60 Degrees Pharmaceuticals Announces Clinical Site Now Open for Patient Enrollment for the B-FREE Chronic Babesiosis Study at Mount Sinai Icahn School of Medicine

November 21, 2025 1:01 PM EST

- 90-day trial will measure change in general fatigue in patients with chronic babesiosis following **tafenoquine** treatment
- Study will run approximately 12 months and enroll up to 100 patients
- Internal estimates of the unmet medical need are between 4,400 and 190,000 cases annually, with no existing FDA-approved treatment for babesiosis

WASHINGTON, Nov. 21, 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 that the central study site for the Company's B-FREE Chronic Babesiosis Study, the Cohen Center for Recovery from Complex Chronic Diseases at Mount Sinai Icahn School of Medicine, is open for patient enrollment. The study is the first to evaluate a therapeutic for chronic babesiosis and will run for approximately 12 months.

The B-FREE Chronic Babesiosis Study (NCT06656351) is a Phase 2 open-label study that will evaluate the efficacy (and safety) of the ARAKODA® regimen of **tafenoquine** over 90 days for resolution of severe fatigue, and parasite eradication in patients diagnosed with chronic babesiosis.

For the purposes of the study, chronic babesiosis is defined as a condition affecting a patient who has experienced disabling fatigue for at least six months, with other symptoms of babesiosis, and laboratory confirmation of exposure to *Babesia* parasites in the prior 12 months. No treatment for babesiosis has been approved by the U.S. Food and Drug Administration (FDA) to date.

The unmet medical need from current claims data suggests approximately 4,400 diagnosable cases of chronic babesiosis with severe fatigue in the U.S. each year, while internal market research indicates the number could be as high as 190,000 if molecular testing confirms broader prevalence. One of the central aims of the B-FREE study is to establish whether *Babesia* infection in patients with a chronic babesiosis diagnosis can be confirmed using validated molecular tests, which will help determine the true size of the patient population. By clarifying whether the market size falls closer to the conservative estimate, or approaches the higher bound, the study is designed not only to advance clinical science but also to quantify the scope of unmet medical need.

"The B-FREE study will help us understand both the potential of **tafenoquine** to improve patients' lives and the true scope of chronic babesiosis, which remains poorly defined," said 60 Degrees Pharmaceuticals, Inc. Chief Executive Officer, Geoff Dow, PhD. "We are delighted to get this important babesiosis study underway."

"At Mount Sinai, we see the toll chronic babesiosis takes on patients who have few options and little recognition of their illness," commented David Putrino, Principal Investigator. "This study is an important step toward better understanding the diagnosis of chronic babesiosis and developing new treatments."

"I'm incredibly proud to be part of the tafenoquine trial team," said CoRE Scientific Director Amy Proal, PhD. "Patients with chronic Babesiosis have been waiting far too long for an approved treatment option. Now there is hope that one may be on the horizon. This trial marks a major step forward in working to identify targeted care for an underserved patient population."

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.

About the B-FREE Chronic Babesiosis Study

B-FREE, an open-label study (NCT06656351), will evaluate the efficacy and safety of the ARAKODA® (**tafenoquine**) regimen over 90 days, treating patients with a 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.

The study will enroll and treat up to 100 patients, with the goal being completion by at least 16 patients for whom *Babesia* infection was confirmed at baseline using the FDA-licensed RNA amplification test used by the American Red Cross to screen blood donations. That test, which is not available for patient care, has the greatest sensitivity and is therefore the most stringent. Accordingly, B-FREE Study data will yield an estimate of the proportion of chronic babesiosis patients for whom it is possible to objectively confirm infection.

As all screening is being conducted outside of New York, in order to remain in compliance with state law and to avoid inadvertently alerting patients to their diagnostic results, we plan to disclose that the first case has been confirmed only after at least one enrolled patient tests negative and at least one enrolled patient tests positive. The overall proportion of patients for whom *Babesia* infection was confirmed will be disclosed once the minimum number of patients has been enrolled.

At baseline, and approximately monthly for six months, patients will be screened using the FDA-licensed RNA amplification test, and two CLIA-validated RT-PCR assays that are commercially available for patient care. Those screening data will provide estimates of the rate at which broadly available commercial assays can detect confirmed infections and will be disclosed once we have completed the minimum enrollment in the

study. This longitudinal molecular testing will also reveal the extent to which *Babesia* infections in this patient population can be eradicated with **tafenoquine**.

Clinical Babesiosis Studies Sponsored by 60 Degrees Pharmaceuticals

In addition to B-FREE (NCT06656351), two other 60 Degrees Pharmaceuticals-sponsored clinical trials (NCT06478641, NCT06207370) are now underway to evaluate **tafenoquine**'s safety and efficacy in treating humans diagnosed with babesiosis.

NCT06207370 is a double-blind randomized multi-site placebo-controlled trial in hospitalized patients which requires a minimum of N=24 patients to be enrolled before an interim data analysis can be conducted. At the end of the 2025 tick season, a total of 19 patients had been randomized. An interim analysis is anticipated in the second half of 2026 after the remaining patients have been enrolled during the 2026 tick season (which starts in June, and ends in early October).

NCT06478641 is an open label, expanded access study of **tafenoquine** (up to 12 months duration) combined with conventional treatments in high-risk relapsing babesiosis patients in whom prior treatment failed. The study does not have a pre-determined minimum sample size. One patient completed the study in October 2025, and the remaining two patients currently enrolled will complete the study between January and September 2026.

In early 2026, the Company will request a Type B meeting with the FDA to discuss requirements for submitting a supplemental New Drug Application (sNDA).

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 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. Insurance claims research commissioned by the Company suggest that the minimum annual incidence of babesiosis is at least 25,000 cases per year, although the true number may be much larger than this. Currently no FDA-approved treatment exists specifically for babesiosis.

Babesia infection persists for months, and potentially for several years following a tick bite. In patients with risk factors (e.g., immunosuppression, age, asplenia), persistent infection may result in recurring clinical relapses of the disease, each with the potential for hospitalization. In individuals without such known risk factors, it has been generally assumed that persistent infection is not clinically meaningful. However, the potential clinical significance of persistent infection in individuals with dysregulated immune systems (e.g., chronic tick-borne diseases, long covid and other long syndromes) has not been studied, but it is hypothesized to complicate recovery from other chronic symptoms. The lack of sufficiently sensitive, FDA-approved diagnostics has stymied prior efforts to study this problem.

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.

Media Contact:
Sheila A. Burke
SheilaBurke-consultant@60degreespharma.com
(484) 667-6330

Investor Contact:
Patrick Gaynes
patrickgaynes@60degreespharma.com
(310) 989-5666

Source: Sixty Degrees Pharmaceuticals