HEPATITIS C

Supporting global elimination efforts by accelerating 'test-and-treat' strategies

Hepatitis C is caused by the blood-borne hepatitis C virus (HCV) and can lead to chronic liver disease, cirrhosis, cancer, and, if not treated, death. Symptoms can take decades to develop, and most people living with the disease do not know they are infected. As a result, HCV is a silent epidemic.

The past decade has seen a revolution in medical innovation for HCV, which can now be cured with just 8 to 24 weeks of safe, simple treatment. And yet, only 20% of people living with the disease worldwide have benefited. While treatment has become more affordable, it remains priced out of reach for vulnerable populations in many middle-income countries. 'Test-and-treat' strategies have the potential to eliminate HCV altogether – a perhaps unique opportunity in the field of infectious diseases – but high prices and a lack of prioritization in many countries leave these strategies underused.

The push for progress

In 2021, we completed development of a simple-to-use, affordable cure for HCV through a unique South-South collaboration in close partnership with the ministries of health of Malaysia and Thailand and pharmaceutical companies in Egypt and Malaysia. Together, we have demonstrated that ravidasvir, a novel direct-acting antiviral (DAA), can cure the disease in 8 to 24 weeks when used with sofosbuvir. Ravidasvir acts as both a powerful new therapeutic option and as a market shaper to bring down the cost of other life-saving HCV drugs in countries where they are priced out of reach. Added to the World Health Organization (WHO) Essential Medicines List in 2023, the treatment is already paving the way for more cost-effective cures for HCV. Together with partners, governments, and civil society organizations, we have advocated for the roll-out of affordable all-oral cures, community-based testing, and improved access in key countries.

Sharing lessons from the South-South collaborative effort and the political commitment that made ravidasvir possible, we have also shone a light on the tremendous potential of alternative pharmaceutical innovation models in markets where high prices are a barrier to treatment access.

OUR GOAL IS NOW to complete our work to extend access to ravidasvir and affordable DAAs more broadly, foster the political will needed for wide-scale roll-out of 'test-and-treat' strategies, and ensure that people facing stigma, discrimination, and other barriers have equitable access to life-saving diagnosis and treatment.

Expanding access to a cost-effective cure

Following DNDi clinical trials, ravidasvir was included in Malaysia's Ministry of Health Medicines Formulary and National Essential Medicines List and recommended as an alternative treatment for people living with both HIV and HCV in the Malaysian Consensus Guidelines on Antiretroviral Therapy in 2023. In early 2024, ravidasvir was granted full registration in the country. In Thailand, we continued working with Mahidol University, Egyptian pharmaceutical company Pharco, and the Thai Government Pharmaceutical Organization to register ravidasvir in the country. Pending registration,

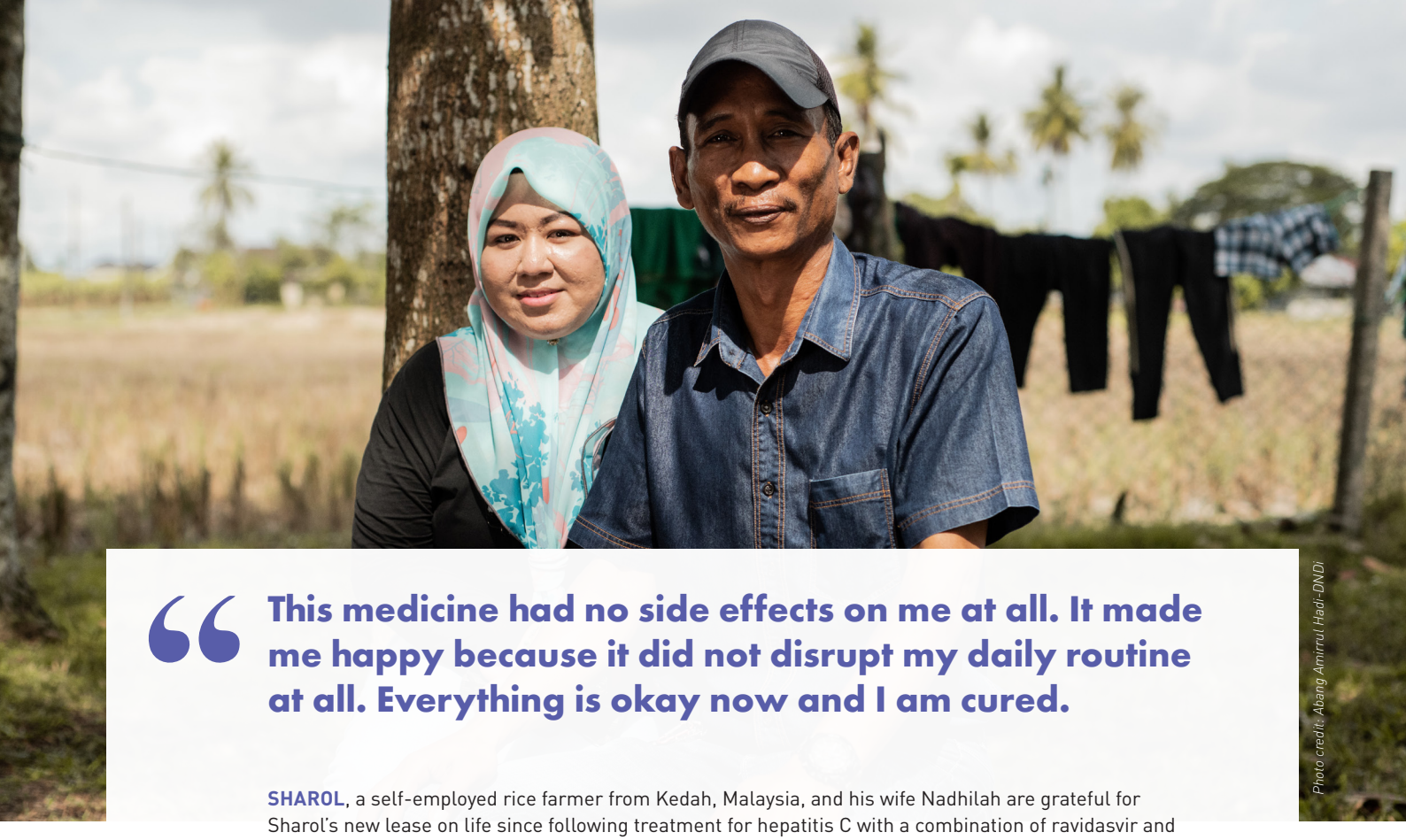
FACTS

50 million
people are living with chronic HCV globally

Only 20%
of diagnosed cases are treated

>650
people die from HCV every day

DNDi
Best Science for the Most Neglected



> **This medicine had no side effects on me at all. It made me happy because it did not disrupt my daily routine at all. Everything is okay now and I am cured.**

Photo credit: Abang Amirrul Hadi-DNDi

SHAROL, a self-employed rice farmer from Kedah, Malaysia, and his wife Nadhilah are grateful for Sharol's new lease on life since following treatment for hepatitis C with a combination of ravidasvir and sofosbuvir. His hope is that no one living with hepatitis C will hesitate to seek treatment.

Mahidol University and Pharco Pharmaceuticals signed a collaboration and license agreement in March 2024 to facilitate the introduction of ravidasvir in Thailand. The treatment was also included in the C-FREE-SEA study led by Dreamlopments to evaluate the use of ravidasvir in marginalized populations. In Brazil, DNDi teams continued to work with the Drug Technology Institute (Farmanguinhos), Oswaldo Cruz Foundation, and Pharco Pharmaceuticals to prepare for registration of ravidasvir, with a regulatory dossier submitted to the Brazilian Health Regulatory Agency (Anvisa) in early 2024.

New evidence for shorter, more effective treatment

In June 2024, the results of a clinical trial testing the effectiveness of 12- or 24-week regimens of ravidasvir + sofosbuvir in patients with the more difficult to treat genotype 3 hepatitis C virus with and without cirrhosis were presented at the 2024 European Association for the Study of the Liver (EASL) Congress in Milan, Italy. The results showed a sustained virological response after 12 weeks in patients without cirrhosis, and 24 weeks in patients with cirrhosis. In October, preliminary results from the EASE study testing shorter regimens (8 to 12 weeks) of ravidasvir and sofosbuvir, sponsored by the Malaysian Ministry of Health, were presented to WHO. Final results presented at the Prince Mahidol Award Conference in early 2025 showed the shorter regimens to be effective in treating patients with HCV without cirrhosis.

A groundbreaking at-home test

Boosting efforts to reach underserved populations at risk of HCV, in July 2024, WHO pre-qualified the first self-test for HCV that can be performed at home, developed and manufactured by OraSure. Building on WHO recommendations in 2021 that aimed to simplify and streamline access to screening, diagnosis, and treatment for vulnerable populations, DNDi and the Hepatitis C PACT had earlier supported FIND and the Malaysian Ministry of Health in evaluating use of the tool in Malaysia to better target HCV services for key populations at high risk of infection.