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ASIA EDITION

FDA accepts Genentech's XOFLUZA for the treatment of Influenza

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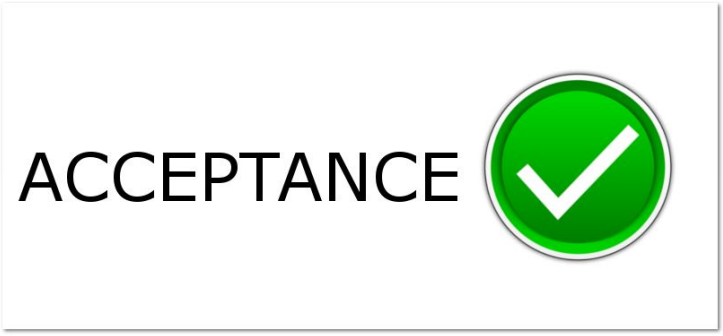
XOFLUZA would be the first antiviral medicine approved specifically for the high-risk population



Genentech, a member of the Roche Group has announced that the U.S. Food and Drug Administration (FDA) has accepted a supplemental New Drug Application (sNDA) for XOFLUZA (baloxavir marboxil) as a single-dose, oral treatment for people at high risk of complications from the flu. The Centers for Disease Control and Prevention (CDC) defines people at high risk for serious flu complications to include adults 65 years of age or older, or those who have conditions such as asthma, chronic lung disease, morbid obesity or heart disease. The FDA is expected to make a decision on approval by November 4, 2019.

“Influenza, or ‘flu,’ can be especially debilitating for people considered to be high risk, as they have an increased likelihood of serious complications, worsening of existing health problems and even hospitalization or death,” said Sandra Horning, M.D., chief medical officer and head of Global Product Development. “XOFLUZA is the first antiviral medicine to demonstrate a significant and clinically meaningful benefit in people at high risk of complications from the flu, for which there are currently no approved medicines.”

The sNDA is based on results from the Phase III CAPSTONE-2 study of a single dose of XOFLUZA compared with placebo or oseltamivir 75 mg, twice daily for five days, in people 12 years of age or older who are at high risk of complications from the flu.

The FDA approved XOFLUZA in October 2018 for the treatment of acute, uncomplicated influenza in people 12 years of age or older. It is the first and only single-dose oral medicine approved to treat the flu, and the first new flu medicine with a novel proposed mechanism of action in nearly 20 years.

XOFLUZA is a first-in-class, single-dose oral medicine with a novel proposed mechanism of action that has demonstrated efficacy in a wide range of influenza viruses, including in vitro activity against oseltamivir-resistant strains and avian strains (H7N9, H5N1) in non-clinical studies. Unlike other currently available antiviral treatments, XOFLUZA is the first in a new class of antivirals designed to inhibit polymerase acidic endonuclease, an enzyme essential for viral replication.

XOFLUZA will be further studied in a Phase III development program including pediatric populations, post-exposure prophylaxis and severely ill hospitalized people with influenza, as well as to assess the potential to reduce transmission in otherwise healthy people.

XOFLUZA was discovered by Shionogi & Co., Ltd. and is being further developed and commercialized globally in collaboration with the Roche Group (which includes Genentech in the U.S.) and Shionogi & Co., Ltd. Under the terms of this

agreement, Roche holds worldwide rights to XOFLUZA excluding Japan and Taiwan, which will be retained exclusively by Shionogi & Co., Ltd.