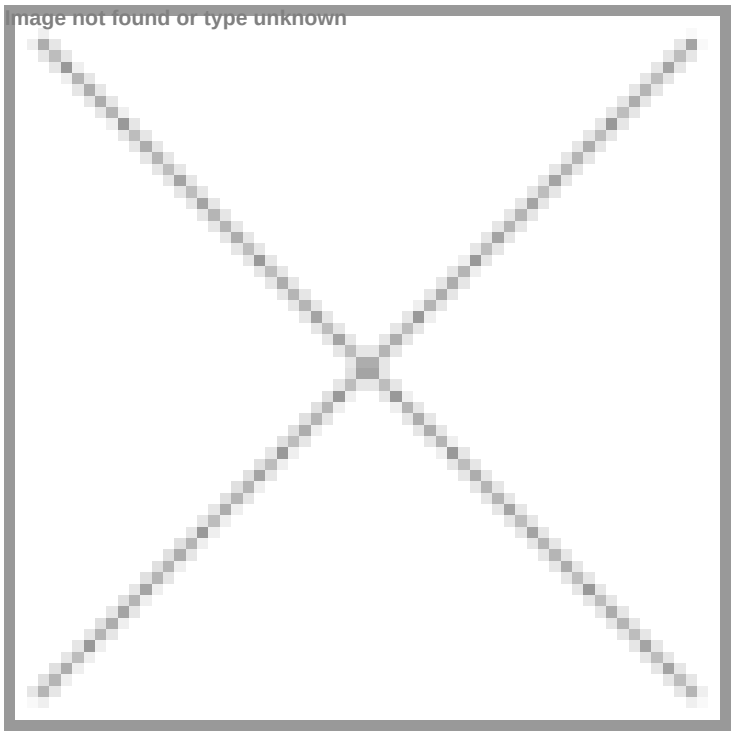
BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

Genentech announces meeting of primary endpoint of Ph III study

04 June 2019 | News

The study was conducted by Shionogi & Co., Ltd. during the 2018-2019 flu season in Japan.



Genentech, a member of the Roche Group has announced that the Phase III BLOCKSTONE study, conducted by Shionogi & Co. Ltd. met its primary endpoint showing that people exposed to a household member with influenza (flu) and treated preventatively with XOFLUZA (baloxavir marboxil) were significantly less likely to develop the disease compared to those treated with placebo (1.9% versus 13.6%, $p<0.0001$). Furthermore, XOFLUZA was well tolerated with no safety signals identified. Full results from the BLOCKSTONE study will be presented at an upcoming medical meeting.

“This positive Phase III study adds to robust existing clinical data for XOFLUZA, and is the first to show that a single treatment with XOFLUZA reduced the likelihood that people living with an infected household member would develop the flu,” said Sandra Horning, M.D., chief medical officer and head of Global Product Development. “Preventing otherwise healthy people from developing the flu virus will reduce the overall societal burden of disease, and we look forward to sharing these data with health authorities around the world.”

XOFLUZA is the first and only one-dose oral medicine approved to treat the flu, and the first new flu medicine approved by the U.S. Food and Drug Administration (FDA) with a novel proposed mechanism of action in nearly 20 years. XOFLUZA is also the only flu treatment with a new mechanism of action shown to be efficacious in both otherwise healthy people with the flu (in the CAPSTONE-1 study) and people at high risk of flu complications (in the CAPSTONE-2 study).

XOFLUZA is currently approved in Japan for the treatment of influenza types A and B in children, adolescents and adults,

and in the U.S. for the treatment of acute, uncomplicated influenza in people 12 years of age and older. In addition, the FDA recently accepted a supplemental New Drug Application (sNDA) for XOFLUZA as a one-dose oral treatment for people at high risk of complications from the flu, which includes adults 65 years of age or older, or those who have conditions such as asthma, chronic lung disease, morbid obesity or heart disease – for these people the flu can be particularly serious or deadly. The FDA is expected to decide on whether to approve this additional indication by November 4, 2019.

BLOCKSTONE is a Phase III, randomized, placebo-controlled, post-exposure prophylaxis study that evaluated a single dose of XOFLUZA compared with placebo in household members (adults and children) in Japan who are living with someone with an influenza infection confirmed by a rapid influenza diagnostic test (the 'index patient'). The study was conducted by Shionogi & Co., Ltd. during the 2018-2019 flu season in Japan.

Participants enrolled in the study were household members of someone who had been diagnosed with influenza. The participants were randomized to receive a single dose of XOFLUZA (dose according to body weight) or placebo as a preventative measure against developing influenza. The primary endpoint of the study was to evaluate the proportion of participants who tested positive for the influenza virus and had fever, and one or more respiratory symptoms between day one and ten.

XOFLUZA showed a significant prophylactic effect on influenza infection after a single oral dose in people exposed to an infected family member. The proportion of household members who became symptomatically ill following infection with flu was significantly lower in those treated preventively with XOFLUZA compared to those treated with placebo (proportion of subjects with influenza virus infection, fever and other influenza symptoms in the 10-day observation period: 1.9% versus 13.6%, $p<0.0001$). The incidence of adverse events was 22.2% and 20.5% in XOFLUZA and placebo respectively. No serious adverse events were reported for XOFLUZA. Secondary objectives were clinical efficacy, pharmacokinetics and safety and tolerability.