60 Degrees Pharmaceuticals Suspends Phase IIB Study of Tafenoquine for COVID-19, Pivots to Refocus on Commercialization of Treatments for Malaria and Tick-Borne Diseases

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- FDA advice to Company suggested execution of ACLR8-LR, a placebo-controlled Phase IIB study of **tafenoquine** in COVID-19 patients, may not be feasible in the U.S.
- Company will therefore focus efforts on further commercialization related to ARAKODA® (**tafenoquine**) for prophylaxis of malaria, and prepare for a Phase IIA study of **tafenoquine** in hospitalized babesiosis patients
- Company is preparing for submission of a pre-IND meeting request with FDA for babesiosis in the current fourth quarter of 2023, and plans to appoint a chief commercial officer to lead ARAKODA commercialization

WASHINGTON, Oct. 12, 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 that its subsidiary, 60P Australia Pty Ltd, will not re-submit its investigational new drug application ("IND") for ACLR8-LR, a Phase IIB study of **tafenoquine** compared to placebo in patients with mild to moderate COVID-19 disease and low risk of disease progression. **Tafenoquine** is the active molecule in ARAKODA®, the Company's U.S. Food and Drug Administration (FDA)-approved regimen for malaria prevention. The Company's Board of Directors decided on October 6, 2023, that recent advice from the FDA made moving forward with the ACLR8-LR clinical development plan unfeasible.

The FDA has approved or authorized two marketed oral products, Lagrevio™ and Paxlovid™, for use in cases of mild-to-moderate COVID-19 disease to reduce the rate of hospitalizations and deaths in patients with high risk of disease progression. However, the FDA has explicitly not authorized the use of those products in patients with low risk of COVID-19 disease progression. Accordingly, Lagrevio and Paxlovid are not recommended by public health agencies for that purpose.

Current literature on COVID-19 shows that low risk patients have a very low risk of hospitalization. However, patients may wish to make a risk-based decision together with their physician to use a therapeutic that accelerates clinical recovery from COVID-19 symptoms if such a therapeutic were available. FDA guidance for industry implies that a regulatory pathway does exist for approval of new therapeutics that produce "sustained clinical recovery" in COVID-19 patients. FDA-approved or authorized oral therapies have either failed or have not been studied against that endpoint.

60P's early, published Phase IIA clinical data suggested the possibility of a 2 – 2.5 day improvement in clinical recovery from cough, fever, and shortness of breath.[1] Simulations of data from the same study suggested this might also be the case for the FDA's preferred endpoint of "sustained clinical recovery" from all acute symptoms excluding impaired taste and smell (see accompanying figure).

However, in a recent IND withdrawal acknowledgement letter from the FDA, the agency implied that a placebo-controlled study in the U.S. is permissible only if study enrollment is "restricted to a patient population in which nirmatrelvir/ritonavir or other approved or authorized therapeutics are not clinically appropriate."

As a practical matter, the population of patients in the U.S. with medical contraindications to Paxlovid™ and Lagevrio™ is vanishingly small, which would make patient recruitment very challenging. The Company also considered the FDA's recommended approach of a standard of care add-on design. However, such a combination approach may not make clinical sense in a low-risk population or be Phase III enabling. In either case, the Company's Board of Directors determined that raising capital to support a protracted development campaign, or one requiring three additional studies, was not feasible in the current market environment.

Accordingly, as outlined in its registration statement and subsequent communications to the investment community, 60P will instead continue to prepare to conduct a Phase IIA study of **tafenoquine** in hospitalized babesiosis patients, with the goal of requesting a pre-IND meeting with FDA before the end of 2023.

An estimated 47,000 cases of babesiosis (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 increasing. Estimates are that 10 percent of Lyme disease patients are co-infected with babesiosis. Post-exposure prophylaxis following a tick bite is a recognized indication to prevent Lyme disease, and it is likely that a drug proven to be effective for this indication for babesiosis would also be used in conjunction with Lyme prophylaxis.

60P also intends to hire a commercial operations executive to expand its commercialization efforts related to ARAKODA (**tafenoquine**), an antimalarial indicated for prophylaxis of malaria in patients 18 years and older and approved by the FDA in 2018. In the second quarter of 2023, sales of ARAKODA increased by 150 percent relative to the same period in 2022, at an accelerating growth rate.

About ARAKODA® (tafenoquine)

Tafenoquine was discovered by Walter Reed Army Institute of Research and the current study was funded by the Department of Defense's (DOD) Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense, in support of the Defense Health Agency, with the goal of

fielding a safe, effective treatment against COVID-19 by repurposing this FDA-approved drug (Contract: W911QY2190011). **Tafenoquine** was approved for malaria prophylaxis in 2018 in the United States as ARAKODA® (**tafenoquine**) 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. It has been shown that **tafenoquine** inhibits SARS-CoV-2 replication in monkey kidney and human epithelial cells, and pharmacokinetic simulations suggest lung levels at the FDA-approved dose for malaria prevention may exceed the EC90 of the drug. These data provided the rationale for conducting the study of ARAKODA in mild-moderate COVID-19 patients. 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.

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.

Reference:

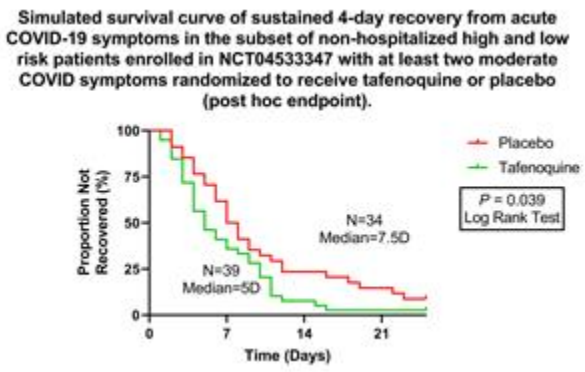
1. G. Dow, B. Smith, A phase II, double blind, placebo-controlled, randomized evaluation of the safety and efficacy of tafenoquine in patients with mild-moderate COVID-19 disease. *New Microbes and New Infections, Vols. 1 to 55; 2013 to 2023.* Published online 2022 Jun 1.

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A photo accompanying this announcement is available at https://www.globenewswire.com/NewsRoom/AttachmentNg/57ef5cc3-2cf8-4a1b-a9d5-eb3a8747459a

TTCR Improvement Tafenoquine v Placebo



Simulated survival curve of sustained 4-day recovery from acute COVID-19 symptoms in the subset of non-hospitalized high and low risk patients enrolled in NCT04533347 with at least two moderate COVID symptoms randomized to receive tafenoquine or placebo (post hoc endpoint).

Source: Sixty Degrees Pharmaceuticals