60 Degrees Pharmaceuticals Receives FDA Orphan Drug Designation for Tafenoquine for Treatment of Patients with Acute Babesiosis

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- With the **tafenoquine** for acute babesiosis orphan drug designation, 60 Degrees Pharmaceuticals now qualifies for certain incentives, including market exclusivity, tax credits, and exemption from certain FDA filing fees.
- 60 Degrees Pharmaceuticals recently announced it has entered into an agreement with Tufts Medical Center in Boston to conduct the world's first clinical trial evaluating the efficacy and safety of **tafenoquine** in treating human babesiosis patients.
- FDA orphan drug designation is granted for therapeutic candidates that may prevent or treat a rare disease or condition, such as acute babesiosis.

WASHINGTON, June 11, 2024 (GLOBE NEWSWIRE) -- 60 Degrees Pharmaceuticals, Inc. (NASDAQ: SXTP; SXTPW) (the "Company" or "60 Degrees Pharmaceuticals"), a pharmaceutical company focused on developing new medicines for infectious diseases, announced today that the U.S. Food and Drug Administration ("FDA") has granted its investigational **tafenoquine** candidate orphan drug designation for the treatment of patients with acute babesiosis.

FDA orphan drug designation is granted for therapeutic candidates that may prevent or treat a rare disease or condition, such as acute babesiosis. Babesiosis is a steadily emerging, infectious disease transmitted by a microscopic parasite, *Babesia*, through the bite of the black-legged (deer) tick, the vector that spreads Lyme disease. Babesiosis may be life-threatening in elderly and immunosuppressed patients. Up to 10 percent of Lyme disease patients may be coinfected with Babesia. Therefore, up to 47,600 of the estimated 476,000 patients with new Lyme infections each year may be co-infected with Babesia.

"Results of recent animal studies of **tafenoquine** show exciting promise for the drug to have potential in human patients with acute babesiosis," said Chief Executive Officer of 60 Degrees Pharmaceuticals, Geoff Dow, PhD. "The FDA granting **tafenoquine** orphan drug designation for acute babesiosis validates the growing need for an additional therapeutic option that infectious disease specialists can use in addressing this very serious, potentially life-threatening illness. We look forward to results of our clinical trial program in coming months and to the prospect of securing a secondary indication for **tafenoquine** in the area of acute babesiosis treatment."

60 Degrees Pharmaceuticals recently announced it has entered into an agreement with Tufts Medical Center in Boston to conduct the world's first clinical trial evaluating the efficacy and safety of **tafenoquine** in treating patients who have acute babesiosis. Recruitment for the trial will begin on June 13, 2024, and will include at least 24 patients hospitalized with babesiosis. Additional recruitment sites at prominent university hospitals in the Northeast U.S. are also planned.

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About Tafenoquine

Tafenoquine is approved for malaria prophylaxis in the United States under the product name ARAKODA®. The safety of the approved regimen of **tafenoquine** for malaria prophylaxis has been assessed in five separate randomized, double-blind, active comparator or placebo-controlled trials for durations of up to six months. **Tafenoquine** has not been proven to be effective for treatment or prevention of babesiosis and is not approved by the U.S. Food and Drug Administration for such an indication.

About the Study of Tafenoquine for Patients Hospitalized with Babesiosis

The study is a randomized, double-blind, placebo-controlled trial that will enroll patients at multiple sites in the Northeast U.S. and will compare the safety and efficacy of **tafenoquine** versus placebo in patients hospitalized for babesiosis with low risk for relapsing disease who will also be administered a standard-of-care antimicrobial regimen. The two main study endpoints will be the time to sustained clinical resolution of symptoms and the time to molecular cure as determined by an FDA-approved nucleic acid test. At least 24, and as many as 33 patients, will be recruited before an interim analysis is conducted. Sufficient enrollment capacity is planned to allow all study subjects to be recruited during the 2024 tick season (June to September) if caseload is high. The interim analysis will include both a test of significance, as well as size re-estimation to allow additional recruitment if required. The study will be conducted at three hospitals in the Northeast U.S. The efficacy and safety of 8-aminoquinolines, a class of drugs that includes **tafenoquine** and primaquine, for prevention and treatment of malaria is well documented. Several case reports of **tafenoquine** use for babesiosis indicate that the drug is already being used for this purpose in the practice of medicine in the U.S.

About ARAKODA® (tafenoquine)
Tafenoquine was discovered by Walter Reed Army Institute of Research. **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.

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; or
- 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 16 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, motion sickness, insomnia, depression, abnormal dreams, and anxiety.

Drug Interactions

Avoid co-administration with drugs that are substrates of organic cation transporter-2 or multidrug and toxin extrusion 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, Inc. at 1- 888-834-0225 or the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch. The full prescribing information of ARAKODA® is located 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. 60 Degrees Pharmaceuticals, Inc. achieved FDA approval of its lead product, ARAKODA® (**tafenoquine**), for malaria prevention, in 2018. 60 Degrees Pharmaceuticals, Inc. also collaborates with prominent research organizations in the U.S., Australia, and Singapore. The 60 Degrees Pharmaceuticals, Inc. mission has been supported through in-kind funding from the U.S. Department of Defense and private institutional investors including Knight Therapeutics Inc., a Canadian-based pan-American specialty pharmaceutical company. 60 Degrees Pharmaceuticals, Inc. is headquartered in Washington D.C., with a majority-owned subsidiary in Australia. Learn more at 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.

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, activities of regulators and future regulations 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 or patient recruitment in our trials might be slow or negligible; 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 the information contained in our Annual Report on Form 10-K filed with the SEC on April 1, 2024, and our subsequent SEC filings. 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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