Babesiosis Incidence in U.S. 10x Higher Than CDC Estimates, According to Insurance Claims Study Commissioned by 60 Degrees Pharmaceuticals

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- 25,000 U.S. adults per year claim reimbursement for medical costs associated with babesiosis v. CDC estimates of 2,000
- A full 45 percent of persistent babesiosis cases include chronic fatigue
- Healthcare providers treating patients who present with unexplained chronic fatigue may wish to consider babesiosis as a differential diagnosis
- Company plans to submit a new drug application (NDA) to FDA in 2026, has two babesiosis clinical trials underway with another anticipated to commence enrollment later this year

WASHINGTON, June 03, 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 results of an insurance claims analysis related to babesiosis and chronic fatigue, as conducted by Komodo Health, a healthcare technology company that delivers the evidentiary standard for real-world data and analytics, contracted by the Company.

Results showed approximately 25,000 Americans seek reimbursement for babesiosis-related medical costs each year, according to 60 Degrees Pharmaceuticals. In contrast, current estimates published by the Centers for Disease Control and Prevention (CDC) show only 2,000 cases in 2020.

Babesia infections last at least 12 months in 14 percent of patients and may relapse up to 27 months later, as documented in the scientific literature. Many physicians treating tick-borne infections speculate the true duration of infection may be much longer.

The claims data indicated approximately 31 percent of babesiosis cases persist longer than 30 days, and that nearly half of those are associated with chronic fatigue lasting longer than six months. Fatigue is the last symptom of babesiosis to resolve in acute disease. Chronic fatigue during babesiosis has not been systematically described in the literature.

Further, the claims data, which captured approximately 40 percent of U.S. diagnostic data, showed that over three years, more than 12 million U.S. adults experienced chronic fatigue greater than six months in duration. Current Infectious Diseases Society of America advice and other professional guidelines do not mandate babesiosis as a differential diagnosis if a patient self-reports experiencing such fatigue.

The Company is testing, through its clinical development program, the medical hypothesis that the true burden of babesiosis is much larger than claims data suggest and is a function of the incidence of chronic fatigue lasting six months or longer, multiplied by the proportion of such individuals with confirmable infections.

A molecular incidence study in patients with chronic fatigue commissioned by the Company was recently completed. Once published, the data will allow establishment of a ceiling on the incidence of persistent babesiosis.

Clinical Babesiosis Studies Sponsored by 60 Degrees Pharmaceuticals
Three 60 Degrees Pharmaceuticals-sponsored clinical trials (NCT06478641, NCT06207370, NCT06656351) are underway or planned to evaluate **tafenoquine**'s safety and efficacy in treating humans diagnosed with babesiosis. Data are expected from one or more of these studies in the first half of 2026 and will be used as part of a planned New Drug Application (NDA) submission to the U.S. Food and Drug Administration for babesiosis, anticipated in 2026.

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 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 Pharmaceuticals, Inc. also collaborates with prominent research organizations in the U.S., Australia, and Singapore. The 60 Degrees Pharmaceuticals, Inc. 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, Inc. 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 safeharbor 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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