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## **US Food and Drug Administration Approves ARAKODA™ (tafenoquine) tablets for oral use; First preventative antimalarial approved in almost two decades**

WASHINGTON, August 9, 2018: 60 Degrees Pharmaceuticals (60P) announced today the U.S. Food and Drug Administration (FDA) approval of ARAKODA™ (tafenoquine) tablets for the prevention of malaria in patients aged 18 years and older. For the first time in more than eighteen years, the U.S. FDA approved a new drug for the prevention of malaria.

Millions of healthy individuals travel to areas where malaria is endemic, including those traveling for leisure, employees of non-governmental organizations, industrial and business workers, and military forces. ARAKODA™ has the potential to protect thousands of U.S. travelers from the devastating and life-threatening effects of malaria.

The marketing approval of ARAKODA™ is the culmination of years of scientific discovery and research by experts in the field of Malariology and Infectious Disease. Tafenoquine was originally discovered by scientists at the Walter Reed Army Institute of Research (WRAIR). The approval was based on a concerted effort by the U.S. Army and 60P, involving over 21 clinical trials and over 3,100 trial subjects, to develop tafenoquine as a weekly prophylactic drug for the prevention of malaria.

“We have worked closely with the U.S. Army as their commercial partners to bring ARAKODA™ to the U.S. market”, said Geoffrey Dow, Ph.D, CEO of 60P. “ARAKODA™ provides effective protection against both of the major types of malaria (*P. vivax* and *P. falciparum*), killing the parasites in both the blood and liver.” Dow continued, “this provides the travel medicine community the option to prescribe an anti-malarial which provides protection in a large spectrum of malaria hot zones while utilizing what is considered by many physicians to be a more compliant dosing regimen. ARAKODA™ is a significant addition to the armamentarium for the prevention of malaria.”

MAJ Victor Zottig, the product manager of tafenoquine for the U.S. Army Medical Materiel Development Activity stated “the FDA approval is a tremendous achievement for 60P and the U.S. military for their long, dedicated effort in the global protection of Service Members and civilian personnel against malaria.”

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ARAKODA™ is supplied in 100 mg tablets for oral use only. After an initial loading dose prior to traveling, ARAKODA™ is intended to be taken once a week which could offer convenience to the traveler.

The U.S. FDA Anti-Microbial Drugs Advisory Committee recently recommended the approval of ARAKODA™ for the prevention of malaria based on its safety and efficacy profile. 60P has committed to the U.S. FDA to perform post-marketing safety surveillance studies to continue to gather data on this important tool against malaria.

## Important Safety Information

### Contraindications

ARAKODA™ should not be administered to:

- G6PD deficiency or unknown G6PD status
- 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
- Known hypersensitivity reactions to tafenoquine, other 8-aminoquinolines, or any component of ARAKODA™

### Warnings and Precautions

- **Hemolytic Anemia:** G6PD testing must be performed before prescribing ARAKODA™ due to the risk of hemolytic anemia. Monitor patients for signs or symptoms of hemolysis.
- **G6PD Deficiency in Pregnancy or Lactation:** ARAKODA™ may cause fetal harm when administered to a pregnant woman with a G6PD-deficient fetus. ARAKODA™ is not recommended during pregnancy. A G6PD-deficient infant may be at risk for hemolytic anemia from exposure to ARAKODA™ through breast milk. Check infant's G6PD status before breastfeeding begins.
- **Methemoglobinemia:** Asymptomatic elevations in blood methemoglobin have been observed. Initiate appropriate therapy if signs or symptoms of methemoglobinemia occur.
- **Psychiatric Effects:** Serious psychotic adverse reactions have been observed in patients with a history of psychosis or schizophrenia, at doses different from the approved dose. If psychotic symptoms (hallucinations, delusions, or grossly disorganized thinking or behavior) occur, consider discontinuation of ARAKODA™ therapy and, evaluation by a mental health professional as soon as possible.
- **Hypersensitivity Reactions:** Serious hypersensitivity reactions have been observed with administration of ARAKODA™. If hypersensitivity reactions occur, institute appropriate therapy.
- **Delayed Adverse Reactions:** Due to the long half-life of ARAKODA™ (approximately 17 days), psychiatric effects, hemolytic anemia, methemoglobinemia, and hypersensitivity reactions may be delayed in onset and/or duration.

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### **Adverse Reactions**

The most common adverse reactions (incidence  $\geq 1\%$ ) were: headache, dizziness, back pain, diarrhea, nausea, vomiting, increased alanine aminotransferase (ALT), motion sickness, insomnia, depression, abnormal dreams and anxiety.

### **Drug Interactions**

Avoid co-administration with drugs that are substrates of organic cation transporter-2 (OCT2) or multidrug and toxin extrusion (MATE) transporters.

### **Use in Specific Populations**

Lactation: Advise women not to breastfeed a G6PD-deficient infant or infant with unknown G6PD status during treatment and for 3 months after the last dose of ARAKODA™.

To report SUSPECTED ADVERSE REACTIONS, contact 60 Degrees Pharmaceuticals at 1-888-834-0225 or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch)

### **About malaria**

Malaria, a life-threatening disease transmitted through the bite of an infected mosquito, caused an estimated 429,000 fatalities and 212 million clinical cases in 2015, according to the CDC. Malaria cases among travelers returning to the U.S. have been trending upwards.<sup>1</sup>

### **About ARAKODA™**

Tafenoquine is an 8-aminoquinoline chemically derived from Primaquine, with activity against all types of malaria. It was first synthesized by scientists at WRAIR in 1978.

60P entered into a cooperative research and development agreement with the U.S. Army Medical Materiel Development Activity (USAMMDA) in 2014 to develop tafenoquine as a weekly prophylactic drug for the prevention of malaria. Since malaria is the top infectious disease threat to U.S. military Service Members overseas, the military maintains a robust anti-malarial drug development effort through internal research and commercial partnerships. The FDA approval is a culmination of over 30 years of research and development with the U.S. Army Medical Research and Materiel Command, from the discovery of tafenoquine at WRAIR through the current collaboration between 60P and USAMMDA.

### **About 60P**

60P, founded in 2010, focuses on discovering, developing and distributing new medicines for treatment and prevention of tropical diseases, including malaria and dengue. 60P's mission is supported through in-kind funding from the U.S. Department of Defense. The company also collaborates with prominent research organizations in the U.S., Australia and Singapore. In addition, 60P has been funded by Knight Therapeutics Inc. (TSX:GUD), a Canadian specialty pharmaceutical company that obtained FDA approval for Impavido, a product for leishmaniasis which is a tropical

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disease. 60P is headquartered in Washington D.C., with a subsidiary in Australia.

Further information is available on the company's website, [www.60degreespharma.com](http://www.60degreespharma.com) .

The statements contained herein may include prospects, statements of future expectations and other forward-looking statements that are based on management's current views and assumptions and involve known and unknown risks and uncertainties. Actual results, performance or events may differ materially from those expressed or implied in such forward-looking statements.

The statements expressed herein are those of 60P and do not necessarily represent those of the U.S. Department of Defense or Department of the Army.

1 Cullen KA, Mace KE, Arguin PM. Malaria Surveillance-United States, 2013 MMWR Surveillance Summary 2016:65 (No.SS-2);1-22 DOI: <http://dx.doi.org/10.15585/mmwr.SS6502a1>