60 Degrees Pharmaceuticals Receives Additional U.S. Patent Covering Tafenoquine for Prevention of Plasmodium Falciparum Malaria

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- 60P was awarded additional U.S. patent protection to further solidify its exclusive rights through 2035 for **tafenoquine** for prevention of *Plasmodium falciparum* malaria in naïve individuals
- **Tafenoquine** kills dormant liver stage of *P. vivax* parasite and clears the blood stages of *P. falciparum*

WASHINGTON, Aug. 22, 2023 (GLOBE NEWSWIRE) -- 60 Degrees Pharmaceuticals ("60P") (Nasdaq: SXTP), specialists in developing and marketing medicines for infectious diseases, today announced that the United States Patent and Trademark Office (USPTO) has awarded 60P a patent covering the use of **tafenoquine** for prevention of *Plasmodium falciparum* malaria. **Tafenoquine** is the active molecule in ARAKODA®, the Company's FDA-approved drug for malaria prevention in individuals aged 18 years and older for up to six months of continuous dosing.

Travelers from and residents of the United States are usually malaria naïve, that is, they have not previously contracted malaria and thus lack immunity to the disease. When contracted by these individuals, malaria can be a life-threatening disease.

"Securing this patent is important for 60P," said Chief Executive Officer, Geoff Dow. "It ensures that 60P can continue to maintain a long-term competitive position for the regimen of **tafenoquine** known as ARAKODA in the U.S. marketplace. **Tafenoquine** is effective against *all* species and stages of malaria. Furthermore, physicians can administer it weekly during travel. The current market leading malaria drugs do not kill latent vivax liver stages and must be given daily. We are pleased to have secured this additional patent on **tafenoquine**."

There were 1,823 symptomatic malaria cases in the United States in 2018 and the overall rate of cases is increasing. In the U.S., 95 percent of malaria cases occurring in returning travelers were in individuals who reported not taking, or failing to adhere to, CDC-recommended malaria chemoprophylactic regimens.

No useful vaccine against malaria is approved in the U.S. Therefore, the CDC recommends the use of malaria chemoprophylactic drugs during travel. Local malaria transmission has become an increasing problem in the United States; Texas, Maryland and Florida have reported a total of nine such cases to date in 2023, prompting a Centers for Disease Control and Prevention (CDC) health warning. The Maryland case involved the parasite *Plasmodium falciparum*, according to the Maryland Department of Health.

60P initially received a U.S. patent in 2019 for **tafenoquine** for the prevention of *P. falciparum* malaria in naïve individuals aged 18 years of age or older. The current patent award is a continuation of the application for that original patent.

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.

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.

Individuals at risk of contracting malaria are prescribed ARAKODA 2 x 100 mg tablets once per day for three days (the loading phase) prior to travel to an area of the world where malaria is endemic, 2 x 100 mg tablets weekly for up to six months during travel, then 2 x 100 mg in the week following travel.

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, specializes in developing and marketing new medicines for the treatment and prevention of infectious diseases that affect the lives of millions of people. 60P achieved FDA approval of its lead product, ARAKODA ® (tafenoquine), for malaria prevention, in 2018. 60P also collaborates with prominent research organizations in the U.S., Australia and Singapore. 60P's mission has been supported through in-kind funding from the United States Department of Defense and private investment from Knight Therapeutics Inc., a Canadian-based pan American specialty pharmaceutical company. 60P is headquartered in Washington D.C., with a majority-owned subsidiary in Australia. Learn more at www.60degreespharma.com.

Cautionary Note Regarding Forward-Looking Statements
This press release may contain "forward-looking statements" within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. Forward-looking statements reflect the current view about future events. When used in this press release, the words "anticipate," "believe," "estimate," "expect," "future," "intend," "plan," or the negative of these terms and similar expressions, as they relate to us or our management, identify forward-looking statements. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, projections, anticipated events and trends, the economy and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of our control. Our actual results and financial condition may differ materially from those indicated in the forward-looking statements. Therefore, you should not rely on any of these forward-looking statements. Important factors that could cause our actual results and financial condition to differ materially from those indicated in the forward-looking statements include, among others, the following: there is substantial doubt as to our ability to continue on a going-concern basis; we might not be eligible for Australian government research and development tax rebates; if we are not able to successfully develop, obtain FDA approval for, and provide for the commercialization of non-malaria prevention indications for tafenoquine (ARAKODA ® or other regimen) or Celgosivir in a timely manner, we may not be able to expand our business operations; we may not be able to successfully conduct planned clinical trials; and we have no manufacturing capacity which puts us at risk of lengthy and costly delays of bringing our products to market. More detailed information about the Company and the risk factors that may affect the realization of forward-looking statements is set forth in the Company's filings with the Securities and Exchange Commission (SEC), including our final prospectus to our Form S-1 (File No.: 333-269483) filed with the SEC on July

13, 2023, and our subsequent annual reports on Form 10-K and our quarterly reports on Form 10-Q filed with the SEC. Investors and security holders are urged to read these documents free of charge on the SEC's web site at www.sec.gov. As a result of these matters, changes in facts, assumptions not being realized or other circumstances, the Company's actual results may differ materially from the expected results discussed in the forward-looking statements contained in this press release. Any forward-looking statement made by us in this press release is based only on information currently available to us and speaks only as of the date on which it is made. We undertake no obligation to publicly update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments, or otherwise.

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