60 Degrees Pharma Withdraws COVID Phase IIB IND, Will Resubmit Pending Assessment of Ability to Meet FDA Requirements

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- Prompted by advice from FDA regarding study design, 60P Australia Pty Ltd, a majority-owned subsidiary of 60 Degrees Pharmaceuticals, has withdrawn its IND for ACLR8-LR, a Phase IIB study of the use of **tafenoquine** in treating COVID-19; Company plans to resubmit a revised IND later in 2023, pending a feasibility assessment
- 60P has paused further study start-up preparations related to ACLR8-LR, decreasing the Company's short-term burn rate
- 60P will continue planned efforts to expand its malaria business and prepare an IND for **tafenoquine** for babesiosis to be submitted to FDA

WASHINGTON, Sept. 18, 2023 (GLOBE NEWSWIRE) -- 60 Degrees Pharmaceuticals, Inc. ("60P") (NASDAQ: SXTP), specialists in developing and marketing medicines for infectious diseases, today announced that 60P Australia Pty Ltd, a majority-owned subsidiary of 60P, has withdrawn its investigational new drug (IND) application for ACLR8-LR, a Phase IIB study of the use of **tafenoquine** in treating COVID-19, and intends to submit a new IND in the fourth quarter.

The Company's decision to withdraw the IND is in response to recent comments from the U.S. Food and Drug Administration (FDA). 60P plans to submit a new IND to FDA within the current year, pending an assessment of whether it is feasible to revise the trial design to meet the agency's expectations while also allowing for confirmation of the acceleration in recovery from COVID-19 symptoms suggested by an earlier study.

In the interim, pending additional interaction with FDA, 60P has paused further start-up activities for its Phase IIB trial (ACLR8-LR), thereby decreasing the Company's burn rate and improving its cash position in the short term. Should the outcome of further interactions with FDA be positive, and depending on market conditions, the Company will make a decision regarding whether to continue its original strategy of self-funding its Phase IIB study or to seek a strategic partner to continue development.

In parallel, as outlined in its registration statement and subsequent communications to the investment community, 60P plans to continue preparation of 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 the calendar year.

At estimated 47,000 cases of babesiosis (red blood cell infections caused by deer tick bites) occur in the United States each year, and the incidence is increasing. Babesiosis is endemic in the U.S. 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 plans to continue its commercialization efforts related to ARAKODA® (tafenoquine), an antimalarial indicated for prophylaxis of malaria in patients 18 years and older and approved by FDA in 2018. In Q2 2023, sales of ARAKODA increased by 150 percent relative to the same period of 2022.

"A clear unmet need remains to provide a safe, effective treatment for the low-risk COVID-19 patient population and we have seen that **tafenoquine** holds promise in meeting that need," said 60 Degrees Pharmaceuticals CEO, Dr. Geoff Dow. "While we determine whether moving forward in modifying ACLR8-LR such that it meets FDA's requirements is feasible, we will continue existing efforts related to expansion of our commercial malaria business and submission of an IND for further study of how **tafenoquine** may be effective in combatting babesiosis."

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.

Neither ARAKODA nor **tafenoquine** has been approved by FDA for treatment or prevention of babesiosis.

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:

- Patients with Glucose-6-phosphate dehydrogenase (G6PD) deficiency or unknown G6PD status
- Lactating women who are breastfeeding 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
- Patients 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 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 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 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 United States Department of Defense 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 our Annual Report on Form 10-K and our subsequent 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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