First Patient Enrolled in 60 Degrees Pharmaceuticals Clinical Trial of Tafenoquine for Babesiosis at Tufts Medical Center; First and Only Study of Its Kind

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- The efficacy and safety of **tafenoquine** in treating human babesiosis will be evaluated in a randomized, double-blind, placebo-controlled trial conducted at Tufts Medical Center in Boston.
- Endpoints are time to sustained clinical resolution of symptoms of babesiosis, and molecular cure as determined by an FDA-approved nucleic acid test (NAT).
- Study is the world's first and only clinical trial evaluating **tafenoquine** in human babesiosis patients.

WASHINGTON, June 27, 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 that the first patient has been enrolled in a randomized, double-blind, placebo-controlled clinical trial to evaluate the efficacy and safety of **tafenoquine** in treating babesiosis in humans. The patient was enrolled at Tufts Medical Center in Boston.

The study will enroll at least 24, and as many as 33 people. It is the world's first and only clinical trial evaluating the efficacy and safety of **tafenoquine** in human patients who have been diagnosed with acute babesiosis.

"With the first patient now enrolled in this groundbreaking clinical study, we have moved into a key phase of development with **tafenoquine** as a potential new treatment option in treating babesiosis," said Geoff Dow, PhD, chief executive officer at 60 Degrees Pharmaceuticals. "Given both the growing prevalence of babesiosis and the difficulty of quickly differentiating it from other illnesses seen in the clinic, we anticipate the numbers of people hospitalized with this serious tick-borne illness will continue to rise over time. In such cases, babesiosis can certainly become life-threatening. Our goal is for **tafenoquine** to play an important role in safely and effectively resolving babesiosis in those patients."

Babesiosis is a steadily emerging, tick-borne disease transmitted through the bite of the black-legged (deer) tick, the vector that spreads Lyme disease. An orphan disease, babesiosis may be life-threatening in elderly and immunosuppressed patients.

The Company is in discussions with other prominent university hospitals to participate in the **tafenoquine** for babesiosis study.

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.

60 Degrees Pharma recently announced **tafenoquine** has been designated as an orphan drug by the U.S. Food and Drug Administration.

About the Tafenoquine in Babesiosis Study
The study is a randomized, double-blind, placebo-controlled trial enrolling patients in multiple sites in the Northeast U.S. comparing the safety and efficacy of **tafenoquine** versus placebo in patients hospitalized for babesiosis, i.e., acute cases. The two main study endpoints will be time to sustained clinical resolution of symptoms of babesiosis and molecular cure as determined by an FDA-approved nucleic acid test (NAT). 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 these patients 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 northeastern United States.

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 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, 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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