ARAKODA® (tafenoquine) clinical safety, tolerability confirmed in long-term safety study; results published in *Tropical Medicine and Infectious Disease*

- Results of a long-term safety study of the clinical safety and tolerability of ARAKODA® (tafenoquine) have been published in *Travel Medicine and Infectious Disease*.
- **ARAKODA**, marketed in the U.S by 60 Degrees Pharmaceuticals since 2019, is an anti-malarial indicated for the prophylaxis of malaria in patients aged 18 years of age and older.
- The study found **ARAKODA** administered for 12 months to healthy volunteers to be generally safe and well tolerated without increased risk of psychiatric or clinically significant ophthalmologic adverse events.
- **ARAKODA** addresses an unmet need for a safe medication administered weekly during travel, that prevents malaria among international travelers and U.S. government personnel deployed to tropical countries everywhere in the world.

WASHINGTON, D.C. — November 19, 2021. Results of a long-term safety study of ARAKODA® (tafenoquine) in healthy volunteers have been published in the peer-reviewed journal *Travel Medicine and Infectious Disease,* according to 60 Degrees Pharmaceuticals, LLC (60P), a pharmaceutical company focused on developing new medicines for tropical diseases.

ARAKODA is an anti-malarial indicated for the prophylaxis of malaria in patients aged 18 years of age and older.

The study, Long-Term Safety Study of Tafenoquine, was a randomized, prospective, double-blind, placebo-controlled study in which ophthalmologic, psychiatric and neurologic and general safety endpoints were evaluated. A total of 601 adult volunteers were randomized [~1:1] to receive tafenoquine or placebo weekly for 12 months following a three-day loading dose. Participants were followed for up to six months following completion of dosing to monitor adverse events.

The study found **ARAKODA** (tafenoquine) administered for 12 months to be generally safe and well tolerated. When administered according to prescribing information, there was no difference observed between **ARAKODA** (tafenoquine) and placebo in terms of the incidence of serious ophthalmologic safety events (the primary endpoint of the study), and no elevated risk of psychiatric events over 12 months of dosing was observed.

“We are pleased to see, as expected based on previous peer-reviewed research, that **ARAKODA** (tafenoquine), when used as directed, does not appear to increase the risk of psychiatric or clinically significant ophthalmologic adverse events,” said Geoffrey Dow, Chief Executive Officer of 60P. “As such, healthcare providers who prescribe **ARAKODA** to prevent malaria in their patients can take an added measure of comfort that this therapy is safe and well tolerated.”

About ARAKODA®

Tafenoquine was discovered by Walter Reed Army Institute of Research and the current study was funded by the United States Army Medical & Materiel Development Activity [USAMMDA]. Tafenoquine was approved for malaria prophylaxis in 2018 in the United States as **ARAKODA** (tafenoquine) and in Australia as KODATEF®. Both were commercially launched in 2019 and are currently distributed through pharmaceutical wholesaler networks in each respective country. They are available at retail pharmacies as a prescription-only malaria prevention drug.

According to the Centers for Disease Control and Prevention, the long terminal half-life of tafenoquine, which is approximately 16 days, may offer potential advantages in less-frequent dosing for prophylaxis for malaria. At approved doses in healthy individuals, tafenoquine does not prolong cardiac repolarization [QTC interval].

ARAKODA is not suitable for everyone, and patients and prescribers should review the **Important Safety Information** below.

ARAKODA (tafenoquine) Important Safety Information

ARAKODA is an antimalarial indicated for the prophylaxis of malaria in patients aged 18 years of age and older.

Contraindications

ARAKODA should not be administered to:

- Glucose-6-phosphate dehydrogenase (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 ≥1 percent) 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. **ARAKODA** full prescribing information is here.

About 60 Degrees Pharmaceuticals

60 Degrees Pharmaceuticals (60P), founded in 2010, focuses on developing 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. and Australia. 60P is headquartered in Washington D.C., with a subsidiary in Australia. Further information is available on the company's website, www.60degreespharma.com.

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