No. 0413.12/231A



Department of Disease Control Ministry of Public Health Tiwanond Road, Nonthaburi 11000, Thailand

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5 April B.E. 2566 (2023)

Dear Sir / Madame,

Subject: Letter of Support: Ravidasvir 200 mg inclusion into WHO's EML

The Department of Disease Control, Ministry of Public Health (MOPH), Thailand strongly supports the inclusion of ravidasvir 200 mg in the WHO List of Essential Medicines (EML) - for treatment of chronic hepatitis C virus (HCV) infection.

According to WHO statistics, estimated 58 million people worldwide are living with chronic HCV infection and around 300,000 people die from liver cancer and cirrhosis caused by untreated HCV infections every year. In Thailand, it is estimated 356,000 individuals infected by HCV, causing a huge burden to the public health system. Due to its nature of disease progression, a lot of HCV infected individuals have no symptoms in early stage of the infections, and hence a lot of our patients are not diagnosed. Effort has been made to improve public awareness about HCV screening, while MOPH initiated a few pilot projects to improve patient linkages to care and access to treatment.

Back in 2016 when the HCV treatment so called Direct-Acting Antiviral Agents (DAAs) was still inaccessible to patients in Thailand due to its high cost of Sofosbuvir, MoPH Thailand in collaboration with the National Science and Technology Development Agency (NSTDA), as well as the Ministry of Science and Technology developed the Ravidasvir as alternative DAA. MOPH has been leading the clinical trial of Ravidasvir in Thailand as principal investigator of the study across the following study centers in Thailand:

- Gastroenterology unit, Department of Internal Medicine, Maharaj Nakorn Chiang Mai Hospital
- Internal Medicine unit, Medical Department, Nakornping Hospital, Chiang Mai
- Internal Medicine, Bamrasnaradura Infectious Diseases Institute, Nonthaburi
- King Chulalongkorn Memorial Hospital/HIV-NAT, Pathum Wan, Bangkok

Ravidasvir is the first HCV treatment developed through a South-South Collaboration involving the Drugs for Neglected Diseases initiative (DNDi), the Malaysia Ministry of Health (MoH), the Egyptian pharmaceutical company Pharco, Pharmaniaga Berhad, and Médecins Sans Frontières (MSF). Clinical trials for ravidasvir (STORM-C) were conducted in Thailand and Malaysia between July 2016 and December 2020. The results of the STORM-C trials showed that the ravidasvir/sofosbuvir combination was safe and effective in curing hepatitis C for 97% of enrolled participants, including those with genotype 3 infection, the hardest to treat genotype.

Ravidasvir/sofosbuvir can be offered as an additional treatment option for HCV high-burden countries such as Thailand. The inclusion of ravidasvir/sofosbuvir in the WHO EML will also serve as the basis for our national essential medicines list. Hence, the Ministry of Public Health, Thailand strongly requests the Expert Committee on the Selection and Use of Essential Medicines to include ravidasvir 200 mg in the EML.

Yours sincerely,

Som I.

(Dr.Sopon lamsirithaworn)

Deputy Director General

For Director General

The WHO Expert Committee on the Selection and Use of Essential Medicines Department of Essential Medicines and Health Products World Health Organization 20 Avenue Appia CH-1211 Geneva 27 Switzerland