60 Degrees Pharmaceuticals Expands Tafenoquine Clinical Trial for Babesiosis to Brigham and Women's Hospital

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- The trial (NCT06207370) evaluates **tafenoquine** combined with standard treatment for babesiosis, addressing a critical unmet medical need.
- The clinical site is led by Brigham and Women's Hospital researchers Ann Woolley, M.D., and David Leaf, M.D.
- The double-blind, placebo-controlled trial will examine outcomes for hospitalized patients with severe babesiosis, a tick-borne illness often found as a co-infection of Lyme disease.

WASHINGTON, Dec. 11, 2024 (GLOBE NEWSWIRE) -- 60 Degrees Pharmaceuticals, Inc. (NASDAQ: SXTP; SXTPW) (60 Degrees Pharmaceuticals or the "Company"), a pharmaceutical company focused on developing new medicines for infectious diseases, announced today it has entered into a clinical trial agreement with Brigham and Women's Hospital (BWH) in Boston to conduct a double-blind, placebo-controlled study evaluating the safety and efficacy of **tafenoquine** in combination with standard of care treatment for hospitalized babesiosis patients.

The study, a randomized, double-blind, placebo-controlled clinical trial evaluating the efficacy and safety of **tafenoquine** in treating human babesiosis patients is also underway at Tufts Medical Center in Boston, Yale University, and Rhode Island Hospital, and is sponsored by 60 Degrees Pharmaceuticals. The two main study endpoints will be the time to sustained clinical resolution of symptoms and the time to molecular cure as determined by nucleic acid test (NAT) approved by the U.S. Food and Drug Administration (FDA).

At least 24, and as many as 33 patients, will be recruited in the summer of 2025, with an interim analysis anticipated early in 2026. The interim analysis will include both a test of significance, and size re-estimation to allow additional recruitment if required.

"We are pleased to be collaborating with Brigham and Women's Hospital on finding answers to the question of how to bring a safe and effective new treatment option to people hospitalized with severe babesiosis, a potentially life-threatening tick-borne illness," said Geoffrey Dow, PhD, chief executive officer and president of 60 Degrees Pharmaceuticals. "In the near term, this collaboration promises to substantially enhance our ability to complete enrollment of this important clinical trial during the 2025 tick season. We look forward to a productive collaboration with the Hospital."

A recently published case study series suggested that **tafenoquine** combined with standard-of-care treatment exhibits a high cure rate in immunosuppressed patients with relapsing babesiosis and for whom prior treatment has failed. 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. Cases of babesiosis are rising in the Northeast U.S. and elsewhere.

60 Degrees Pharmaceuticals has found that the total cumulative accessible market through the end of U.S. patent protection in December, 2035 for ARAKODA® (**tafenoquine**) for babesiosis may exceed 400,000 patients.

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 FDA for such an indication.

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.

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 website 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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