Generic Name:
Tafenoquine
Trade Name:
Krintafel
Company:
GSK and Medicines for Malaria Venture
Notes:

GSK and Medicines for Malaria Venture announced FDA approval of single-dose tafenoquine for the radical cure (prevention of relapse) of *Plasmodium vivax* malaria in patients aged 16 years and older who are receiving appropriate antimalarial therapy for acute *P. vivax* infection.

Tafenoquine is an 8-aminoquinoline derivative with activity against all stages of the *P. vivax* life cycle, including hypnozoites. It was first synthesised by scientists at the Walter Reed Army Institute of Research in 1978.

Approval was based on efficacy and safety data from a comprehensive global clinical development *P. vivax* radical cure program designed in agreement with FDA. Thirteen studies in healthy volunteers and patients directly supported the program.

The primary evidence for clinical efficacy and safety of the 300-mg single dose was provided by three randomized, double-blind studies: DETECTIVE Part 1 and Part 2 (TAF112582) and GATHER (TAF116564) involving 800 participants. Results of the two Phase III studies were announced in June 2017. The submission included data analyzed from 33 studies involving more than 4,000 trial participants treated with the 300-mg single-dose and other doses of tafenoquine.

The most common adverse reactions (5%) observed in clinical trials were dizziness, nausea, vomiting, headache, and decreased hemoglobin.

Medication Monitor Categories:
New Drug Approvals