60 Degrees Pharmaceuticals Announces Completion of Long-Term Safety Assessment of ARAKODA® (tafenoquine) in Healthy Adult Volunteers

WASHINGTON, D.C.—August 5th, 2021. 60 Degrees Pharmaceuticals, LLC (60P), a pharmaceutical company focused on developing new medicines for tropical diseases and travel medicine, announced today that a long-term safety study of **ARAKODA®** (tafenoquine) in healthy volunteers has been completed.

The study [NCT0332174, see trial design at: Long-Term Safety Study of Tafenoquine - Full Text View - ClinicalTrials.gov] was a randomized, prospective, double-blind, placebo-controlled study, in which ophthalmologic, psychiatric, neurologic, and general safety endpoints were evaluated. A total of 600 volunteers were randomized [~1:1] to receive tafenoquine or placebo weekly for 12 months following a three-day loading dose. Participants were followed for at least three 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. A manuscript is in preparation and will be submitted to a peer reviewed journal for publication and dissemination.

Tafenoquine was originally discovered by Walter Reed Army Institute of Research and this study was funded by the United States Army Medical and Materiel Development Activity [USAMMDA]. It was approved for malaria prophylaxis in 2018 in the United States as **ARAKODA®** and Australia as **KODATEF®**. Both were commercially launched in 2019 and currently distributed through pharmaceutical wholesaler networks in each respective country. They are available at retail pharmacies as a prescription-only malaria prevention drug for adults 18 and older.

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

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

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%) 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 in Australia contact Biocelect at 1-300-848-628.

About 60 Degrees Pharmaceuticals

60 Degrees Pharmaceuticals, 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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[i] https://wwwnc.cdc.gov/travel/news-announcements/tafenoquine-malaria-prophylaxis-and-treatment

[ii] Green JA, Patel AK, Patel BR, Hussaini A, Harrell EJ, McDonald MJ, Carter N, Mohamed K, Duparc S, Miller AK. 2014. Tafenoquine as therapeutic concentrations does not prolong Fridericia-corrected QT interval in healthy subjects. J Clin Pharmacol 54:995-1005.