



60 Degrees Pharmaceuticals Announces No Detection of Babesia Infection in First Patient Following Treatment with Tafenoquine in Relapsing Babesiosis Study

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- Breakthrough Therapy Designation request has been submitted to FDA
- Company to request a Type B meeting with FDA in early 2026 to discuss requirements for a supplementary New Drug Application (sNDA)
- Results obtained using highest sensitivity test available; licensed by FDA for blood donation screening
- Remaining enrolled patients will complete the study between January and October 2026
- Study intended to confirm the high cure rate for **tafenoquine** in immunosuppressed patients with relapsing babesiosis, as reported by Yale in a 2024 publication

WASHINGTON, Oct. 15, 2025 (GLOBE NEWSWIRE) -- [60 Degrees Pharmaceuticals, Inc.](#) (NASDAQ: SXTF; SXTFW) ("60 Degrees" or the "Company"), a pharmaceutical company focused on developing new medicines for vector-borne disease, today announced that the first patient to have completed the regimen in the Company's trial of relapsing babesiosis in immunosuppressed patients has tested negative for babesiosis. The trial is an expanded access study of ARAKODA[®] (tafenoquine) in combination with conventional treatments for relapsing babesiosis ([NCT06478641](#)).

Babesiosis is a tick-borne illness caused by *Babesia* parasites that develop and multiply in red blood cells. Symptoms include fevers, chills, sweats, and fatigue. In severe cases, babesiosis can be life-threatening in elderly and immunosuppressed patients. Incidence of the disease is rapidly rising, particularly in the Northeast. The disease may relapse multiple times in patients with risk factors such as asplenia (no spleen) or individuals who have been administered immunosuppressive drugs. *Babesia* parasites frequently develop resistance to conventional drugs when they are used persistently to manage disease in such patients.

WHAT IS BABESIOSIS?

A rare, debilitating, potentially serious disease caused by infection with *Babesia* parasites, which infect red blood cells.

Transmitted primarily through the bite of the black-legged deer tick – the same one that spreads Lyme disease.

Babesiosis is emerging in many U.S. regions

Accurate and early diagnoses and treatment can help prevent progression to serious health issues—and even death

WHO IS AT RISK?

Everyone. People who have a compromised immune system, no spleen or who are over the age of 65, face the greatest danger if infected



Up to 20% of Lyme disease cases also carry Babesiosis

U.S. incidence is at least 8X higher than official estimates

A HIDDEN EPIDEMIC

25,000 vs. **2,000**

U.S. adults per year seek reimbursement for medical costs associated with babesiosis

U.S. official estimate, based on 2020 data

No FDA-approved treatment currently on the U.S. market*

*As of mid-2025

Symptoms of Babesiosis



Relapsing fever



Anemia



Debilitating fatigue



Anorexia



Drenching sweats

No "bulls-eye" rash. Sometimes, no symptoms appear. Some symptoms may show up weeks or months after exposure to an infected tick.

Anemia, debilitating fatigue, anorexia, relapsing fever, and drenching sweats can appear as the infection progresses without effective treatment.

Bitten by a tick? Talk with your doctor immediately and be tested for Babesiosis



No U.S. Food and Drug Administration (FDA)-approved treatment or vaccine exists for babesiosis.

The Company's study aims to confirm the high cure rate for **tafenoquine** in enrolled immunosuppressed patients with relapsing babesiosis, as reported by Yale in a 2024 [Clinical Infectious Diseases](#) publication. It is an open label, expanded access, multi-site study evaluating the safety and efficacy of the ARAKODA® regimen of **tafenoquine** combined with standard of care medications in patients with risk factors for severe disease with relapsing babesiosis who have previously failed conventional antimicrobial regimens.

Sixty days following clinical resolution and cessation of study drug administration, the study protocol calls for a follow-up visit at which two molecular tests are administered to assess parasite infection status. One test is an RT-PCR from Mayo Clinic. The second is an FDA-approved RNA amplification test used for blood donation screening that is at least 100 times more sensitive than standard commercial RT-PCRs such as the Mayo test. Since blood donation screening using RNA amplification tests commenced in 2020, the number of babesiosis infections contracted through the U.S. blood donation system has declined precipitously.

The first patient in the 60 Degrees expanded access relapsing babesiosis study tested negative for babesiosis infection using both the Mayo and RNA amplification assays.

On October 3, 2025, the Company submitted a Breakthrough Therapy Application to the FDA for use of **tafenoquine** for treatment of babesiosis patients requiring medical treatment.

The remaining patients now enrolled are anticipated to complete the study between January and October, 2026.

The Company plans to request a Type B meeting with FDA in early 2026 to discuss requirements for a supplementary New Drug Application (sNDA).

Tafenoquine is not currently approved by the FDA for the treatment and prevention of babesiosis. **Tafenoquine** is approved for malaria prophylaxis in the United States under the product name ARAKODA® (**tafenoquine**).

Clinical Babesiosis Studies Sponsored by 60 Degrees Pharmaceuticals

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

babesiosis.

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, offers the advantage of less frequent dosing for the prophylaxis of 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 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 (ALT), 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 Celgivosir 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 Contacts:

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

Investor Contact:

Patrick Gaynes
patrickgaynes@60degreespharma.com

A photo accompanying this announcement is available at <https://www.globenewswire.com/NewsRoom/AttachmentNg/aafe096f-fee5-4824-a359-dd3d0a6bc17e>



What is Babesiosis?

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WHO IS AT RISK?
 Everyone. People who have a compromised immune system, live outdoors or who are over the age of 55 face the greatest danger if infected.

Up to 30% of Lyme disease cases also carry Babesiosis.

U.S. incidence is at least 8X higher than official estimates

A HIDDEN EPIDEMIC

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Symptoms of Babesiosis

- Relapsing fever
- Anemia
- Debilitating fatigue
- Anorexia
- Drinking sweets

No “bull’s-eye” rash. Sometimes, no symptoms appear. Some symptoms may show up weeks or months after exposure to an infected tick. Anemia, debilitating fatigue, anorexia, relapsing fever, and drinking sweets can appear as the infection progresses without effective treatment.

Biten by a tick? Talk with your doctor immediately and be tested for Babesiosis.

Learn how babesiosis, a rare but serious parasitic infection, spreads, who's most at risk, and why early diagnosis matters.

Source: Sixty Degrees Pharmaceuticals