60 Degrees Pharmaceuticals Announces Detection of Babesia Infection in 24 Percent of Patients Presenting with Chronic Fatigue in Peer-Reviewed, Sponsored Study at NC State

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- Further validates continuation of the B-FREE Study to evaluate the efficacy and safety of ARAKODA® (**tafenoquine**) for treatment of chronic babesiosis
- Data support theory among specialists that *Babesia* infection may prolong recovery times in patients with chronic fatigue

WASHINGTON, Dec. 29, 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, today announced that infection with *Babesia*, a parasite that causes the emerging tick-borne illness called babesiosis, was found in 24 percent of a cohort of 50 patients with chronic fatigue in a study conducted by researchers at North Carolina State University, and published in *Pathogens*.

Results announced today contribute to efforts to confirm a long-held theory within the U.S. vector-borne disease community that *Babesia* and chronic disease may be linked – specifically, that *Babesia* infection may prolong recovery times in patients with chronic fatigue.

The results also reinforce the importance of the B-Free Chronic Babesiosis Study (NCT06656351), which is evaluating efficacy and safety of the ARAKODA regimen of **tafenoquine** over 90 days for resolution of severe fatigue in patients with chronic babesiosis. The Company's B-Free Study is now enrolling at the Icahn School of Medicine at Mount Sinai in New York.

"Healthcare providers who treat tick-borne illness may not be surprised by the results of this study," said 60 Degrees Pharma Chief Executive Officer, Geoffrey Dow. "While the results don't prove that *Babesia* infection causes chronic disease, they are consistent with that hypothesis and highlight the need for prospective controlled studies which the Company is now undertaking."

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 North Carolina State University Chronic Fatigue Study

The study involved a cohort of 50 participants selected from a group of 173 individuals who self-reported a history of chronic diseases and potential exposure to arthropod vectors. Participants had all experienced fatigue for at least six months with concurrent neurological symptoms. Participants provided three blood samples over a week, which were archived and later cultured and tested for *Babesia* DNA using PCR assays.

The study was conducted under an Institutional Review Board (IRB)-approved protocol and was funded in part by 60 Degrees Pharma.

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 U.S. Food and Drug Administration (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 is hypothesized to complicate recovery from other chronic symptoms. The lack of sufficiently sensitive, FDA-approved diagnostics has stymied efforts to study this problem.

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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