medicines patent pool

BALOXAVIR MARBOXIL

PANDEMIC & EPIDEMIC THREATS
INFLUENZA

Roche

DISEASE BURDEN

Worldwide, influenza annual epidemics are estimated to result in about 3 to 5 million cases of severe illness, and about 300 to 600 thousand respiratory deaths.

CLINICAL RELEVANCE

Baloxavir marboxil is approved by FDA for both the treatment and the prevention of influenza. A single-dose of baloxavir marboxil is safe and has superior efficacy to placebo and similar efficacy to oseltamivir (administered twice daily for 5 days) for ameliorating influenza symptoms in high-risk outpatients, with 86% reduction in risk of developing clinical influenza. Baloxavir marboxil could prove to be a useful tool for addressing pandemic preparedness.

INTELLECTUAL PROPERTY LANDSCAPE

Primary patents on baloxavir marboxil have been filed or granted in several LMICs and they are expected to expire between 2030-2036. Secondary patents may provide exclusivity in few LMICs until 2037.

SERVICE DELIVERY ENABLERS

Single oral administration, with no requirements for companion drugs, simplifies treatment delivery. Influenza testing is not mandatory, and prescription could be based on clinical judgment.

REGULATORY

Product approved by stringent regulatory authorities. Potential sublicensees of baloxavir marboxil could rely on mechanisms like USFDA Para III, Swissmedic MAGHP, EU-M4all or WHO Prequalification (if included) for quality assurance. Bioequivalence studies are necessary. Biowaivers will not be an option.

MANUFACTURING

The production involves a standard manufacturing process for tablets. There are no challenges with respect to excipients or final packaging. Probable OEB category 4, special facility might be required. Shelf life is at least 3 years at room temperature.

MARKET

The product is currently available in a small number of LMICs at prices that are generally higher than oseltamivir. Based on an analysis of data of sales in HICs and UMICs where it is available, its price would be beyond the reach of most people and could potentially constitute a constraint on the ability of health systems in LMICs to respond to a possible influenza pandemic outbreak.