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US FDA Advisory Committee votes in favor of Tafenoquine for the prevention of malaria

Washington DC, July 26, 2018 –60 Degrees Pharmaceuticals (60P) announced today that the Antimicrobial Drugs Advisory Committee (AMDAC) of the United States Food and Drug Administration (FDA) voted to support Tafenoquine, an investigational drug for the prevention of malaria in adults, voting (11 for; 2 against) on its efficacy and (9 for; 4 against) for its safety.

Tafenoquine will be marketed under the brand name Arakoda™.

"If approved, we feel Tafenoquine will provide a significant advancement in protecting individuals traveling to parts of the world where malaria is endemic," said Dr. Geoffrey Dow, CEO, 60P. "Arakoda™ could be an ideal option for people traveling for leisure, employees of non-governmental organizations, industrial and business workers, and military forces." Tafenoquine is a convenient once-a-week dosing option, which could help ensure compliance while on travel. Clinical trials indicate the product is effective against the two primary types of malaria (P. Vivax and P. Falciparum).

AMDAC provides the FDA with independent advice from outside experts on issues related to infectious diseases. The advisory committee provides recommendations for the FDA to consider about the safety and efficacy of a drug. The FDA, however, makes the final decisions.

In December, 60P submitted a new drug application (NDA) to the FDA for the use of Tafenoquine to prevent malaria in adults. A regulatory submission was also made to the Australian Therapeutic Goods Administration (TGA) in September 2017.

About malaria
Malaria, a life-threatening disease transmitted through the bite of an infected mosquito, caused an estimated 429,000 fatalities and 212 million clinical cases in 2015, according to the CDC. It poses a significant risk to millions of healthy individuals traveling in many parts of the world. Malaria cases among travelers returning to the U.S. have been trending upwards. 1

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About tafenoquine
Tafenoquine is an 8-aminoquinoline chemically derived from Primaquine, with activity against all types of malaria. It was first synthesized by scientists at the Walter Reed Army Institute of Research in 1978.

60P entered into a cooperative research and development agreement with the U.S. Army Medical Materiel Development Activity (USAMMDA) in 2014 to develop Tafenoquine as a weekly prophylactic drug for the prevention of malaria. Since malaria is the top infectious disease threat to U.S. Military service members overseas, the military maintains a robust anti-malarial drug development effort through internal research and commercial partnerships. The NDA submission is a culmination of over 30 years of research and development with the U.S. Army Medical Research and Materiel Command, from the discovery of Tafenoquine at the Walter Reed Army Institute of Research through the current collaboration between 60P and USAMMDA.

About the regulatory submission
The regulatory submission included efficacy and safety data on tafenoquine from animal studies and 21 clinical trials involving more than 3,100 participants who have taken tafenoquine.

About 60P
60P, founded in 2010, focuses on discovering, developing and distributing new medicines for treatment and prevention of tropical diseases, including malaria and dengue. 60P's mission is supported through in-kind funding from the United States Department of Defense. The company also collaborates with prominent research organizations in the U.S., Australia and Singapore. In addition, 60P has been funded by Knight Therapeutics Inc. (TSX:GUD), a Canadian specialty pharmaceutical company that obtained FDA approval for Impavido, a product for leishmaniasis, a tropical disease, and monetized a PRV. 60P is headquartered in Washington DC, with a subsidiary in Australia. Further information is available on the company's website, www.60degreespharma.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.

The statements expressed herein are those of 60P and do not necessarily represent those of the United States Department of Defense or Department of the Army.

1 Cullen KA, Mace KE, Arguin PM. Malaria Surveillance-United States, 2013 MMWR Surveillance Summary 2016:65 (No.SS-2);1-22 DOI:http://dx.doi.org/10.15585/mmwr.SS6502a1