60 Degrees Pharmaceuticals to Sponsor Pilot Study of Tafenoquine for Treatment of Canine Babesiosis

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- Study to be conducted by North Carolina State University in 2024
- Standard of care fails in 20 percent of cases and drug resistance is a problem
- Standard of care is expensive

WASHINGTON, April 03, 2024 (GLOBE NEWSWIRE) -- 60 Degrees Pharmaceuticals, Inc. (NASDAQ: SXTP; SXTPW) (or the "Company"), a pharmaceutical company focused on developing new medicines for infectious diseases, announced today that the Company will sponsor a pilot study of **tafenoquine**, the active molecule in its U.S. Food and Drug Administration (FDA)-approved human malaria prevention medication, ARAKODA®, for the treatment of babesiosis in dogs. The study will support a broader effort now being led by 60 Degrees Pharmaceuticals to evaluate **tafenoquine** for various babesiosis indications.

Tafenoquine has not been proven to be effective for treatment or prevention of canine babesiosis and is not approved by the FDA for such an indication.

About the Tafenoquine for Canine Babesiosis Pilot Study
The study will involve an evaluation of a three-day loading dose followed by weekly dosing for a month in dogs recruited in veterinary clinics across the United States. The study has been approved by an Institutional Animal Care and Use Committee (IACUC) ethics committee. No dogs will be harmed in this study. Efficacy will be monitored via episodic PCR testing, and results are expected in 12 months. The pilot study of **tafenoquine** for treatment of canine babesiosis will be conducted by North Carolina State University this year.

About Canine Babesiosis
Canine babesiosis, caused by the protozoan, *Babesia*, is an emerging infection of dogs. Several thousand dogs may be treated each year in the U.S. This emergence may be related to increasing ticks (range expansion and abundance) and dog importation. Specific breeds (i.e. some members of the Terrier group, Greyhounds) are at increased risk of infection. Dogs can have subclinical disease (i.e. no clinical signs) or illness that ranges from mild (e.g. lethargy, reduced appetite) to severe (e.g. pallor and weakness related to anemia). Severe disease can result in death. Infection is spread through tick bites and exposure to infected dog blood. Infected dogs, even those without clinical signs, can spread the infection to other dogs, particularly in kennels.

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 for humans.

Disclaimer & Cautionary Note Regarding Forward-Looking Statements
The statements made about our **tafenoquine**-babesiosis clinical trial in this press release are based on both written correspondence from the FDA ahead of the Company's Type C meeting on January 17, 2024, and the Company's minutes from the meeting. The Company has been advised, but cannot guarantee, it will receive FDA comments by April 30, 2024. Any information released by us about the protocol on clinicaltrials.gov, our website or elsewhere should be considered out of date as of the date of this press release. The Company has not yet rewritten its clinical protocol in light of FDA comments and there is no guarantee it will receive Institutional Review Board or FDA approval of the protocol when resubmitted. The protocol will be resubmitted under our malaria Investigational New Drug Application, and is not subject to the minimum 30-day holding period required for a new Investigational New Drug Application. However, the FDA can at its discretion require changes to protocols at any time.

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 the information contained in the final prospectus to our Registration Statement on Form S-1 (File No. 333-269483), as amended, initially filed with the SEC on January 31, 2023 relating to our initial public offering, and our subsequent SEC filings.

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

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