60 Degrees Pharmaceuticals Registers ACLR8-LR, a Phase IIB Study of Tafenoquine for Treatment of COVID-19, on ClinicalTrials.gov

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- ACLR8-LR, a double-blind, randomized, placebo-controlled Phase IIB study to determine efficacy of the ARAKODA® regimen of **tafenoquine** in COVID-19 patients with mild-moderate symptoms and low risk of disease progression, has been registered on ClinicalTrials.gov
- 60P's majority-owned subsidiary, 60P Australia Pty Ltd, has opened a new IND and will conduct the trial, enrolling patients at U.S. clinics beginning in fourth quarter of 2023
- Primary endpoint of ACLR8-LR will be time to sustained clinical recovery from COVID-19 symptoms
- 60P was recently awarded a U.S. patent covering **tafenoquine** for treatment of COVID-19 and other lung infections. **Tafenoquine** is the active molecule in 60P's FDA-approved drug for malaria prevention, ARAKODA
- 60P estimates that 25 percent of U.S. population without risk factors for progression to serious COVID is not appropriate for currently marketed, oral treatments – a significant unmet need

WASHINGTON, Aug. 15, 2023 (GLOBE NEWSWIRE) -- 60 Degrees Pharmaceuticals, Inc. ("60 Degrees Pharmaceuticals" or "60P") (NASDAQ: SXTP), a company specializing in developing and marketing medicines for infectious diseases, today announced that ACLR8-LR, a double-blind, randomized, placebo-controlled Phase IIB study to determine the efficacy of the ARAKODA® regimen of **tafenoquine** in COVID-19 patients with mild-moderate symptoms and low risk of disease progression, is now listed on ClinicalTrials.gov.

The trial will be conducted by 60P's majority-owned subsidiary, 60P Australia Pty Ltd, which opened a new IND on August 14, 2023.

The primary endpoint of ACLR8-LR is time to sustained clinical recovery from COVID-19 symptoms. 60P plans to enroll patients in ACLR8-LR, recruited in up to 30 out-patient clinics across the U.S., beginning in the fourth quarter of 2023. 60P is also planning a second, larger COVID-19 study that is anticipated to commence in 2024.

"Publicly registering ACLR8-LR represents an important milestone in 60P's clinical research strategy," said Chief Executive Officer of 60 Degrees Pharmaceuticals, Geoffrey Dow. "We remain optimistic that results of ACLR8–LR will play an important role in public health efforts to address gaps in the standard of care for COVID-19."

Public health interest in combating COVID-19 remains high. Currently marketed orally administered COVID-19 therapeutics are not appropriate for use by at least 25 percent of the U.S. population who do not have risk factors for progression to severe disease or by travelers who may wish to protect themselves from COVID-19 for extended periods - an unaddressed multi-billion-dollar market opportunity.

Data from a Phase II study published in New Microbes and New Infections, Vol. 47, April – May 2022, a peer-reviewed, open-access journal, suggested a positive therapeutic signal in mild-moderate COVID-19 disease using the ARAKODA regimen of **tafenoquine**; the time to clinical recovery from COVID-19 symptoms was accelerated by about 2 – 2.5 days in the **tafenoquine** arm.

In April, the United States Patent and Trademark Office (USPTO) issued a patent covering the use of **tafenoquine** as a treatment for COVID-19 disease. **Tafenoquine** is the active molecule in 60P's FDA-approved regimen for malaria prevention, ARAKODA. 60P now owns the exclusive rights for the use of **tafenoquine** for treatment of lung infections including COVID-19 in the U.S. through 2040.

ARAKODA, an oral tablet containing 100 mg of a **tafenoquine** base, is indicated for the prophylaxis of malaria in patients aged 18 years and older for up to 6 months of continuous dosing in the U.S. ARAKODA is not currently FDA-approved for the treatment of symptoms caused by the COVID-19 virus.

About the ARAKODA® Regimen of Tafenoquine for COVID-19

Clinical trial data suggesting the ARAKODA® regimen of **tafenoquine** exhibits a positive therapeutic signal in mild-moderate COVID-19 disease were published last year in New Microbes and New Infections, Vol. 47, April – May 2022, a peer-reviewed, open-access journal. The drug increased the proportion of clinically recovered patients by between 9 percent (intent to treat population) and 14 percent (per protocol population); the drug decreased the proportion of clinically unrecovered patients by between 27 percent (intent to treat population) and 47 percent (per protocol population). The study, however, was underpowered to show statistical significance for the primary endpoint due to early termination of the study at n=86 patients. Results also showed that time to clinical recovery from COVID-19 symptoms was accelerated by about 2 – 2.5 days in the **tafenoquine** arm of the double-blind, randomized, placebo-controlled Phase II study.

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. 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. 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.

ARAKODA® (tafenoquine) Important Safety Information

ARAKODA® is an antimalarial indicated for the prophylaxis of malaria in patients aged 18 years of age and older.

Important Safety Information

Contraindications

ARAKODA® should not be administered to patients:

- With Glucose-6-phosphate dehydrogenase (G6PD) deficiency or unknown G6PD status;
- Who are breastfeeding or lactating when the infant is found to be G6PD deficient or if G6PD status is unknown;
- With a history of psychotic disorders or current psychotic symptoms; or
- With 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 ≥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 at 1-888-834-0225 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch. **ARAKODA®** full prescribing information is 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 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 United States Department of Defense and private investment from 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 our final prospectus to our Form S-1 (File No.: 333-269483) filed with the SEC on July 13, 2023, and our subsequent annual reports on Form 10-K and our quarterly reports on Form 10-Q. 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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