60 Degrees Pharmaceuticals Selects Icahn School of Medicine at Mount Sinai as Central Clinical Trial Site for Phase II Study to Evaluate Tafenoquine for Chronic Babesiosis

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- 90-day trial measuring change in general fatigue in chronic babesiosis patients
- Enrollment expected to commence Q4 2025 and to be completed by Q2 2026
- Site has clinical expertise in infectious disease trials and access to a robust patient population with tick-borne illness, including chronic babesiosis
- No FDA-approved treatment exists for chronic babesiosis, a debilitating illness

WASHINGTON, Aug. 19, 2025 (GLOBE NEWSWIRE) -- 60 Degrees Pharmaceuticals, Inc. (NASDAQ: SXTP; SXTPW) ("60 Degrees Pharma" or the "Company"), a pharmaceutical company focused on developing new medicines for vector-borne disease, announced today it has signed a clinical trial agreement with the Icahn School of Medicine at Mount Sinai in New York City as the central site for a Phase II clinical study of **tafenoquine** in treating chronic babesiosis.

For the purposes of the study, chronic babesiosis is defined as a patient with disabling fatigue of at least six months duration, with other symptoms, and laboratory confirmation of, babesiosis.

The open-label study (NCT06656351) will evaluate the efficacy and safety of the ARAKODA® (**tafenoquine**) regimen over 90 days, treating patients with a presumptive diagnosis of chronic babesiosis. The primary endpoint will be resolution of fatigue assessed using a patient reported outcome measure (the multi-dimensional fatigue inventory general fatigue subscale) at Day 90 compared with baseline. Participants will have experienced significant functional impairment for at least six months. **Tafenoquine** (2 x 100 mg tablets) will be self-administered orally with food on Days 1, 2, 3, 4, then weekly thereafter for a total 12-week treatment period. Weekly treatment will start on Day 11 and end on Day 89.

Tafenoquine is approved for malaria prophylaxis in the United States under the product name ARAKODA®. **Tafenoquine** has not been proven to be effective for treatment or prevention of babesiosis and is not approved by the United States Food and Drug Administration for such an indication.

"We are pleased to welcome the Icahn School of Medicine at Mount Sinai research team into the 60 Degrees Pharma **tafenoquine** for babesiosis clinical trial program," said 60 Degrees Pharmaceuticals, Inc. Chief Executive Officer, Geoff Dow, PhD. "They bring deep expertise and skill in researching tick-borne illnesses, along with a focus on supporting the development of novel therapies to meet the critical unmet needs of patients with chronic disease."

Clinical Babesiosis Studies Sponsored by 60 Degrees Pharmaceuticals

Three 60 Degrees Pharmaceuticals-sponsored clinical trials (NCT06478641, NCT06207370, NCT06656351) are underway or planned to evaluate **tafenoquine**'s safety and efficacy in treating humans diagnosed with babesiosis. Data are expected from one or more of these studies in the first half of 2026 and will be used as part of a planned New Drug Application (NDA) submission to the U.S. Food and Drug Administration for babesiosis, anticipated in 2026.

About Babesiosis
Babesiosis is a tick-borne illness caused by *Babesia* parasites that develop and multiply in red blood cells. Its symptoms include fevers, chills, sweats, and fatigue, and in severe cases, can be life-threatening threatening in elderly and immunosuppressed patients. Incidence of the disease is rapidly rising, particularly in the Northeast. Transmitted through the bite of the black-legged (deer) tick, the vector that spreads Lyme disease, babesiosis is an orphan disease. *Babesia* infection may persist for at least a year; fatigue is usually the symptom of infection that takes longest to resolve and may be debilitating over the long term in some patients.

About ARAKODA® (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 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.

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 commercializing new medicines for the treatment and prevention of vector-borne disease. The Company achieved U.S. Food and Drug Administration approval of Its lead product, ARAKODA® (**tafenoquine**), for malaria prevention, in 2018. ARAKODA is commercially available in the U.S. and Australia. 60 Degrees Pharmaceuticals, Inc. also collaborates with prominent research and academic organizations in the U.S. and Australia. 60 Degrees Pharmaceuticals, Inc. is headquartered in Washington, D.C., with a 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 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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