Data Safety Monitoring Board Recommends Completion of Phase II Study to Evaluate the Efficacy and Safety of ARAKODA® (tafenoquine) for Treatment of Mild-Moderate Covid-19 Disease

WASHINGTON, D.C.—October 8, 2021. 60 Degrees Pharmaceuticals, LLC (60P), a pharmaceutical company focused on developing new medicines for infectious diseases, announced today that a Data Safety Monitoring Board had recommended continuation of its clinical trial that is evaluating the safety and efficacy of **ARAKODA®** (tafenoquine) for the treatment of mild-moderate COVID-19 disease in adults aged 18 years of age and older [see details of the study at: Tafenoquine in Patients With Mild to Moderate COVID-19 - Full Text View - ClinicalTrials.gov].

The trial has the goal of randomizing up to 275 ambulatory patients with confirmed COVID-19 disease into two treatment groups, half of whom will receive tafenoquine and half placebo. Clinical recovery within 14 days of treatment is being evaluated as the primary endpoint. A protocol mandated futility analysis based on efficacy was conducted by the study's Data Safety Monitoring Board, after approximately one third of subjects completed their Day 14 visit. The DSMB recommended completion of the study after conducting the analysis.

"Based on this recommendation, we are hopeful that **ARAKODA®** (tafenoquine) may have potential to be effective in the treatment pathway for COVID-19 and look forward to the complete trial results," said Geoffrey Dow, CEO of 60P.

60P is seeking partners to complete the research, development, and, potentially, future commercialization of **ARAKODA®** (tafenoquine) for additional indications.

ARAKODA® (tafenoquine) has not been proven safe to treat or prevent COVID-19. Testing for G6PD (Glucose-6-phosphate dehydrogenase deficiency) is mandatory before prescribing **ARAKODA®**.

The clinical study was funded by 60 Degrees Pharmaceuticals LLC and the DOD's Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense's (JPEO-CBRND) Joint Project Manager for Chemical, Biological, Radiological and Nuclear Medical's (JPM CBRN Medical), with the goal of fielding a safe, effective treatment against COVID-19 by repurposing the FDA-approved drug.

Tafenoquine was originally discovered by Walter Reed Army Institute of Research. The U.S. Army Medical Materiel Development Activity (USAMMDA) and 60P first entered into a cooperative research and development agreement in 2014, to develop tafenoquine as a weekly prophylactic drug for the prevention of malaria. After becoming the first anti-malarial product in over 18 years to gain approval from the FDA, 60P made their first significant shipment of tafenoquine to the U.S. Army in 2019. **ARAKODA®** is distributed through pharmaceutical wholesaler networks in the U.S. and is available at retail pharmacies as a prescription-only malaria prevention drug.

According to the CDC, the long terminal half-life of tafenoquine 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.

ARAKODA® (tafenoquine) Indication and 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.

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.

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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.