60 Degrees Pharmaceuticals Awarded Canadian Patent Covering Tafenoquine for Prevention of Malaria in Malaria-Naive Subjects

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- Patent provides exclusive use of tafenoquine for prevention of malaria in malaria-naive individuals in Canada until late 2035.
- Tafenoquine is the active molecule in 60 Degrees Pharmaceuticals' USFDA-approved drug for malaria prevention, ARAKODA®.
- Most travelers from Canada and the United States to tropical countries are malaria-naïve and malaria is life-threatening if contracted.
- There are no vaccines approved to prevent malaria in malaria-naïve travelers so public health agencies recommend the use of malaria chemoprophylactic drugs.

WASHINGTON, July 31, 2023 (GLOBE NEWSWIRE) -- 60 Degrees Pharmaceuticals Inc. ("60P" or the "Company") (Nasdaq: SXTP), a pharmaceutical company focused on developing new medicines for infectious diseases, today announced that the Canadian Intellectual Property Office (CIPO) has issued the Company a patent covering the use of novel regimens of **tafenoquine** for the prevention of malaria in malaria-naive individuals. Travelers from, and residents of, Canada and the United States, are usually malaria naïve because they have not previously contracted malaria and thus lack immunity to the disease.

Tafenoquine is the active molecule in the Company's U.S. Food and Drug Administration-approved regimen for malaria prevention, ARAKODA®. ARAKODA, an oral tablet containing 100 mg of **tafenoquine** base, is an anti-malarial indicated in the U.S. for the prophylaxis of malaria in individuals aged 18 years and older. Travelers or individuals at risk of contracting malaria are prescribed 2 x 100 mg tablets once per day for three days (the loading phase) prior to travel, 2 x 100 mg tablets weekly for up to six months during travel, then 2 x 100 mg in the week following travel. ARAKODA is not approved by Health Canada for the prevention of malaria.

The newly issued Canadian patent provides exclusive use of **tafenoquine** for preventing malaria in malaria-naive patients in Canada to December 2, 2035. The Company was previously issued a U.S. patent covering the use of **tafenoquine** for malaria prevention in malaria-naïve individuals. The U.S. and Canadian patents cover the ARAKODA dosing regimen approved in the U.S. for malaria prevention.

Malaria is a life-threatening disease when contracted by malaria-naïve individuals. There are no vaccines useful for travelers that have been approved by Canadian or U.S. regulatory authorities, so CDC and Health Canada recommend the use of malaria chemoprophylactic drugs during travel. There were 1,823 symptomatic malaria cases in the United States in 2018 and 489 cases were reported to Health Canada in 2014, and the overall rate of cases is increasing. In the U.S. 95% of malaria cases occurring in returning travelers were in individuals who reported not taking or failing to adhere to CDC-recommended malaria chemoprophylactic regimens. Local malaria transmission is also an increasing problem in the southern United States – Texas and Florida have reported eight such cases to date in 2023, prompting a CDC health warning.

About ARAKODA® (tafenoquine)

Tafenoquine was discovered by Walter Reed Army Institute of Research and 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. 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.

Contraindications

ARAKODA® should not be administered to patients with:

Glucose-6-phosphate dehydrogenase (G6PD) deficiency or unknown G6PD status

Lactating women who are 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

Patients with 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 greater than or equal to 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, 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 institutional investors including 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. 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 fact, 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 because of new information, future developments, or otherwise.

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