60 Degrees Pharmaceuticals Awarded U.S. Patent Covering Tafenoquine for Treatment of COVID-19 and Other Lung Infections

- Patent provides exclusive use through 2040 of **tafenoquine** for treatment of COVID-19 and other lung infections. **Tafenoquine** is the active molecule in 60P's FDA-approved drug for malaria prevention, ARAKODA®.
- Data from a Phase II study completed last year suggest a positive therapeutic signal in mild-moderate COVID-19 disease using the ARAKODA regimen of **tafenoquine**.
- Later this year the Company will launch a Phase IIB study enrolling COVID-19 patients in 30 U.S. outpatient clinics.
- 60P expects Phase IIB study will demonstrate ARAKODA regimen of **tafenoquine** accelerates time to sustained clinical recovery from COVID-19 symptoms.

Washington D.C., April 26, 2023 – 60 Degrees Pharmaceuticals ("60P"), specialists in developing and marketing medicines for infectious diseases, today announced that the United States Patent and Trademark Office (USPTO) has issued a patent covering the use of **tafenoquine** as a treatment for COVID-19 disease. **Tafenoquine** is the active molecule in the Company's FDA-approved regimen for malaria prevention, ARAKODA®.

60P now owns the exclusive rights for the use of **tafenoquine** for treatment of viral lung infections including COVID-19 in the U.S. through 2040.

ARAKODA, an oral tablet containing 100 mg of a **tafenoquine** base, is indicated for the prophylaxis of malaria in patients aged 18 years and older for up to 6 months of continuous dosing in the U.S. ARAKODA is not currently FDA-approved for the treatment of symptoms caused by the COVID-19 virus.

60P plans to conduct a double-blind, randomized, placebo-controlled Phase IIB trial to study the efficacy of the ARAKODA regimen of **tafenoquine** in COVID-19 patients with mild-moderate symptoms and low risk of disease progression. The primary endpoint of the Phase IIB study will be time to sustained clinical recovery from COVID-19

symptoms. The study will enroll patients in 30 out-patient clinics across the U.S. The Company is also planning a larger study that will commence in 2024.

Data from a Phase II study published in New Microbes and New Infections, Vol. 47, April – May 2022, a peer-reviewed, open-access journal, suggested a positive therapeutic signal in mild-moderate COVID-19 disease using the ARAKODA regimen of **tafenoquine**; the time to clinical recovery from COVID-19 symptoms was accelerated by about 2 – 2.5 days in the **tafenoquine** arm.

Public health interest in combating COVID-19 remains high. Currently marketed FDA-approved oral COVID-19 therapeutics are not appropriate for use by at least 25 percent of the U.S. population who do not have risk factors for progression to severe disease or by travelers who may wish to protect themselves from COVID-19 for extended periods – an unaddressed multi-billion-dollar market opportunity.

60P is optimistic that the ARAKODA regimen of **tafenoquine** will play an important role in public health efforts to address gaps in the standard of care for COVID-19.

About the ARAKODA® Regimen of Tafenoquine for COVID-19

Clinical trial data suggesting the ARAKODA® regimen of **tafenoquine** exhibits a positive therapeutic signal in mild-moderate COVID-19 disease were published last year in New Microbes and New Infections, Vol. 47, April – May 2022, a peer-reviewed, open-access journal. The drug increased the proportion of clinically recovered patients by between 9 percent (intent to treat population) and 14 percent (per protocol population); the drug decreased the proportion of clinically unrecovered patients by between 27 percent (intent to treat population) and 47 percent (per protocol population) but was underpowered to show statistical significance for the primary endpoint due to early termination of the study at n=86 patients. Results also showed that time to clinical recovery from COVID-19 symptoms was accelerated by about 2 – 2.5 days in the **tafenoquine** arm of the double-blind, randomized, placebo-controlled Phase II study.

About ARAKODA® (tafenoquine)

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. **Tafenoquine** was approved for malaria prophylaxis in 2018 in the United States as ARAKODA® 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. It has been shown that **tafenoquine** inhibits SARS-CoV-2 replication in monkey kidney and human epithelial cells, and pharmacokinetic simulations suggest lung levels at the FDA-approved dose for malaria prevention may exceed the EC90 of the 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. **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.

Important Safety Information

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

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 Degree Pharmaceuticals, Inc.

60 Degrees Pharmaceuticals, Inc., founded in 2010, focuses on discovering, developing and distributing new medicines for the treatment and prevention of tropical diseases, including malaria and dengue. 60P's mission is supported through in-kind funding from

the United States 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, a tropical disease, and monetized a PRV. 60P is headquartered in Washington D.C., with a majority-owned subsidiary in Australia. Learn more at www.60degreespharma.com.

Forward-Looking Statements

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. Factors or events that could cause our actual results to differ may emerge from time to time, and it is not possible for us to predict all of them. The statements expressed herein are those of 60P and do not necessarily represent those of the United States Department of Defense or the Department of the United States Army.

Forward-looking terminology, such as “may,” “will,” “should,” “expect,” “anticipate,” “project,” “estimate,” “intend,” “continue” or “believe” or the negatives thereof, or other variations thereon or comparable terminology, may discuss our plans, strategies, prospects and expectations concerning our business, operating results, financial condition and other similar matters. However, we are not able to predict accurately or control these matters. Any forward-looking statement made by us in this press release speaks only as of the date on which we make it. We undertake no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

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