



60 Degrees Pharmaceuticals Plans January 2027 Hospitalized Babesiosis Data Readout; Will Seek Pre-sNDA Meeting with FDA

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- After a scheduled interim analysis of the severe babesiosis study on October 1, 2026, the DSMB recommended completing the study with the originally planned number of patients (N=33); the study remains blinded
- As of the same date, the Company had enrolled 30 patients
- Given the limited incremental statistical power from enrolling three additional patients and the seasonal nature of babesiosis, which would otherwise delay unblinding until fall 2027, the Company has decided to conclude enrollment and proceed with unblinding. Primary and secondary endpoint results are expected in January 2027
- No safety signals were identified in the study
- Published case reports and the Company's prospective expanded access study support the potential of tafenoquine-containing regimens in treatment-refractory, relapsing babesiosis, and additional data will be disclosed from this study in early November 2026
- Company sees a viable regulatory pathway for severe and/or treatment-refractory disease and will request a pre-sNDA meeting with FDA in January 2027 to discuss data requirements, patient population, regulatory pathway, and post-marketing requirements

WASHINGTON, Oct. 06, 2026 (GLOBE NEWSWIRE) -- [60 Degrees Pharmaceuticals, Inc.](#) (NASDAQ: SXTX; SXTXW) ("60 Degrees" or the "Company"), a pharmaceutical company that develops and commercializes new medicines for vector-borne disease, today announced that it intends to conclude enrollment in its randomized clinical study of tafenoquine in patients hospitalized with severe babesiosis at 30 subjects. The Company plans to unblind the study and report its primary and secondary endpoint results in January 2027, and to submit a request for a pre-supplemental New Drug Application (sNDA) meeting with the U.S. Food and Drug Administration (FDA) that same month.

60 Degrees is the sponsor of the double-blind, randomized, multisite, placebo-controlled clinical trial entitled "Oral Tafenoquine Plus Standard of Care Versus Placebo Plus Standard of Care for Babesiosis" ([NCT06207370](#)), which is evaluating the efficacy and safety of tafenoquine in treating severe babesiosis in humans. Patients were enrolled at multiple sites in the U.S., including Tufts Medical Center, Rhode Island Hospital, Yale University, Brigham and Women's Hospital, and Westchester Medical Center.

The DSMB conducted an interim analysis of time to sustained clinical resolution of babesiosis, the study's primary endpoint, and time to molecular clearance of *Babesia* parasites, a key secondary endpoint. Following its review, the DSMB recommended completing the initially planned enrollment of 33 patients. As of October 1, 2026, the Company had enrolled 30 subjects. Due to the marginal impact an additional three subjects would have on power to detect a difference on the study endpoints and the seasonality of babesiosis and its potential to delay unblinding by a year if additional subjects were to be recruited, the Company intends to proceed with final analysis of the enrolled population. The DSMB's recommendation does not establish whether the study met its endpoints; those results will be determined following unblinding and final analysis. The DSMB analysis did not identify any safety issues.

A growing body of published case reports suggests that tafenoquine, administered in combination with atovaquone-containing regimens for at least eight weeks, may achieve a high cure rate in high-risk patients with treatment-refractory, relapsing babesiosis. Consistent with these reports, the Company has confirmed molecular cure, using a highly sensitive nucleic acid amplification test (NAT), in the first three patients enrolled in its expanded access study of tafenoquine combined with atovaquone-containing regimens in relapsing, treatment-refractory babesiosis ("Expanded Use in Persistent *B. Microti* Babesiosis" — [NCT06478641](#)). Final screening data from two additional patients are expected in early November 2026. Irrespective of the ultimate results of the severe babesiosis study to be reported in January, the Company believes an approval pathway based on case reports in the treatment-refractory population is possible.

The Company intends to request a pre-sNDA meeting with FDA to discuss the clinical evidence and data requirements for an sNDA submission for tafenoquine treatment of babesiosis. Should the data package be supported by literature and expanded access cases only, the Company plans to ask FDA to consider NAT-based molecular clearance as a surrogate endpoint reasonably likely to predict clinical benefit, potentially supporting an accelerated approval pathway. The Company would also propose a post-approval confirmatory study in an appropriate patient population. The availability of an accelerated approval pathway and the adequacy of the submission will be subject to FDA review.

No FDA-approved treatment or vaccine exists for human babesiosis. While tafenoquine is approved for the prevention of malaria, it is not currently approved by FDA for the treatment or prevention of babesiosis.

About Babesiosis

Babesiosis is a tick-borne illness caused by *Babesia* parasites that develop and multiply in red blood cells. It is often found as a co-infection of Lyme disease. Symptoms include fevers, chills, sweats, and fatigue. In severely immunocompromised patients, standard antimicrobial regimens can fail to clear infection, resulting in relapsing disease that may persist for months or years and has been associated with the emergence of antimicrobial-resistant *Babesia* strains. Incidence of babesiosis is rapidly rising, particularly in the Northeast, and the Centers for Disease Control and Prevention has advised that emergency room visits for tick bites are currently at historically high levels in many regions of the U.S.

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 won U.S. Food and Drug Administration approval of its lead product, ARAKODA® (**tafenoquine**), for malaria prevention in 2018 and currently has 3 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 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; 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 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.

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