60 Degrees Pharmaceuticals Unveils Name of Chronic Babesiosis Clinical Trial: B-FREE Chronic Babesiosis Study

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- Company engaged patients diagnosed with chronic babesiosis via social media in a nationwide naming competition
- A $5K donation from the Company was split between ILADEF and GLA to recognize the winning name
- B-FREE, a Phase 2 trial, will commence in early November and run for approximately 12 months

WASHINGTON, Oct. 09, 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 the name of its chronic babesiosis trial is the B-FREE Chronic Babesiosis Study.

The B-FREE study (NCT06656351), the first in the world to evaluate a potential new therapeutic for chronic babesiosis, will run for approximately 12 months. It 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 with chronic babesiosis, a potentially disabling condition carried by the same tick that spreads Lyme disease.

No U.S. Food and Drug Administration-approved drug or professional society-recommended treatment for chronic babesiosis is currently available.

"60 Degrees Pharma is so proud to be conducting this pioneering study of chronic babesiosis, a key plank in our plan to bring an FDA-approved babesiosis therapy to patients," said Company Chief Executive Officer, Geoffrey Dow. "We are grateful to the patients who participated in the B-FREE naming study, and to the distinguished scientific advisory boards and organizations we consulted for their assistance in drafting the study protocol. We also appreciate the staff at our contract research organization, Fast Track, and Mount Sinai for their valuable assistance in getting this first-of-its-kind study off the ground."

To identify the name for the B-FREE study, 60 Degrees engaged directly with the tick-borne disease patient community. A naming survey was shared through social media channels and distributed to patients and advocates, inviting them to contribute study names that that reflected the purpose of the trial. In turn, as a goodwill gesture, 60 Degrees Pharmaceuticals donated a total of $5,000 to the Global Lyme Alliance (GLA) and to the International Lyme and Associated Diseases Education Foundation (ILADEF), thus ensuring that patient input not only shaped the B-FREE study's identity but also directly supported organizations that are advancing research and care.

"Babesiosis poses a growing public health threat—especially for vulnerable populations such as the elderly and immunocompromised individuals," said Meghan Bradshaw, MPH, Government Relations Manager at the Center for Lyme Action. "Patient involvement in research ensures that studies reflect the real-world needs and experiences of those living with tick-borne illnesses, making the findings more meaningful and actionable. Beyond the science, this kind of work elevates awareness and drives the momentum needed for urgently needed solutions."

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 using the FDA-approved RNA amplification test used by the American Red Cross to screen blood donations. This test has the greatest sensitivity but is not commercially available for patient care. The data will provide an estimate of what proportion of chronic babesiosis patients it is possible to objectively confirm infection using the most stringent available test. At baseline, and monthly for six months, patients will also be screened using the blood bank test and two CLIA-validated RT-PCR assays which are broadly commercially available for patient care. Those data will provide estimates of the rate at which broadly available commercial assays can detect confirmed infections, and the extent to which they can be eradicated with **tafenoquine**.

About Chronic Babesiosis and Babesiosis
Chronic babesiosis is a poorly described medical condition in which persistent *Babesia* infection is hypothesized to exacerbate the symptoms of, or prolong recovery times from, symptoms of "Long Diseases" such as long COVID, chronic fatigue syndrome and long Lyme, given that these diseases involve patients who have dysregulated immune systems.

Babesiosis is a tick-borne illness caused by *Babesia* parasites that develop and multiply in red blood cells. Babesiosis symptoms include fevers, chills, sweats, and fatigue, and in severe cases, can be life-threatening threatening in elderly and immunosuppressed patients. Incidence of babesiosis 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 diseases) has not been studied, but it 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.

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