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

7 April 2023

Letter of support for the inclusion of ravidasvir into WHO's EML

Dear committee members,

Knowledge Ecology International (KEI) supports the inclusion of ravidasvir into the World Health Organization (WHO) Model List of Essential Medicines (WHO EML) for the treatment of chronic hepatitis C virus (HCV) infection in adults.

The WHO estimates that "*58 million people have chronic hepatitis C virus infection, with about 1.5 million new infections occurring per year…WHO recommends therapy with pan-genotypic direct-acting antivirals (DAAs) for all adults, adolescents and children down to 3 years of age with chronic hepatitis C infection.*"[1]

In April 2016, the Drugs for Neglected Diseases Initiative (DNDi) and Pharco Pharmaceuticals announced that DNDi would 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.*
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> *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.*[2]

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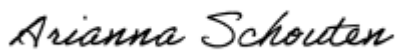
[1] WHO Fact sheet on Hepatitis C, https://www.who.int/news-room/fact-sheets/detail/hepatitis-c,
[2] DNDi Press release, Drugs for Neglected Diseases initiative and Pharco Pharmaceuticals to test affordable hepatitis C regimen with support of Malaysian and Thai governments, Potentially

Ravidasvir is an antiviral medication used in the treatment of chronic hepatitis C virus (HCV) infection. According to clinical trials, ravidasvir and sofosbuvir regimens have shown high efficacy in reducing HCV viral loads, leading to sustained virologic response rates of over 90% in some studies. Importantly, the combination drugs were even effective in some of the harder-to-treat patients (e.g., genotype 3 of the virus). Additionally, ravidasvir 200mg is well-tolerated by patients and has a low risk of adverse effects. These results demonstrate the efficacy and safety of ravidasvir 200mg in the treatment of chronic HCV infection, providing hope for those living with this disease, particularly those who do not currently have access to HCV treatment.

Ravidasvir+sofosbuvir is available at a fraction of the cost of existing HCV medicines currently on the market. HCV treatments that exist on the market are highly effective but due to their high cost, they are out of reach for many. As such, the positive results of the combination of ravidasvir and sofosbuvir, as compared to existing HCV treatments but at a much lower price, present an ideal candidate for inclusion in the EML. Overall, ravidasvir is an effective and lower-cost treatment that will reduce HCV-related mortality and morbidity in countries where affordable treatment is currently inaccessible. As a result, KEI strongly supports its inclusion in the WHO Model Essential Medicines List as a necessary step to contribute to the global effort to fight HCV.

Yours sincerely,

Arianna Schouten



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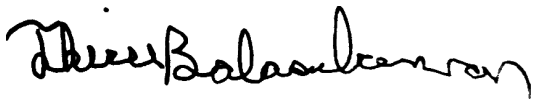

Geneva Representative
Knowledge Ecology International

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pan-genotypic combination of ravidasvir and sofosbuvir to be tested in Malaysia and Thailand with target price of under $300
https://dndi.org/press-releases/2016/dndi-pharco-hepc-malaysia-thailand/,