

# Low-cost generic direct-acting antiviral treatment for hep C is equivalent to branded formulations

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Data presented today demonstrates that generic direct-acting antivirals (DAAs) are as effective and safe as branded treatments to cure Hepatitis C.

The summary results presented today at The International Liver Congress 2016 in Barcelona, Spain, showed high sustained virologic response (SVR) after [treatment](#) with generic sofosbuvir, ledipasvir, daclatasvir and [ribavirin](#), confirming clinical efficacy equivalent to outcomes seen in Phase 3 [clinical trials](#) of branded combination treatments.

The high costs of branded DAAs prevent access to treatment in many countries.<sup>1</sup> Generic DAAs are being mass-produced and are available for less than 1% of the retail price of their branded counterparts. Medication costing \$94,000 per person in the US can currently be obtained for less than \$1,000 as a generic, and a 12 week course of treatment could be produced for as little as \$200 in the future.<sup>1</sup>

"Our interim data suggests a potential solution for Hepatitis C patients in areas where treatment access has been restricted as a result of the high prices demanded for branded treatment," said Dr James Freeman, of GP2U Telehealth, Hobart, Australia and lead author of the study. "At the price level of generic direct-acting antivirals, treating the entire global Hepatitis C epidemic could be financially feasible. Furthermore, if a

patient is cured of Hepatitis C, there is evidence for improved survival, and lower risks of liver cancer and liver cirrhosis and cured patients could return to work, delivering further economic benefits to society."

In this study, people with HCV legally imported low-cost generic treatment to cure their infection. The study included people treated in Australia, USA, UK, Canada, Europe, SE Asia and Africa.

Generic DAAs were first evaluated for quality in Australia, using high precision liquid chromatography, nuclear magnetic resonance and mass spectroscopy. Patients were assessed pre-treatment, during treatment, and then at weeks 4 (SVR4) and 12 (SVR12) following the end of treatment. The objective of the analysis was to assess the efficacy and safety of generic DAAs legally imported for each patient's personal use.

The interim results show that for genotype 1 the overall SVR rate was 95%. Treatment with generic sofosbuvir and ledipasvir led to SVR4 rates of 93% and treatment with generic sofosbuvir and daclatasvir led to SVR4 rates of 97%.

"Across all genotypes, the SVR rate was 94% after treatment with generic DAAs. This indicates that generic DAAs can deliver the same success rates as branded equivalents, but at a price which is 1/100th of the current cost," explained Dr James Freeman.

"There is a clear role for generic treatments such as these for people with Hepatitis C across the world. The implications of increased availability of these drugs could be enormous, presenting more people with the possibility of a 'cure' for what is often a debilitating condition," said Professor Laurent Castera, EASL Secretary General.

**More information:** Reference:

1 Andrieux-Meyer I, et al. Disparity in market prices for hepatitis C virus direct-acting drugs. *The Lancet Global Health*. Volume 3, No.11, e676-e677, November 2015.

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