BALOXAVIR MARBOXIL

PANDEMIC & EPIDEMIC THREATS
INFLUENZA

Roche

CLINICAL RELEVANCE

Baloxavir marboxil is an USFDA-approved oral antiviral for both the treatment and prevention of influenza. It allows for a single-dose, one-time administration, with superior efficacy compared to placebo and similar efficacy to oseltamivir (administered twice daily for 5 days) in reducing influenza symptoms in high-risk outpatients, showing an 86% reduction in the risk of developing clinical influenza. Baloxavir has also the potential to reduce influenza transmission due to a rapid effect in decreasing viral shedding. Baloxavir is also valuable in pandemic preparedness for highly virulent strains, as it provides an option against viruses resistant to other antivirals. The WHO includes baloxavir in its revised influenza guidelines, with a conditional recommendation for its use in people with suspected or confirmed non-severe influenza at high risk of progression to severe illness. It is also recommended for asymptomatic individuals exposed to zoonotic influenza viruses like H5N1, which are associated with high mortality.

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. The increasing global risk of species jumps highlights the importance of preparedness for a rapid coordinated response to contain epidemic spread.

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 2039.

SERVICE DELIVERY ENABLERS

A single oral dose, without the need for companion drugs, simplifies treatment delivery. For patients with suspected non-severe influenza who are at high risk of progressing to severe disease, WHO recommends rapid diagnostic testing. The need for performing a test could pose some challenges. Influenza tests may not be accessible in many LMICs settings. Additionally, while these tests can deliver results within 30 minutes, their accuracy depends on proper specimen collection, storage, and transport. Timing is also crucial, as baloxavir must be administered within 48 hours of symptom onset.

REGULATORY

The product is 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 related to excipients or final packaging. As it is a probable occupational exposure band (OEB) category 4, a special facility might be required. Shelf life is at least three 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.

EU-M4All: The European Medicines Agency (EMA), in cooperation with the World Health Organization (WHO), can provide scientific opinions on high priority human medicines, including vaccines, that are intended for markets outside of the European Union (EU). The procedure is called EU-Medicines for all or 'EU-M4all'; LMICs: low-income, lower middle-income and upper middle-income countries as per World Bank classification; OEB: occupational exposure band; Swissmedic MAGHP: Swissmedic procedure for scientific advice and Marketing Authorisation for Global Health Products; USFDA: The United States Food and Drug Administration; WHO: The World Health Organization