Researchers to test affordable hepatitis C regimen with Malaysian and Thai governments

April 13 2016

The Drugs for Neglected Diseases initiative (DNDi) and the Egyptian drug manufacturer Pharco Pharmaceuticals have signed agreements covering the clinical testing and scale-up of a hepatitis C treatment regimen at a price of just under $300.

"If our clinical trials are successful, this regimen could become part of a public health approach to treating hepatitis C that will be an alternative to today's high drug prices and treatment rationing," said Dr Bernard Pécoul, Executive Director of DNDi. "An affordable cure for this deadly disease that treats all strains, or 'genotypes,' of the disease, is essential to tackling the worldwide hepatitis C epidemic."

DNDi will be launching clinical trials to test a combination treatment of the drug candidate ravidasvir and the registered hepatitis C drug sofosbuvir in pan-genotypic patient populations in Malaysia and Thailand, as soon as the necessary approvals are received. Ravidasvir is an NS5A inhibitor, one of a new generation of direct-acting antivirals (DAAs) that are revolutionizing the treatment of hepatitis C. In a Phase III clinical trial in Egypt, conducted by Pharco, ravidasvir showed cure rates of up to 100% in patients with genotype 4 when used in combination with sofosbuvir, which also is a DAA.

DNDi has licensed rights for ravidasvir in low- and middle-income countries from Presidio Pharmaceuticals.

Pharco has agreed to supply DNDi with the combination sofosbuvir plus ravidasvir for its clinical studies for $300 per course of treatment. For the scale-up of this regimen, once approved, Pharco has agreed to set the commercial price at $294 or less per treatment course.

"Because of the high prices of new hepatitis C medicines, it has been almost impossible for governments to provide access to treatment at the necessary scale," said YB Datuk Seri Dr. S. Subramaniam, the Minister of Health in Malaysia. "We are pleased to support this project and hope data from these studies will support our efforts to introduce this combination as soon as possible and scale up to reach all patients in need."

DNDi's Phase II/III studies in Malaysia and Thailand will be conducted with the full cooperation of both governments and will compare sofosbuvir plus ravidasvir with a current standard of care, sofosbuvir plus daclatasvir. These studies will enroll approximately 1,000 participants and will evaluate the efficacy, safety, and pharmacokinetics of the sofosbuvir plus ravidasvir combination in patients with various levels of liver fibrosis, various genotypes, and with/without HIV co-infection.

"We are encouraged by the signing of these agreements as they will help millions of people who are affected by chronic hepatitis C infection around the world," said Dr. Amnuay Gajeena, Director General of the Department of Disease Control in Thailand. "Accessibility to affordable DAAs is key and participation in this research will facilitate the process of scaling up effective treatment of hepatitis C infection, and foster the prevention and control of the disease."

Malaysia and Thailand are among the many middle-income countries that are excluded from the voluntary licensing agreements that Gilead and Bristol-Myers Squibb, the intellectual property holders of the

hepatitis C drugs sofosbuvir and daclatasvir, respectively, have concluded with generic companies. Of the up to 150 million people infected with chronic hepatitis C globally, approximately 75% live in middle-income countries.

"Once these trials have been successfully completed and the safety and efficacy data of this combination assessed, we will encourage governments to design their national health strategies to use all options at their disposal to gain access to life-saving DAAs, including price negotiation, voluntary licensing, or the use of TRIPS flexibilities such as patent oppositions and compulsory licensing," added Dr. Pécoul.

Before DAAs became available, hepatitis C treatment consisted of multiple injections over a period of up to one year and frequently caused severe side effects. Treatment was only successful 40-80% of the time. DAAs have transformed treatment options for patients and clinicians, but multiple barriers to access for patients exist, in particular, price. As with the introduction and scale-up of antiretroviral therapy for HIV/AIDS over the past 15 years, new and innovative public health approaches to HCV treatment will require affordable access to DAAs.

"Egypt has the world's highest hepatitis C prevalence, yet thanks to an Egyptian Presidential program that aims to treat one million patients a year, economies of scale have helped make DAAs affordable and are helping to reach our goal of a world free from hepatitis C," said Dr. Sherine Helmy, CEO of Pharco Pharmaceuticals. "We hope that our collaboration with DNDi to develop a combination treatment that costs $3.50 per day or less - as opposed to $1000 per day for only one pill - will lead to widespread access to safe, effective, and affordable treatment for hepatitis C patients around the world."

Provided by Drugs for Neglected Diseases Initiative