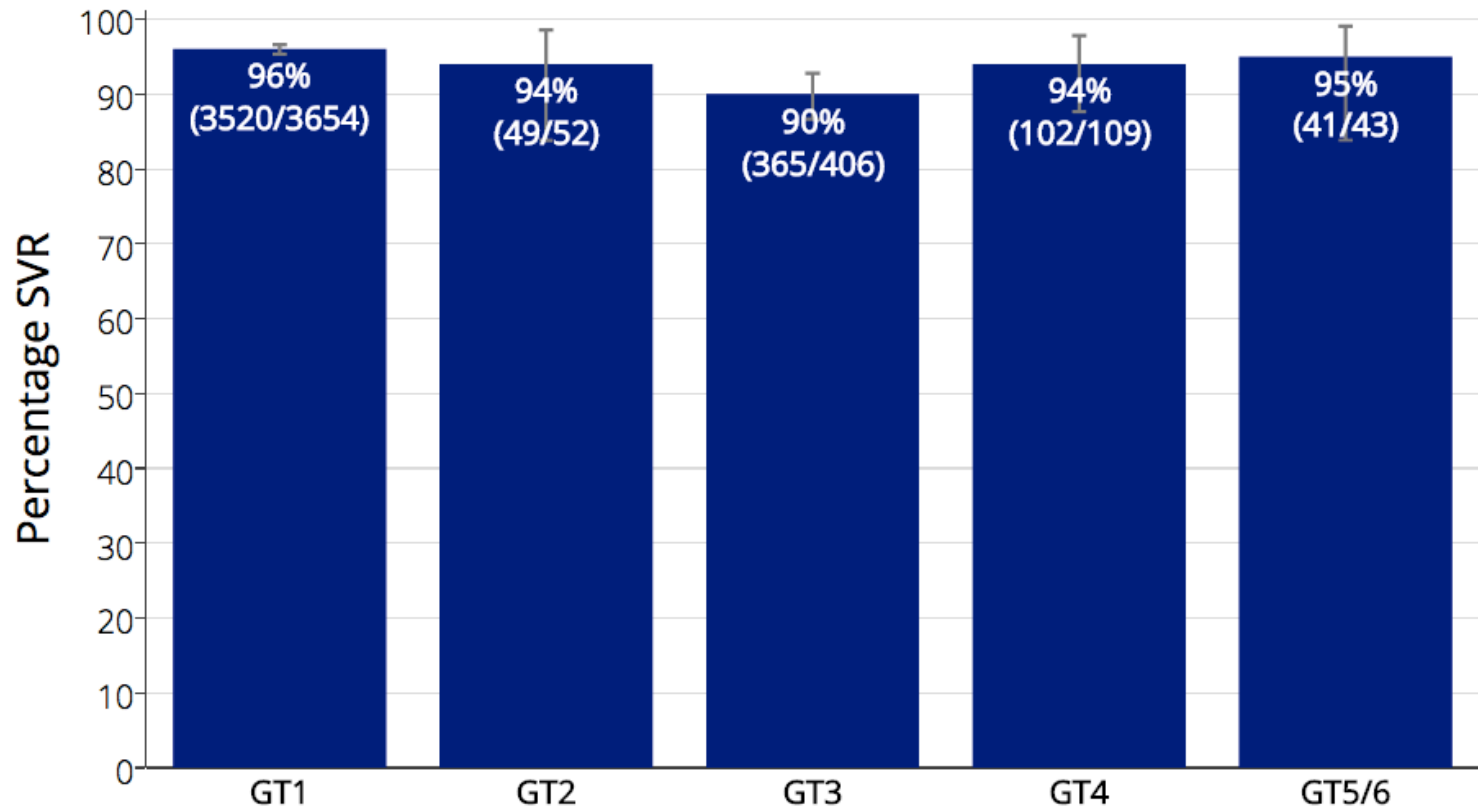


1) <http://www.ncbi.nlm.nih.gov/pubmed/26261007>

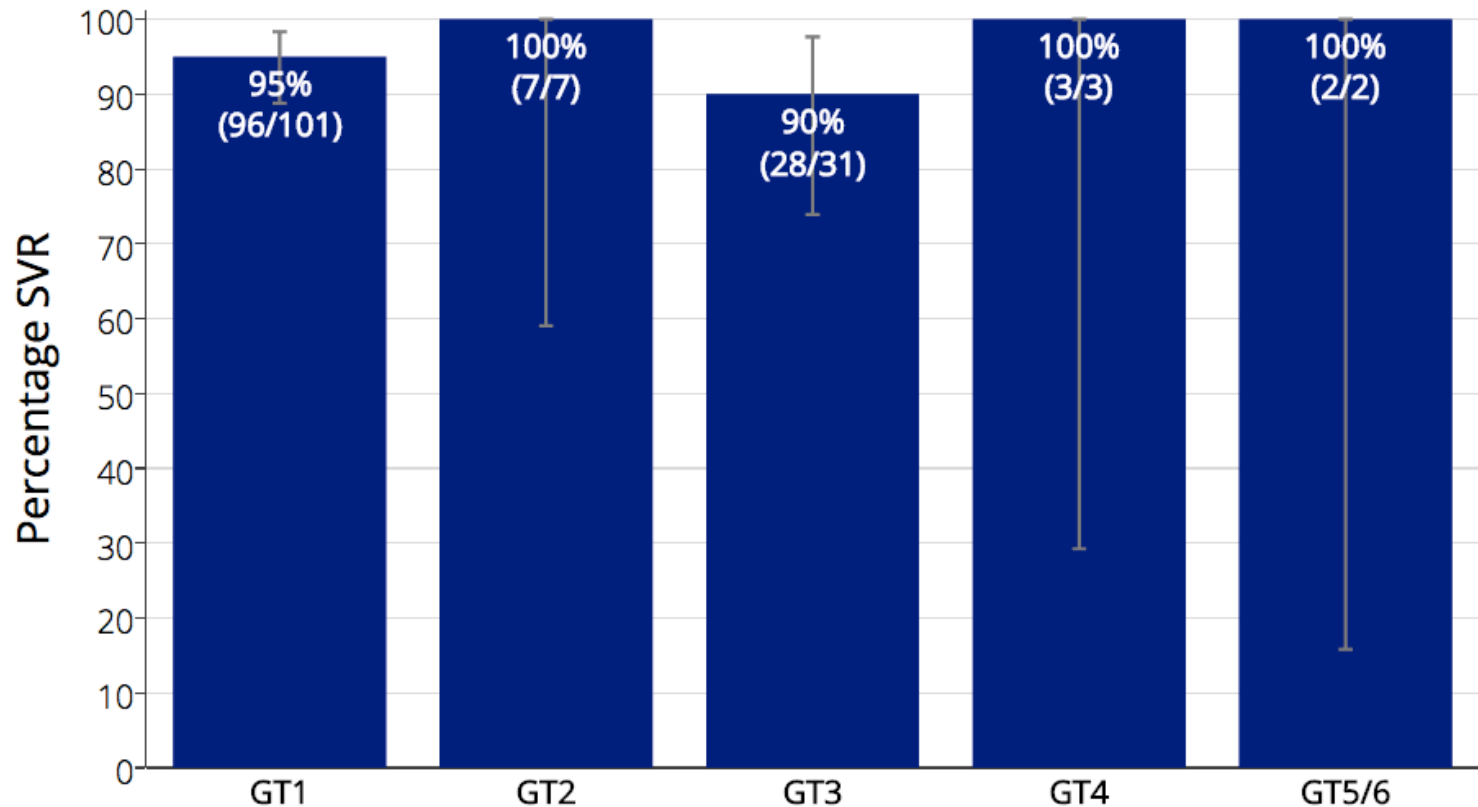
# REDEMPTION-1 HCV RNA < LLOQ at EOT and SVR4



# Published SVR12 Results SOF+LDV and SOF+DCV



# REDEMPTION-1 Overall SVR4 Results For Generics



Note: Some small percentage loss of SVR is expected during the SVR4 to SVR12 period

# Patient Safety

- No new or unknown side effects were reported with headache, fatigue and insomnia being the most common
- 3 patients with compensated cirrhosis temporarily decompensated on treatment initiation but continued
- 4 patients who enrolled died, all from HCC
  - 1 patient died prior to treatment commencement
  - 2 withdrew early in treatment and entered palliative care
  - 1 patient died prior to SVR4

# Summary

- In this interim analysis, treatment with legally imported generic DAAs led to high SVR rates
- These SVR rates are similar to those seen in the Phase 3 trials of branded treatments
- Mass global treatment with generic DAAs is a feasible alternative where high prices prevent access to branded treatment



# Conclusions

- Generic cure for Hepatitis C is available now for \$1000 and works as expected
- Given current API pricing and production costs \$200/patient treatment with SOF+DCV is possible, not in the future, but right now<sup>1</sup>
- Without treatment the future for millions of patients infected with HCV looks like this...

1. [Hill A. Minimum Costs for Producing Hepatitis C Direct-Acting Antivirals. Clin Inf Dis. 2014](#)



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# More Information

- <http://fixhepc.com>
- <https://gp2u.com.au>
- <https://clinicaltrials.gov/ct2/show/NCT02657694>
- HCV Decision Support Tool with expected SVR  
<https://gp2u.com.au/hcv>