



“ Every day, more people are infected than put on treatment. Hepatitis C is the 'silent epidemic' because people are unaware of their infection and go untreated for years. This is the challenge we are addressing. ”

Sasikala Siva, Clinical Project Manager in Kuala Lumpur, Malaysia, is a key figure in ensuring DNDi's hepatitis C clinical trials run smoothly. Pictured here, she is showing her support for the test and treat #dontignorewhatucantc campaign.



HEPATITIS C

MEETING THE NEEDS OF MILLIONS STILL WAITING FOR AFFORDABLE TREATMENT FOR A CURABLE DISEASE

Hepatitis C (HCV) is a blood-borne virus which can lead to chronic and debilitating liver disease, including fibrosis, cirrhosis, and cancer. It's a silent epidemic, as the huge majority of those infected are not aware of their status, show no symptoms of the disease, and therefore do not seek treatment. And yet HCV is curable. If people were diagnosed and treated early enough, they could avoid infecting others, prevent liver disease from developing, and the disease could be eliminated as a public health problem.



ABOUT
71 MILLION
people are living with hepatitis C globally,
80% of whom are unaware that they
are infected



ONLY
7%
have had access to treatment



OF WHOM
75%
live in low- and middle-income countries



400,000
people die every year from hepatitis C

THE TREATMENT CHALLENGE

Direct-acting antiviral medicines to treat HCV are highly effective, but treatment prices are still not low enough for most national health systems to implement 'test-and-treat' strategies to find and cure people living with HCV. Simple, affordable treatments that minimize the burden on health systems and patients alike are needed to treat everyone.

DNDi aims to deliver:

- **A safe, effective, and easy-to-use direct-acting antiviral regimen, to be used as an affordable combination paving the way for a public health approach to HCV.**
- Increased access to affordable treatments by supporting policy change and encouraging political will to treat HCV.
- Innovative programmes to improve access to HCV diagnosis and treatment in a variety of countries.

Promising results presented in 2018

DNDi identified ravidasvir (RDV), developed by US biopharmaceutical company Presidio, as a promising drug candidate in late-stage clinical development. In March 2016, DNDi concluded a licence agreement with Presidio for low- and middle-income countries, and an agreement with Egyptian generic manufacturer Pharco to secure supplies of RDV and generic sofosbuvir (SOF). The idea was to develop RDV as part of a simple-to-use and affordable treatment combination that could cure any of the six HCV genotypes (genetic variations), which respond differently to treatment.

The STORM-C ('Strategic Transformation of the Market for Hepatitis C Treatments') programme was launched with the support of Médecins Sans Frontières (Doctors Without Borders) to assess the efficacy, safety, tolerance, and pharmacokinetics of the RDV/SOF combination. The first clinical trial began in Malaysia in 2016 co-sponsored by the Malaysian Ministry of Health, and in Thailand in 2017 in partnership with the Thai government.

The study enrolled 301 patients with various levels of liver fibrosis and different genotypes, with and without HIV co-infection. Initial results from the trial were presented in April 2018 and found that 12 weeks after treatment completion, 97% of those enrolled were cured. The results indicate that the RDV/SOF combination is comparable to the very best hepatitis C therapies available today. The tolerability and the absence of safety signals, even for patients with multiple illnesses, suggests that the safety profile of RDV/SOF supports a simplified treatment model for HCV.

To confirm that the RDV/SOF combination could effectively cure any of the six HCV genotypes, a second trial was launched in December 2018 in Malaysia, and in Thailand in May 2019. Additional trials are envisioned in other parts of the world, for vulnerable patient groups including people who use drugs.

Registration of RDV will be pursued in Malaysia and other middle-income countries, including in Argentina, with the help of DNDi's pharmaceutical partners Pharmaniaga and Elea Phoenix. DNDi signed a technology transfer agreement with Pharco (Egypt) and Pharmaniaga in late 2017.

STORM-C-1 TRIAL – SUSTAINED VIRAL RESPONSE 12 WEEKS AFTER END OF TREATMENT (SVR12) - INTERIM RESULTS

Outcomes in intention-to-treat analysis with full analysis set

