60 Degrees Pharmaceuticals Announces Positive Results of Cell Culture Testing of ARAKODA® (tafenoquine) for COVID-19

In vitro testing demonstrates that tafenoquine exhibits antiviral activity against SARS-CoV-2

WASHINGTON, D.C.—July 14, 2020. 60 Degrees Pharmaceuticals, LLC (60P), a pharmaceutical company focused on developing new medicines for tropical diseases, announced today that initial testing in cell culture shows that **ARAKODA®** (tafenoquine) is active against SARS-CoV-2 at clinically relevant concentrations.

60P collaborated with Biointelect, 360 Biolabs, Biocelect, and Certara to conduct testing on tafenoquine. In vitro testing and modeling and simulation with Certara's Simcyp™ Simulator demonstrate that tafenoquine shows antiviral activity at concentrations that are pharmacologically relevant and may be achievable in lung tissue. In vitro testing in Vero E6 cells shows that tafenoquine seems to interfere with infectious virus replication and reduce the yield of progeny virus. Tafenoquine [an 8-aminoquinoline] also appears to exhibit greater potency and a different mode of action than hydroxychloroquine [a 4-aminoquinoline], which is consistent with known differences in structure and modes of action against other organisms. Analysis and results are available in a preprint manuscript on bioRxiv, which is not yet peer reviewed.

"Based on this data, we believe that there is pharmacological plausibility and proof of hope that **ARAKODA®** may have potential to be effective in the treatment pathway for COVID-19," said Geoffrey Dow, chief executive officer of 60P. "We are encouraged by these results and are excited to evaluate this further to help identify a safe and effective therapeutic to stem the COVID-19 pandemic."

60P intends to conduct further preclinical and clinical studies to evaluate the clinical relevance of these findings and is seeking financing and research partners in pursuit of this objective.

Tafenoquine was originally discovered by Walter Reed Army Institute of Research. It was approved for malaria prophylaxis in 2018 in the United States as **ARAKODA®** and Australia as **KODATEF®**. Both were commercially launched in 2019 and 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 CDC, the long terminal half-life of tafenoquine may offer potential advantages in less-frequent dosing for prophylaxis for malaria.[i] At approved doses in healthy individuals, tafenoquine does not prolong cardiac repolarization [QTC interval].[ii]

To learn more about **ARAKODA®**, please join CEO Geoffrey Dow in a webinar on Tuesday, July 28th at 11am Eastern Time.

ARAKODA® [tafenoquine] has not been evaluated in COVID-19 patients, and no tafenoquine-containing product is FDA-approved to treat or prevent COVID-19. Testing for G6PD (Glucose-6-phosphate dehydrogenase deficiency) is mandatory before prescribing **ARAKODA®** and **KODATEF®**.
ARAKODA® is not suitable for everyone, and patients and prescribers should review the **Important Safety Information** below.

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
- 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%) 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. In Australia, contact Biocelect at 1-300-848-628.

About 60 Degrees Pharmaceuticals

60 Degrees Pharmaceuticals, founded in 2010, focuses on developing new medicines for treatment and prevention of tropical diseases, including malaria and dengue. 60P's mission is supported through in-kind funding from the U.S. Department of Defense. The company also collaborates with prominent research organizations in the U.S. and Australia. 60P is headquartered in Washington D.C., with a subsidiary in Australia. Further information is available on the company's website, www.60degreespharma.com.

About Biocelect

Biocelect, founded in 2014, is actively involved in the sourcing, in-licencing and commercialization of pharmaceuticals, vaccines and in-vitro diagnostics that will meet the unmet medical needs of patients in Australia and the region. Biocelect combined with its companion company Biointelect (www.biointelect.com) has an experienced team that provides a range of partnering solutions to local and international companies looking to launch their products in Australia and the region. For more information about **KODATEF®** visit www.biocelect.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.

Media Contact
Geoffrey Dow, CEO of 60P
202-327-5422
inquiries@60-p.com

Australia Media Contact
Jennifer Herz, Director of 60P
+61-415-275-893
jherz@biocelect.com

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[i] https://wwwnc.cdc.gov/travel/news-announcements/tafenoquine-malaria-prophylaxis-and-treatment

[ii] Green JA, Patel AK, Patel BR, Hussaini A, Harrell EJ, McDonald MJ, Carter N, Mohamed K, Duparc S, Miller AK. 2014. Tafenoquine as therapeutic concentrations does not prolong Fridericia-corrected QT interval in healthy subjects. J Clin Pharmacol 54:995-1005.