60 Degrees Pharmaceuticals Receives FDA Comments on Tafenoquine-Babesiosis Clinical Trial Protocol; No Material Changes Required

May 2, 2024 11:59 AM EDT

- Trial planning and execution to proceed as planned

WASHINGTON, May 02, 2024 (GLOBE NEWSWIRE) -- 60 Degrees Pharmaceuticals, Inc. (NASDAQ: SXTP; SXTPW) (the "Company"), a pharmaceutical company focused on developing new medicines for infectious diseases, announced today that the U.S. Food and Drug Administration (FDA) has provided comments on the protocol of a planned clinical trial that will study the use of **tafenoquine** in treating babesiosis. Babesiosis, a potentially life-threatening disease in immunosuppressed patients, is a tick-borne illness steadily emerging in the United States.

The FDA had some questions and recommendations that will be addressed. Nothing in the comments requires the Company to change the trial design/protocol in a material way. The Company is continuing preparatory actions to facilitate initiation of patient enrollment later in 2024.

The Company conducted a Type C regulatory meeting with the FDA on January 17, 2024, at which a synopsis of the current version of the **tafenoquine** for babesiosis study protocol was discussed. In February 2024, the Company submitted a full protocol to the FDA under its malaria Investigational New Drug ("IND") application, incorporating FDA feedback from the January 17, 2024 meeting.

Because the protocol was submitted under an existing (rather than a new) IND application per the FDA's advice, no formal statutory response time was required by the FDA. The FDA informed the Company in March 2024, however, that comments on that protocol would be provided by April 30, 2024. The FDA provided this feedback on April 26, 2024.

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 Babesiosis and the Tafenoquine Study
This study is a randomized double-blind placebo-controlled trial anticipated to enroll at least 24 patients in the U.S. in 2024. The two main study endpoints will be time to sustained clinical resolution of symptoms of babesiosis and molecular cure as determined by an FDA-approved nucleic acid test. 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.

There may be approximately 47,000 cases per year in the U.S. based on the observation of 476,000 Lyme infections and an estimated babesiosis coinfection rate of 10 percent. The Company estimates that more than a million U.S. citizens could benefit if approved prophylactic options become available.

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 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, 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 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.

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.

Media Contact:
Sheila A. Burke

SheilaBurke-consultant@60degreespharma.com
(484) 667-6330

Investor Contact:
Patrick Gaynes
patrickgaynes@60degreespharma.com
(310) 989-5666

Source: Sixty Degrees Pharmaceuticals