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Taiwan approves Japan-based Shionogi's influenza drug for paediatric use

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Xofluza is a first-in-class, single-dose oral medicine with an innovative mechanism of action

Japanese pharma behemoth Shionogi & Co. has announced that its group company Taiwan Shionogi has received approval of a supplemental New Drug Application (sNDA) for Xofluza (baloxavir marboxil) for the treatment and postexposure prophylaxis for influenza virus infection for paediatrics aged 5 to <12 years.

Xofluza is available for adults and children of ?12 years of age for treating influenza A or B virus acute infection and the postexposure prophylaxis of influenza in Taiwan. The newly approved indication extends the option for treating and preventing influenza virus infections to children aged 5 to <12 years, who weigh >20 kg, offering a new choice for managing influenza.

It is a first-in-class, single-dose oral medicine with an innovative mechanism of action that has demonstrated efficacy among several influenza viruses, including in vitro activity against oseltamivir-resistant and avian strains (H7N9, H5N1) in nonclinical studies. Xofluza is designed to inhibit the cap-dependent endonuclease protein, which is essential for viral replication and approved in >70 countries for treating influenza types A and B.

Xofluza was discovered by Shionogi and is being further developed and commercialised globally in collaboration with the Roche Group (including Genentech in the US) and Shionogi & Co.. Under this agreement, Roche holds worldwide rights of Xofluza, excluding Japan and Taiwan, which will be retained exclusively by Shionogi. Moreover, the Roche Group is preparing to apply for an expansion of the indication to include <1-year-old children.