60 Degrees Pharma Announces IRB Approval of Phase IIA Study to Evaluate Tafenoquine for Babesiosis, an Emerging Tick-Borne Disease; Type C Meeting Re-Scheduled by FDA to January 17, 2024

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- Investigational Review Board (IRB) approval has been granted for 60 Degrees Pharma's double-blind, placebo-controlled study to investigate **tafenoquine** for treatment of hospitalized babesiosis patients
- The previously announced Type C meeting with FDA has been rescheduled by FDA from January 15 to January 17, 2024, due to a federal holiday

WASHINGTON, Dec. 26, 2023 (GLOBE NEWSWIRE) -- 60 Degrees Pharmaceuticals, Inc. (NASDAQ: SXTP; SXTPW) ("60P" or the "Company"), a pharmaceutical company focused on developing new medicines for infectious diseases, announced today the approval of an Investigational Review Board (IRB) sanctioned Phase IIA clinical study. The study aims to investigate the efficacy and safety of the ARAKODA® regimen of **tafenoquine** in combination with standard of care medications for treatment of hospitalized babesiosis patients at lower risk of relapse.

Additionally, the U.S. Food and Drug Administration (FDA) rescheduled the Company's previously announced January 15 Type C meeting to January 17, 2024, due to a federal holiday. The agenda and all material submitted by SXTP to FDA in support of the Type C meeting remain unchanged.

Babesiosis is a potentially life-threatening, tick-borne illness steadily emerging in the United States. Total babesiosis patients in the U.S. may be approximately 47,000 per year based on the observation of 476,000 Lyme infections and an estimated babesiosis coinfection rate of 10 percent.

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 the Phase IIA Tafenoquine for Babesiosis Study
The Phase IIA study, titled, "Double-blind Placebo-controlled Study to Assess the Safety and Efficacy of Oral Tafenoquine plus Standard of Care versus Placebo plus Standard of Care in Patients Hospitalized for Babesiosis," is anticipated to enroll at least 24 patients in the U.S., beginning in Q2 2024. The primary endpoint of the study will be time to molecular cure as determined by an FDA-approved nucleic acid test (NAT). The study will be conducted at three hospitals in the northeastern United States.

The efficacy and safety of 8-aminoquinolines, a class of drugs that includes **tafenoquine** and primaquine, for prevention and treatment of malaria is well established. The appearance of several case studies of **tafenoquine** use for babesiosis in the literature suggests that the drug is being used for this purpose in the practice of medicine in the U.S.

About Babesiosis
An estimated 47,000 cases of babesiosis (i.e., infections caused by red blood cell parasites similar to malaria that are transmitted by deer tick bites) occur in the United States each year and the incidence rate is steadily increasing. An estimated 10 percent of Lyme disease patients are co-infected with babesiosis. The mortality rate of babesiosis patients who have cardiac complications approaches 10 percent.

Babesiosis is spread by the bite of an infected blacklegged tick, Ixodes scapularis. It can also be spread by transfusion of contaminated blood.

Anyone can get babesiosis, but it can be more severe in the elderly, people who have had their spleen removed, and in people who have weakened immune systems (for example, those who have cancer, HIV/AIDS, or a transplant). Most cases occur in coastal areas in the Northeast and upper Midwest, particularly in parts of New England, New York State, New Jersey, Wisconsin, Minnesota and in some European countries. In the Northeast, babesiosis occurs in both inland and coastal areas, including offshore islands such as Nantucket and Martha's Vineyard, which are off Massachusetts, as well as in Long Island and the Hudson Valley in New York State.

Hospitalizations as a result of babesiosis are usually seasonal, occurring June through August. Clinical complications include severe anemia, renal failure, cardiorespiratory failure, and death. Babesiosis was designated a nationally notifiable disease in the United States in 2011, meaning that states where it was reportable were charged to voluntarily notify the Centers for Disease Control and Prevention (CDC) of cases. As of 2015, babesiosis was reportable in 33 states.

About ARAKODA® (tafenoquine)
Tafenoquine was discovered by Walter Reed Army Institute of Research and the current study was funded by 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.

According to the Centers for Disease Control and Prevention, the long terminal half-life of **tafenoquine**, which is approximately 16 days, may offer potential advantages in less-frequent dosing for prophylaxis for 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 of age 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 17 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 (OCT2) or multidrug and toxin extrusion (MATE) 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. 60P successfully achieved FDA approval of its lead product, ARAKODA® (**tafenoquine**), for malaria prevention, in 2018. 60P also collaborates with prominent research organizations in the U.S., Australia, and Singapore. 60P's mission has been supported through in-kind funding from the DOD and private institutional investors including Knight Therapeutics Inc., a Canadian-based pan-American specialty pharmaceutical company. 60P is headquartered in Washington D.C., with a majority-owned 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, 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 the final prospectus to our Registration Statement on Form S-1 (File No.: 333-269483), as amended, initially filed with the SEC on January 31, 2023 relating to our initial public offering, and our subsequent Quarterly Report on Form 10-Q for the period ended June 30, 2023. 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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