Babesiosis Disease Burden in United States is Substantially Higher Than Official Estimates, According to Preliminary Results of 60 Degrees Pharma Survey

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- In a survey representative of the general U.S. adult population, 1.26 percent of respondents – equivalent to about 3 million people – reported having received a medical diagnosis of babesiosis during their life-time; CDC data imply only about 73,000 people in that category.
- At the time they replied to the survey, 3.7 percent of respondents – equivalent to about 9.9 million people – reported they had been experiencing fatigue, a common symptom of babesiosis, for six months or longer.

WASHINGTON, April 22, 2025 (GLOBE NEWSWIRE) -- 60 Degrees Pharmaceuticals, Inc. (NASDAQ: SXTP; SXTPW) ("60 Degrees" or the "Company"), a pharmaceutical company focused on developing new medicines for infectious diseases, today announced findings that the actual burden of babesiosis in the United States (U.S.) may be significantly higher than Centers for Disease Control and Prevention (CDC) statistics suggest. Preliminary results of an online survey conducted by the Company showed that nearly 3 million Americans (1.26 percent of the adult population in 2020) may have received a babesiosis diagnosis from a medical practitioner in their lifetime.

In contrast, CDC reports 1,834 cases of babesiosis in 2020. Even though this annual number relies on different methodologies and timeframes, and is not directly comparable to the Company's estimates, the disparity suggests the possibility that babesiosis is significantly underdiagnosed or underreported in existing public health reporting data. The Company believes this may indicate a greater demand for effective treatment than suggested by current CDC statistics.

The survey included responses from 6,000 participants selected to match the U.S. adult demographic distribution.

Babesiosis is a serious, emerging tick-borne disease often found as a co-infection with Lyme disease. It may be life-threatening in immunocompromised and elderly individuals.

An as yet untested medical hypothesis advanced by some prescribing physicians in the Lyme disease community is that persistent *Babesia* infection contributes to chronic fatigue and other problems. If this is true, millions of Americans with persistent fatigue, a common symptom of babesiosis, may be living with an undiagnosed but potentially treatable illness.

The Company commissioned the survey as part of its goal to define the size of the commercial market for babesiosis treatment candidates now in development. It was conducted by Format Analytics, an independent market research agency.

The online quantitative survey was conducted among a general adult population sample of 6,000 adults, with demographic variables (gender, age, ethnicity, income) matched to U.S. census data for optimal representation of the U.S. population. Babesiosis was reported as a diagnosed medical condition experienced by 1.26 percent of respondents, implying that 3 million Americans may have experienced babesiosis (1.26 percent of 268 million U.S. residents). Moreover, approximately 17 percent of babesiosis patients reported having experienced a duration of illness of six months or more, implying that at least 570,000 U.S. adults have experienced chronic disease (17 percent of 1.26 percent of 268 million U.S. adults).

Another objective of the survey was to estimate what proportion of U.S. residents are currently experiencing fatigue lasting longer than six months (inclusive of those who have received a formal diagnosis of chronic fatigue syndrome/encephalomyelitis). Approximately 3.7 percent of respondents to the survey, equivalent to about 9.9 million Americans per a U.S. adult population of 268 million U.S. adults, reported experiencing chronic fatigue of six months or longer at the time the survey was conducted. Approximately 56 percent of them (representing about 1.9 percent of total respondents) reported having received a formal diagnosis of Chronic Fatigue Syndrome (CFS). In contrast, in a 2021/2022 telephone survey, the CDC found that approximately 1.3 percent of respondents had received a formal diagnosis of CFS.

"These survey results, which will be submitted for publication soon, suggest that official statistics may not capture the lived experiences of babesiosis patients in the U.S.," said Chief Executive Officer of 60 Degrees Pharmaceuticals, Geoffrey Dow. "Infectious disease specialists seeking to treat patients who present with unexplained chronic fatigue should consider babesiosis as a differential diagnosis."

About Babesiosis and ARAKODA®

Babesiosis is a rapidly emerging tick-borne disease often found as a co-infection with Lyme disease. Based on Lyme disease insurance claims and Babesia co-infection rates, 60 Degrees surmises that approximately 46,000 Americans are diagnosed with acute (short-term) babesiosis each year. Most people recover within 90 days when treated with standard antimicrobials recommended by the Infectious Diseases Society of America. These treatments are assumed to reduce the number of parasites enough for the immune system to clear the rest.

However, in some individuals, *Babesia* infection may persist for at least a year, or they might recover and then feel unwell again up to two years later. Fatigue is usually the last clinical symptom of babesiosis to resolve. The actual number of people living with chronic or persistent (long-term) *Babesia* infection in the U.S. has not been described in the scientific literature.

Medical literature suggests that ARAKODA (**tafenoquine**), a medicine licensed and manufactured by 60 Degrees may have the potential to clear *Babesia* parasites and ease symptoms. The Company is currently running two clinical trials (NCT06207370 and NCT06478641) to confirm these findings. A third study is being planned for people with a presumptive diagnosis of babesiosis and experiencing severe and disabling chronic fatigue (NCT06656351). One of the hypotheses the study will test is that 20 percent of patients entering the study will have a *Babesia* infection confirmable

using commercially available molecular tests.

ARAKODA 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**. ARAKODA** has not been proven to be effective for treatment or prevention of babesiosis and is not approved by the U.S. Food and Drug Administration (FDA) for such an indication.

About 60 Degrees Pharmaceuticals, Inc.
60 Degrees Pharmaceuticals, Inc., founded in 2010, specializes in developing and marketing new medicines for the treatment and prevention of infectious diseases that affect the lives of millions of people. 60 Degrees Pharmaceuticals, Inc. achieved FDA approval of its lead product, ARAKODA® (**tafenoquine**), for malaria prevention, in 2018. 60 Degrees also collaborates with prominent research organizations in the U.S., Australia, and Singapore. The 60 Degrees Pharmaceuticals mission has been supported through in-kind funding from the U.S. Department of Defense and private institutional investors including Knight Therapeutics Inc., a Canadian-based pan-American specialty pharmaceutical company. 60 Degrees Pharmaceuticals is headquartered in Washington D.C., with a majority-owned 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 March 27, 2025, 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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