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# 60° Pharmaceuticals (60P) Submits New Drug Application to US FDA for Antimalarial Drug Tafenoquine:

## 60P Will Continue Global Regulatory Strategy and Pursue Additional Dossier Submissions

**Washington DC, December 18, 2017 –** 60 Degrees Pharmaceuticals (60P) announced it has submitted a New Drug Application (NDA) to the United States Food and Drug Administration for the use of Tafenoquine to prevent malaria in adults traveling to areas where malaria is prevalent.

Malaria, a life-threatening disease caused by *Plasmodium* parasites that are transmitted to people through the bite of an infected mosquito, caused an estimated 429,000 fatalities and 212 million clinical cases in 2015.[1] It poses a significant risk to millions of healthy individuals traveling in many parts of the world, including employees of non-governmental organizations (NGOs), casual vacationers, industrial and business workers, and military forces.[2] Malaria cases among returning travelers in the U.S. have been trending upwards, with 84% of those infected requiring hospitalization.[3]

"There are real problems with the few anti-malarial drugs we currently have, including both resistance and safety issues. In particular, there can be a problem finding acceptable drugs to safeguard travelers and deployed military personnel," said Dr. Stephen Toovey, Pegasus Research. "Tafenoquine should prove a useful alternative in combating malaria."

"60P is proud of this significant milestone, a first for our organization," stated Geoffrey Dow, Ph.D., CEO 60 Degrees Pharmaceuticals. "The work that has been done to date, including significant legacy research at the Walter Reed Army Institute of Research (WRAIR), establishes that Tafenoquine targets all types of malaria including the most common parasites (*P. vivax* and *P. falciparum*). We hope to market this product with a convenient weekly dosing regimen in the United States and eventually around the world," Dr. Dow continued. "It is our belief our dossier will receive priority review, expediting the review of Tafenoquine, and 60P may qualify for a priority review voucher (PRV). This will help us acquire needed resources to provide this product to travelers who wish to be protected against deadly malaria parasites."

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. As 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.

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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 Walter Reed Army Institute of Research (WRAIR) through the current collaboration between 60P and USAMMDA.

Researched for more than 30 years for both the prevention and treatment of malaria, Tafenoquine works against the major malaria parasites and all stages of the parasite's lifecycle. Tafenoquine has been studied in more than 30 clinical trials involving more than 4,000 study participants.

A recent analysis of five clinical trials to assess the safety and tolerability of an investigational antimalarial agent, Tafenoquine, has been published in *Travel Medicine and Infectious Disease*, a peer-reviewed journal. The authors of the analysis conclude that the antimalarial agent 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]CDC. 2017. Malaria Facts. https://www.cdc.gov/malaria/about/facts.html

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

[3]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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