60 Degrees Pharma Provides University of Kentucky with Right of Reference to ARAKODA® NDA in Support of SJ733 Phase IIb Study

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- University of Kentucky will commence a Phase IIb clinical study of drug development candidate SJ733 for treatment of vivax malaria.
- SJ733 will be combined with a single dose of **tafenoquine** in the study.
- The right of reference allows FDA to review 60 Degrees Pharma's regulatory file when the agency evaluates new study protocols for the SJ733-**tafenoquine** Phase IIb program.

WASHINGTON, Aug. 12, 2024 (GLOBE NEWSWIRE) -- 60 Degrees Pharmaceuticals, Inc. (NASDAQ: SXTP; SXTPW) (the "Company" or "60 Degrees Pharma"), a pharmaceutical company focused on developing new medicines for infectious diseases, announced today that it has granted the University of Kentucky a right of reference to the Company's new drug application ("NDA") for ARAKODA ® (**tafenoquine**).

ARAKODA is the Company's anti-malarial approved by the U.S. Food and Drug Administration ("FDA") in 2018, indicated for the prophylaxis of malaria in patients aged 18 years of age and older.

The right of reference will allow FDA to review clinical efficacy and safety data, non-clinical data, and chemistry, manufacturing and control information on ARAKODA as the agency reviews protocols and new Investigational New Drug ("IND") application submissions related to the University of Kentucky's investigational SJ733 Phase IIb program.

SJ733 is an oral ATP4 inhibitor of *Plasmodium*, which has been shown to have a favorable safety profile and rapid anti-parasitic effect. The Phase IIb study being conducted by the University of Kentucky and Eisai Co. Ltd. ("Eisai") will combine SJ733 with **tafenoquine** – the active ingredient in ARAKODA – to evaluate the safety, tolerability, and pharmacokinetics of a single-dose combination of the two drugs. The trial is funded by the Global Health Innovative Technology Fund. The current state-of-the-art treatment for vivax malaria is a combination of **tafenoquine** and chloroquine administered over three days; however, resistance of *P. vivax* to chloroquine is widespread in some parts of the world.

"Innovations in treating *P. vivax* malaria, which infects an estimated 14 million people a year, have been limited in recent decades," said Dr. R. Kip Guy, principal investigator on the Phase IIb study, and Professor and Dean of the University of Kentucky College of Pharmacy. "The upcoming study of SJ733 combined with **tafenoquine** has the potential to pave the way for very meaningful improvement in malaria treatment around the world."

60 Degrees Pharma will supply **tafenoquine** and placebos as study drugs in the University of Kentucky Phase IIb trial.

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.

About the SJ733 Phase IIb Clinical Trial at University of Kentucky

The overall objective of the Phase IIb study is to examine the clinical safety and efficacy of the combination of SJ733 and TQ for radical cure of *P.* uncomplicated *P. vivax* malaria in adults with a 1, 2, or 3-day schedule of the SJ733-**tafenoquine** combination. The purpose is to develop an SJ733-TQ combination drug suitable for treatment of all patients with uncomplicated *P. vivax* malaria. The targeted results for this study are data that support 1 to 3 doses of an SJ733-TQ fixed-dose combination for radical cure of *P. vivax* mono-infected patients. This will set the stage for subsequent pivotal Phase 3 studies.

SJ733 is a PfATP4 inhibitor that meets criteria for treatment of uncomplicated malaria. Three clinical trials of SJ733 have been completed. Phase I examined safety and pharmacokinetics of SJ733. Phase I tested pharmacodynamics in the human challenge model. Phase II (NCT04709692) determined the parasite reduction ratio, parasite reduction half-life and minimum inhibitory concentration of SJ733 in adults with uncomplicated malaria and assessed the exposure-response relationship (PK/PD). Current Phase Ia, Ib, and IIa human data show an excellent safety profile and tolerability, good oral availability, and moderate drug clearance.

Eisai and the University of Kentucky have collaboratively designed the Phase IIb study and supportive non-clinical safety and pharmacokinetics studies, which will be contracted to rigorously qualified CROs and overseen by Eisai's subject matter experts. Eisai will manage the manufacture of a new batch of SJ733 clinical trial material, as well as oversee conduct of the supportive non-clinical safety and pharmacokinetics studies.

The University of Kentucky will oversee the regulatory filings to amend the current US-FDA IND (held by Professor Guy) for development of SJ733 and the Phase IIb clinical trial work, including the local ethics and regulatory submissions.

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, 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:

1. Glucose-6-phosphate dehydrogenase ("G6PD") deficiency or unknown G6PD status;
2. Breastfeeding by a lactating woman when the infant is found to be G6PD deficient or if G6PD status is unknown;
3. Patients with a history of psychotic disorders or current psychotic symptoms; or
4. 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 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 three 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 for 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 for 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 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 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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