60 Degrees Pharma Announces IRB Approval of Clinical Study of Tafenoquine for Treatment of Babesiosis in Immunocompromised Patients with Persistent Babesia microti Despite Prior Treatment

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WASHINGTON, July 09, 2024 (GLOBE NEWSWIRE) -- 60 Degrees Pharmaceuticals, Inc. (NASDAQ: SXTP; SXTPW) ("60 Degrees Pharmaceuticals" or the "Company"), a pharmaceutical company focused on developing new medicines for infectious diseases, today announced ethics approval of an open label, expanded access study of the ARAKODA® regimen of **tafenoquine** in combination with standard of care regimens in immunosuppressed patients with persistent/relapsing babesiosis.

The goal of the study is to confirm the findings of an 80 percent babesiosis cure rate in humans observed in a similar population in an earlier case series of **tafenoquine** completed by Yale School of Public Health (YSPH) in April 2024 and published in the journal, Clinical Infectious Diseases. The YSPH case series showed a cure rate (with a 95 percent confidence interval) of 80 percent (30-100 percent) in a series of five immunosuppressed patients who were administered weekly **tafenoquine** following a loading dose in combination with standard of care medications.

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 U.S. Food and Drug Administration (FDA) for such an indication.

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. 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. It may be life-threatening in elderly and immunosuppressed patients.

"**Tafenoquine** is showing exciting promise in addressing babesiosis within various human patient populations," said Chief Executive Officer of 60 Degrees Pharmaceuticals, Geoffrey Dow, PhD. "With babesiosis rates now rising in key regions of the United States and given the very serious nature of this tick-borne illness, especially in the elderly and immunocompromised people, we are moving quickly in an effort to confirm Yale's observations while advancing the clinical program for hospitalized babesiosis patients which is now enrolling at Tufts Medical Center. Ultimately, we aim to re-purpose **tafenoquine** as a new babesiosis treatment."

Sometimes called "compassionate use," expanded access is a potential pathway for a patient with a serious or immediately life-threatening disease or condition to gain access to an investigational medical product (drug, biologic, or medical device) for treatment outside of clinical trials when no comparable or satisfactory alternative therapy option is available.

About the 60 Degrees Pharmaceuticals Program for Tafenoquine in Babesiosis
60 Degrees Pharmaceuticals is engaged in advancing multiple clinical trials to establish the safety and efficacy of **tafenoquine**. They are the: 1.) study of hospitalized (i.e., acute) babesiosis patients, now enrolling at Tufts Medical Center; 2.) expanded access for **Tafenoquine** in Babesiosis trial intended to confirm recent findings by Yale School of Public Health; and 3.) expanded access study being planned for chronic babesiosis, the design of which will be gated by an ongoing epidemiological study at North Carolina State College of Veterinary Medicine assessing whether *Babesia* spp parasites are present in samples from human patients who have chronic fatigue/neurologic symptoms.

The three studies address unmet medical need in three important populations of human babesiosis patients: (i) patients hospitalized with severe disease; (ii) patients with persistent disease who have risk factors for relapse; and (iii) individuals with a diagnosis of chronic babesiosis based on clinical manifestations and prior medical history. Based on eventual data from all three trials, 60 Degrees Pharmaceuticals plans to file a New Drug Application with the FDA in the second quarter of 2026 for a supplemental indication for **tafenoquine** in babesiosis.

The Company believes that the total accessible market through the end of patent protection in December 2035 in the U.S. for ARAKODA (**tafenoquine**) for babesiosis is 38,000 (hospitalized and immunosuppressed) acute patients and at least 375,000 patients with chronic babesiosis. The prevalence of patients with chronic disease may be higher and is the subject of ongoing market research and epidemiological studies being conducted by the Company. This is in addition to the potential 1.7 million travelers who could benefit from the use of ARAKODA for malaria prophylaxis over the same period.

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** has not been proven to be effective for treatment or prevention of babesiosis and is not approved by the FDA for such an indication.

About ARAKODA® (tafenoquine)
Tafenoquine was discovered by Walter Reed Army Institute of Research with funding from the United States Army Medical Materiel Development Activity. **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.

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. The statements expressed herein are those of 60 Degrees Pharmaceuticals, Inc. and do not necessarily represent those of the U.S. Department of Defense.

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 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 web site 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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