60 Degrees Pharmaceuticals Study Results Published by New Microbes and New Infections Demonstrate Tafenoquine Exhibits Broad Spectrum Antifungal Activity

August 30, 2023 11:32 AM EDT

- Data showed tafenoquine does not exhibit cross-susceptibility with fluconazole against *Candida* spp.
- Effective treatment of drug-resistant *Candida* infections is an unmet need in U.S. market
- Presumed mode of action differentiated from standard of care treatment

WASHINGTON, Aug. 30, 2023 (GLOBE NEWSWIRE) -- 60 Degrees Pharmaceuticals, Inc. ("60P") (NASDAQ: SXTP), specialists in developing and marketing medicines for infectious diseases, today announced the journal, *New Microbes and New Infections*, has published non-clinical study results showing **tafenoquine** exhibits broad spectrum antifungal activity, including against *Candida* spp. in cell culture, and decreases fungal burden in the lungs in an invasive pulmonary model of *Rhizopus* in mice.

New Microbes and New Infections is a peer-reviewed, open-access journal. The research was funded by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH).

Tafenoquine is the active ingredient in an anti-malarial approved by the FDA in 2018 and is indicated for the prophylaxis of malaria in patients aged 18 years of age and older. 60P was recently awarded a U.S. patent covering **tafenoquine** for treatment of COVID-19 and other lung infections.

"A substantial unmet need exists for clinical therapies that treat and prevent life-threatening fungal infections," said Chief Executive Officer of 60 Degrees Pharmaceuticals, Geoffrey Dow. "Even when antifungal treatments approved by the FDA are administered to patients, the morbidity, mortality, and clinical incidence of rapidly emerging, dangerous fungal infections such as *Candida* and *Rhizopus* remain high. Data from this set of studies confirm that **tafenoquine** holds promise in addressing that unmet need in the U.S. It is particularly interesting that **tafenoquine** did not exhibit any cross-resistance to fluconazole against *Candida* species, and that the presumed mode of action, through the induction of oxidative stress, differs from standard of care treatments. We are pursuing this hypothesis as part of our research strategy."

About *Candida auris (C. auris)* and *Rhizopus*

Candida auris (C. auris) is an emerging fungus that presents a serious global health threat, according to the Centers for Disease Control and Prevention (CDC). *C. auris* is often multi-drug-resistant, meaning that it is resistant to multiple antifungal drugs commonly used to treat *Candida* infections.

C. auris carries a high mortality rate, killing more than 1 in 3 people with infections. Infections often emerge in healthcare settings, where people are particularly vulnerable. Rates are rising; the CDC reports annual cases of *C.auris* in the United States have risen from fewer than 500 in 2019 to nearly 1,500 in 2023.

Rhizopus species, one of the most common types of mucormycetes that cause mucormycosis, is a rare, life-threatening fungal infection that primarily affects immunocompromised humans, with an estimated mortality rate of 23–100 percent. Humans contract mucormycosis through contact with the fungal spores in the environment. The pulmonary form of the infection can occur after a person inhales the spores. Pulmonary and GI mucormycosis due to *Rhizopus* in children can be fatal when not promptly diagnosed and treated. In immunocompromised patients, the disease is typically progressive and frequently fatal.

About the Tafenoquine Antifungal Study
Minimum inhibitory concentrations (MICs) of medically important fungal pathogens were determined using conventional cell culture assays. The daily maximum tolerated dose (MTD) of **tafenoquine** was determined in neutropenic mice and the effect of two dose levels of **tafenoquine** on survival and fungal burden were assessed in *Rhizopus* and *Aspergillus* lung infections models. Mean MICS against panels of yeasts and dimorphic/filamentous fungi were 4.5 and 8.3 ug/mL. The MTD of **tafenoquine** was 5 mg/kg/day. Against Aspergillus, **tafenoquine** at the MTD did not increase survival or decrease fungal burden. Against Rhizopus, **tafenoquine** at the MTD decreased lung fungal burden in a dose-related manner. Survival in the high-dose MTD **tafenoquine** group was 30 percent whereas it was 0 percent in the vehicle group and in most legacy studies.

This research has used the NIAID suite of preclinical services for *in vitro* and *in vivo* assessments (Contract No. HHSN272201700039I 75N93019F00131).

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 fungal infections.

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.

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