



60 Degrees Pharmaceuticals Announces Clinical Improvement and Negative PCR Results in All Completed Expanded Access Babesiosis Study Patients

October 27, 2026 12:06 PM EDT

- All five completed patients (100%) reported much or very much improved clinical outcomes and tested negative for *Babesia* on conventional PCR tests
- Four of five completed patients (80%) were negative on highly sensitive post-treatment NAT testing
- Results reinforce favorable retreatment-free outcomes reported with **tafenoquine**–atovaquone regimens
- Two additional patients remain on treatment, bringing total enrollment to seven; study remains open pending potential discussions with FDA

WASHINGTON, Oct. 27, 2026 (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 clinical and molecular results from the first five patients to complete treatment with **tafenoquine**-containing combination regimens in the Company's expanded access study of relapsing babesiosis in immunosuppressed patients ([NCT06478641](#)).

All five patients reported being much improved or very much improved on study-completion forms, and each had negative conventional polymerase chain reaction (PCR) test results for *Babesia* documented during treatment or subsequent follow-up. Four of the five patients (80%) were also nonreactive on a highly sensitive blood-donor nucleic acid amplification test (NAT) for *Babesia* performed on blood collected after treatment. The remaining patient had a reactive blood-donor NAT despite a negative follow-up conventional PCR result from Mayo Clinic.

Human babesiosis is a tick-borne illness that can cause fever, chills, sweats, joint aches, and fatigue. In immunosuppressed patients, infection can persist or recur despite treatment and can be life-threatening. Krause and colleagues reported fatal outcomes in three of 14 patients (21%) with persistent or relapsing babesiosis in their 2008 study. A broader 2025 multicenter study by Kakoullis and colleagues reported 12-month all-cause mortality of 7% among patients who were immunocompromised and/or had impaired splenic function, compared with 1% among immune-intact patients. Human babesiosis is an orphan disease.

The Company's open-label, multi-site expanded access study evaluates the safety and efficacy of **tafenoquine** combined with atovaquone and other antimalarial or antibiotic medications in patients with relapsing babesiosis and risk factors for severe disease. The study builds on findings published in *Clinical Infectious Diseases* in 2024 by researchers from the Yale School of Public Health, Tufts Medical Center, Brown University and other institutions.

Current guidance emphasizes the importance of duration of therapy, recommending at least six consecutive weeks of antibabesial therapy for highly immunocompromised patients, including two final weeks without parasites detected on blood smears before stopping treatment. Microscopy can miss low-level parasitemia capable of causing relapse despite clinical improvement, creating a need for more sensitive measures of parasite clearance. The guidance also allows for more sensitive conventional PCR testing to inform treatment discontinuation on a case-by-case basis but does not specify PCR-based stopping criteria.

The expanded access protocol standardizes the treatment discontinuation decision, requiring that **tafenoquine**, given as part of an atovaquone combination regimen, be continued until two weeks after two consecutive negative conventional PCR tests and resolution of babesiosis symptoms. The study then prospectively assesses parasite clearance using a blood-donor NAT assay that is 500-fold more sensitive than conventional PCR and is not routinely available for patient care. Transfusion-transmitted babesiosis has fallen substantially since NAT screening of blood donations was introduced. NAT samples from the five completed patients were collected 66–120 days after completion of **tafenoquine** treatment.

Current guidance does not establish a standardized definition of cure for relapsing babesiosis in immunosuppressed patients. However, Krause and colleagues' 2008 publication in *Clinical Infectious Diseases*, on which the prolonged-treatment recommendations are based, defined cure as the absence of symptoms and parasites detectable on blood smear for more than three months after treatment ended. A 12-week retreatment-free interval means no additional babesiosis treatment for at least 12 weeks after treatment ends. It provides a practical indicator of sustained clinical response over a comparable follow-up period.

The Company has conducted an analysis of published relapsing babesiosis cases and found that six of seven patients (85.7%) treated with **tafenoquine**–atovaquone combinations remained retreatment-free for at least 12 weeks after treatment—approximately 3.6 times the model-estimated 23.5% expected from conventional treatment accounting for the duration of atovaquone coadministration, the accompanying non-**tafenoquine** medications and prior treatment history. The association was statistically significant in an exploratory Cox comparison (approximate patient-clustered score test; two-sided $p = 0.019$). Together with sequential negative conventional PCR tests in many of these cases, this finding supports the rationale for the expanded access study: the potential for a higher cure rate when **tafenoquine** is added to atovaquone-containing therapy.

To the Company's knowledge, this is the first prospective study in immunosuppressed patients with relapsing babesiosis to combine a predefined PCR-guided **tafenoquine**–atovaquone treatment approach with objective post-treatment assessment using a highly sensitive blood-donor NAT assay. Favorable clinical and conventional-PCR outcomes in all five completed patients and an 80% post-treatment NAT-negative rate provide molecular evidence consistent with definitive cure in four of five patients. These findings support the Company's hypothesis that post-treatment NAT nonreactivity

reflects the absence of a biologically relevant circulating parasite burden, marks parasite eradication and predicts freedom from further babesiosis relapse. The Company reiterates its call for treatment guidance to be updated to address **tafenoquine**-containing combinations and sensitive molecular monitoring.

The Company plans to pursue accelerated approval if the efficacy section of its registration dossier is based primarily on data from immunosuppressed patients with relapsing babesiosis. In that setting, the Company would propose post-treatment blood-donor NAT nonreactivity as a surrogate endpoint reasonably likely to predict durable clinical benefit, with a postmarketing confirmatory study designed to verify that benefit and confirm the relationship between NAT nonreactivity and sustained freedom from relapse.

Two additional patients remain on treatment in the expanded access study, bringing total enrollment to seven. The study remains open pending potential discussions with the U.S. Food and Drug Administration (FDA).

The Company expects to unblind its separate randomized, placebo-controlled study of **tafenoquine** or placebo added to standard-of-care therapy in patients hospitalized for babesiosis ([NCT06207370](#)) in January 2027. Following unblinding, the Company intends to request a pre-supplemental New Drug Application (pre-sNDA) meeting with FDA to discuss data from the hospital and expanded access studies and the appropriate regulatory pathway for **tafenoquine** in babesiosis.

Tafenoquine is not FDA-approved for the treatment or prevention of babesiosis. It is approved in the United States for malaria prophylaxis under the brand name ARAKODA®.

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 the 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 malaria prophylaxis. 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 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 in the following situations:

- 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 the G6PD status of the infant 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 the 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, develops and commercializes 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 and currently has active clinical trials underway for babesiosis, an emerging tick-borne disease. ARAKODA is sold commercially in the U.S. and Australia. 60 Degrees also collaborates with prominent research and academic organizations in the U.S. and Australia to advance science around vector-borne disease. The Company is headquartered in Washington, D.C., with a subsidiary in Australia. Learn more at www.60degreespharma.com.

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 castanospermine 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; and we have no manufacturing capacity, which puts us at risk of lengthy and costly delays in bringing our products to market. Findings from a small, uncontrolled expanded access study and historical case comparisons may not predict outcomes in larger studies. A 12-week retreatment-free interval, clinical improvement and negative conventional PCR results have not been established as equivalent to post-treatment blood-donor NAT nonreactivity. Post-treatment NAT nonreactivity has not been established as a predictor of sustained freedom from relapse, and FDA may not accept historical comparisons or post-treatment NAT nonreactivity as a surrogate for clinical benefit or as sufficient evidence to support approval. 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 March 30, 2026, 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.

Contacts

Media Contact:

Kristen Landon
kristenlandon@60degreespharma.com

Investor Contact:

Patrick Gaynes
patrickgaynes@60degreespharma.com

