Shionogi and the Medicines Patent Pool (MPP) sign licence agreement for COVID-19 oral antiviral treatment candidate to increase access in low- and middle-income countries

OSAKA and GENEVA, 4 October 2022 — Japanese pharmaceutical company Shionogi & Co., Ltd. and the Medicines Patent Pool (MPP), a United Nations-backed public health organisation, reflecting a shared commitment to increase access to life-saving medicines for low- and middle-income countries (LMICs), today announced that they have signed a voluntary licence agreement for Shionogi's antiviral candidate ensitrelvir fumaric acid (S-217622). The agreement, signed today at a ceremony held at Shionogi's headquarters in Osaka, will enable MPP to facilitate additional production and distribution of the investigational antiviral, pending regulatory authorisation or approval, by granting sublicences to qualified generic manufacturers, with the goal of expanding access to people living in LMICs. Ensitrelvir is being evaluated for the treatment of COVID-19 to be administered as an oral tablet formulation taken once daily for five days.

Under the terms of the licence agreement between Shionogi and MPP, qualified generic manufacturers that are granted sublicences by MPP will be able to manufacture and supply ensitrelvir to 117 countries. Shionogi will waive royalties on sales in all countries covered by the agreement while COVID-19 remains classified as a Public Health Emergency of International Concern by the World Health Organization.

Takuko Sawada, Director and Vice Chairperson of the Shionogi Board, said: "Shionogi is proud to work on such an innovative licence agreement with the Medicines Patent Pool. This licence agreement will allow people in LMICs to have rapid access to ensitrelvir, following appropriate regulatory approvals. We consistently strive to supply the best possible medicines to protect the health and wellbeing of the patients we serve. It is another great example of what partnerships can achieve to advance global health."

Charles Gore, Executive Director of MPP said: "This public health-oriented licensing agreement has the potential to increase the affordable options for people living in LMICs to fight COVID-19 and support our collective efforts to put an end to the pandemic and its unacceptable death toll. Moreover, we are delighted to sign our first agreement with Shionogi – indeed our first with a Japanese company – and we hope this new partnership will encourage other companies to collaborate with us." It is not the first connection between MPP and Shionogi, however, as dolutegravir, an HIV drug licensed from Shionogi to ViiV Healthcare, has been extensively provided to LMICs through MPP's agreements with ViiV.

Dr Philippe Duneton, Executive Director of Unitaid, said: “Availability of oral antivirals, such as ensitrelvir, is a priority to prevent severity of disease and further deaths due to COVID-19. We welcome the licence agreement signed by Shionogi and MPP that will enable increased access to the oral antiviral ensitrelvir in low- and middle-income countries, once it is authorised by regulatory bodies. It is crucial to have a range of optimal treatments, alongside adequate testing, readily available and affordable everywhere in the world, including in resource-limited settings.”

Access the licence agreement

MPP invites Expressions of Interest (EoI) from potential sublicensees based anywhere in the world for sublicences to manufacture and sell ensitrelvir in the licensed territory:

Access the EoI portal

More information about the EoI process

Deadline for applying: 26 November 2022, 11.59pm CET

About ensitrelvir fumaric acid (S-217622)

Ensitrelvir, an investigational drug for COVID-19, is a 3CL protease inhibitor created through joint research between Hokkaido University and Shionogi. SARS-CoV-2 has an enzyme called 3CL protease, which is essential for the replication of the virus. Ensitrelvir suppresses the replication of SARS-CoV-2 by selectively inhibiting 3CL protease. Recently, Shionogi announced ensitrelvir achieved the primary endpoint in the Phase 3 part of a Phase 2/3 study conducted in Asia. The study was conducted during the Omicron phase of the pandemic, making ensitrelvir the first investigational oral antiviral to demonstrate a statistically significant effect compared to placebo, a difference of 24 hours (p=0.04), in the time to resolution of five key typical Omicron-related symptoms (stuffy or runny nose, sore throat, cough, feeling hot or feverish, and low energy or tiredness). With regard to safety, ensitrelvir was well tolerated, and there were no serious adverse events or deaths in this study. The Phase 2b/3 part of a trial in Asian patients (mainly in Japan) with asymptomatic/mild symptoms is still in progress. The global Phase 3 trial (SCORPIO-HR) for SARS-CoV-2 infected patients is also underway.

About the Medicines Patent Pool

The Medicines Patent Pool (MPP) is a United Nations-backed public health organisation working to increase access to, and facilitate the development of, life-saving medicines for low- and middle-income countries. Through its innovative business model, MPP partners with civil society, governments, international organisations, industry, patient groups, and other stakeholders, to prioritise and license needed medicines and pool intellectual property to encourage generic manufacture and the development of new formulations. To date, MPP has signed agreements with 17 patent holders for 13 HIV antiretrovirals, one HIV technology platform, three hepatitis C direct-acting antivirals, a tuberculosis treatment, four long-acting technologies, three oral antiviral treatments for COVID-19 and 12 COVID-19 technologies. MPP was founded by Unitaid, which continues to be MPP's main funder. MPP's work on access to essential medicines is also funded by the Swiss Agency for Development and Cooperation (SDC). MPP's activities in COVID-19 are undertaken with the financial support of the Japanese Government, the French Ministry for Europe and Foreign Affairs, and SDC. More information at https://medicinespatentpool.org/ and follow us on Twitter, LinkedIn and YouTube.

About Shionogi

Shionogi & Co., Ltd. is a leading global research-driven pharmaceutical company based in Japan dedicated to bringing benefits to patients based on its corporate philosophy of "supplying the best possible medicine to protect the health and wellbeing of the patients we serve." The company has discovered and developed novel medicines for HIV, influenza and antimicrobial resistance and currently markets products in several therapeutic areas including anti-infectives with the first siderophore cephalosporin. Other therapeutic areas, and the focus of the company's pipeline, include CNS/psychoneurological diseases, oncology and pain. For more information on Shionogi & Co., Ltd., visit https://www.shionogi.com/global/en/.

Shionogi Inc. is the U.S. subsidiary of Shionogi & Co., Ltd. based in New Jersey. For more information on Shionogi Inc., please visit https://www.shionogi.com/us/en/.

Shionogi B.V. is the European headquarters of Shionogi & Co., Ltd. For more information on Shionogi B.V., please visit https://www.shionogi.com/eu/en/ .

Other partners

Ping An

Ping An Insurance (Group) Company of China, Ltd. is collaborating with Shionogi to develop ensitrelvir in Asia through their joint venture companies and both companies are committed to support access to medicines for patients living in low- and middle-income countries (LMICs). To help make ensitrelvir affordable and available to more people in Asia, Ping An Insurance (Group) Company of China, Ltd. supports the Shionogi collaboration with MPP.

Shionogi Media Contact:

SHIONOGI Website Inquiry Form: https://www.shionogi.com/global/en/contact.html

MPP Media Contact

press@medicinespatentpool.org (Geneva, Switzerland)

PSingh@burness.com (Washington, D.C., USA)