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60 Degrees Pharmaceuticals, LLC
Washington DC USA
Contact: Doug Loock Phone: 202.327.5422
inquiries@60-p.com

Arakoda™ (tafenoquine) tablets, first prescription drug approved for malaria prevention by US FDA in over 18 years, now available in US

WASHINGTON – Nov. 21, 2019 – 60 Degrees Pharmaceuticals (60P) has initiated distribution of Arakoda™ (tafenoquine) into the US healthcare marketplace. This significant milestone complements the regulatory approval of Arakoda™ by the United States Food and Drug Administration (FDA).

Arakoda (tafenoquine) is approved for the prevention of malaria in adults and was the first anti-malarial product approved for prevention in over 18 years. Arakoda has the potential to protect thousands of U.S. travelers and military personnel from the devastating and life-threatening effects of malaria.

60P's first significant shipment of Arakoda occurred in September, 2019, to the U.S. Army. The product is now commercially available via select retail pharmacy outlets and pharmaceutical wholesalers. 60P continues to work closely with distribution networks and third-party insurance companies to provide extensive access to the product.

"Malaria is one of the most malicious diseases, on the rise in both U.S. and other parts of the world," said Geoffrey Dow, chief executive officer of 60P Pharmaceuticals. "It poses a significant risk to millions of healthy individuals traveling to areas where malaria is endemic, including those traveling for leisure, employees of non-governmental organizations, industrial and business workers, and military forces."

Arakoda™ (tafenoquine) Patent Issued to 60P by USPTO

Earlier this year the U.S. Patent and Trademark Office (USPTO) issued a patent covering the use of Arakoda (tafenoquine) tablets for the prevention of symptomatic *Plasmodium falciparum* malaria in human subjects. *P. falciparum* is present everywhere where prophylactic malaria drugs are prescribed for travelers and is the cause of most of the deaths from malaria among travelers returning from malaria hot zones (to the US). The patent summary is now listed in the US FDA The Orange Book (https://www.accessdata.fda.gov/scripts/cder/ob/patent_info.cfm?Product_No=001&Appl_No=210607&Appl_type=N).

The marketing approval of Arakoda was the culmination of years of scientific discovery and research by experts in the field of Malariology and Infectious Disease. Tafenoquine was 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 25 clinical trials and over 3,000 trial subjects, to develop tafenoquine as a weekly prophylactic drug for the prevention of malaria.

The patent's term will extend to 2035 and will provide 60P and its commercial partner, the US Army, with protection for a product which has been under development for a long time and for which significant financial resources have been invested. Corresponding patent applications are in prosecution in Europe, Canada, Australia and elsewhere.

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.

For Full Prescribing Information go to: https://arakoda.com

For ordering information call 202-327-5422 or e-mail: www.inquiries@60-p.com

If you should have medical or technical questions regarding ARAKODA (tafenoquine), please don't hesitate to call 1-888-834-0225.

Important Safety Information

Contraindications

- 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.

Adverse Reactions

The most common adverse reactions (incidence $\geqslant$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

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.[1]

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.

About ARAKODA™

ARAKODA contains tafenoquine as its active ingredient. 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 a significant 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. 60P is headquartered in Washington D.C., with a subsidiary in Australia. Further information is available on the company's website, **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.

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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 -#-