

## Roche's Xofluza approved for influenza treatment

February 2019—Roche announced that the FDA has approved Xofluza (baloxavir marboxil) for the treatment of acute, uncomplicated influenza in people 12 years of age and older. Xofluza is a single-dose oral medicine with a novel proposed mechanism of action that inhibits polymerase acidic endonuclease. Xofluza has demonstrated efficacy against a range of influenza viruses, including oseltamivir-resistant strains and avian strains (H7N9, H5N1) in nonclinical studies.

Xofluza was approved based on results from the phase three CAPSTONE-1 study of a single dose of Xofluza compared with placebo or oseltamivir 75 mg, twice daily for five days, in otherwise healthy people with the flu, as well as results from a placebo-controlled phase two study in otherwise healthy people with the flu. Xofluza significantly reduced the duration of flu symptoms compared with placebo and demonstrated similar efficacy compared with oseltamivir. In clinical trials, Xofluza was safe and well tolerated with a side effect profile similar to placebo.

[Roche](#), +41-61-688-1111