Arakoda™ (tafenoquine) – New drug approval

- On August 9, 2018, 60 Degrees Pharmaceuticals announced the FDA approval of Arakoda (tafenoquine), for the prophylaxis of malaria in patients aged 18 years and older.

- According to the World Health Organization, there were an estimated 216 million cases of malaria worldwide in 2016, including 445,000 fatalities.

- Arakoda is active against pre-erythrocytic (liver) and erythrocytic (asexual) forms as well as gametocytes of *Plasmodium* species that include *P. vivax* and *P. falciparum*. The activity of tafenoquine against the pre-erythrocytic liver stages of the parasite prevents the development of the erythrocytic forms.

- The first tafenoquine product to be approved by the FDA was Krintafel™, for the radical cure (prevention of relapse) of *P. vivax* malaria in patients aged 16 years and older who are receiving appropriate antimalarial therapy for acute *P. vivax* infection. Launch of Krintafel is currently pending.

- The pivotal trials evaluating the safety and efficacy of Arakoda included three placebo-controlled clinical trials, as well as one trial comparing Arakoda to mefloquine.

    — All three placebo-controlled trials showed that Arakoda was statistically significantly better at preventing the incidence of parasitemia compared to placebo.
    — In the last trial, all patients treated with Arakoda and mefloquine were free of malaria during the 26-week prophylactic phase. However, since the precise degree of exposure to malaria in study subjects is unknown, this study provides only supportive evidence of efficacy.

- Arakoda is contraindicated in patients with glucose-6-phosphate dehydrogenase (G6PD) deficiency or unknown G6PD status due to the risk of hemolytic anemia; breastfeeding by a lactating woman when the infant is found to be G6PD deficient or if G6PD status is unknown; patients with a history of psychotic disorders or current psychotic symptoms; and patients with known hypersensitivity reactions to tafenoquine, other 8-aminoquinolines, or any component of Arakoda.

- Other warnings and precautions include hemolytic anemia, methemoglobinemia, psychiatric effects, hypersensitivity reactions, and delayed adverse reactions.

- The most common adverse reactions (incidence ≥ 1%) with Arakoda use were headache, dizziness, back pain, diarrhea, nausea, vomiting, increased alanine aminotransferase, motion sickness, insomnia, depression, abnormal dreams, and anxiety.

- The recommended oral dosage of Arakoda is as follows:

Regimen name	Timing	Dosage
Loading regimen	For each of the 3 days before travel to a malarious area	200 mg (2 of the 100 mg tablets) once daily for 3 days
Maintenance regimen	While in the malarious area	200 mg (2 of the 100 mg tablets) once weekly – start 7 days after the last loading regimen dose

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Terminal prophylaxis regimen	In the week following exit from the malarious area	200 mg (2 of the 100 mg tablets) one-time 7 days after the last maintenance dose

  - All patients must be tested for G6PD deficiency prior to prescribing Arakoda.
  - Pregnancy testing is recommended for females of reproductive potential prior to initiating treatment with Arakoda.
  - Swallow the tablet whole. Do not break, crush, or chew the tablets.
  - Complete the full course of Arakoda including the loading dose and the terminal dose.

- 60 Degrees' launch plans for Arakoda are pending. Arakoda will be available as 100 mg tablets.