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60 Degrees Pharmaceuticals Fast Tracked For Malaria Drug

Washington DC, January 4, 2018 –60 Degrees Pharmaceuticals (60P) has received Fast Track designation from the United States Food and Drug Administration (USFDA) for the investigation of Tafenoquine for prevention of malaria in adults.

A drug is designated as a fast track product "for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition," [1] according to the FDA.

In December, 60P submitted a New Drug Application (NDA) to the USFDA for the use of Tafenoquine to prevent malaria in adults traveling to areas where the disease is prevalent.

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. [2] It poses a significant risk to millions of healthy individuals traveling in many parts of the world, including employees of non-governmental organizations, casual vacationers, industrial and business workers, and military forces. [3] Malaria cases among travelers returning to the U.S. have been trending upwards, with 84% of those infected requiring hospitalization. [4]

"Finding acceptable drugs to safeguard travelers and deployed military personnel against malaria is a real problem," said Geoffrey Dow, Ph.D., CEO 60 Degrees Pharmaceuticals.
We see Fast Track Designation as a next step toward marketing this product with a convenient weekly dosing regimen in the United States, and eventually around the world. It is our continued belief our dossier will receive priority review, thereby expediting the review of Tafenoquine. This better positions 60P for a priority review voucher (PRV) thus assisting 60P to acquire needed resources to launch Tafenoquine."

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.

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A recent analysis of five clinical trials to assess the safety and tolerability of Tafenoquine has been published in *Travel Medicine and Infectious Disease,* a peer reviewed journal. The authors concluded that Tafenoquine appeared to be safe and well tolerated when the anticipated clinical regimen (ACR) was administered.

In all five studies, the majority of adverse events (AEs) were mild or considered unrelated to the study drug. For the full article, "Tafenoquine for malaria prophylaxis in adults: An integrated safety analysis," by Moreno et al., 2017, please go to: http://www.travelmedicinejournal.com/article/S1477-8939(17)30079-0/fulltext

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 Guidance for Industry, Expedited Programs for Serious Conditions-Drugs and Biologics, U.S. Department of Health and Human Services Food and Drug Administration, May 2014, http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM358301.pdf

2 CDC. 2017. Malaria Facts. https://www.cdc.gov/malaria/about/facts.html

3 WWARN. 2017. Antimalarial Drug Resistance http://www.wwarn.org/about-us/malaria-drug-resistance

4 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

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