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60° Pharmaceuticals (60P) Receives Priority Review Designation For Malaria Drug

Washington DC, February 7, 2018 – 60 Degrees Pharmaceuticals (60P) received Priority Review Designation from the United States Food and Drug Administration (USFDA) for Tafenoquine (TQ) for prevention of malaria in adults.

The FDA informed 60P of this designation upon filing of its' New Drug Application (NDA).

USFDA priority review is granted when a drug is intended to treat a serious condition and would "provide a significant improvement in safety or effectiveness"[1] over currently available options. The USFDA goal for completing a priority review of an NDA is six months. This designation is often used in combination with other expedited review processes.

In January 2018, 60P received USFDA Fast Track Designation 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, 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.[2] Malaria cases among travelers returning to the U.S. are trending upwards, with 84% of those infected requiring hospitalization.[3] In 2015, there were 212 million clinical cases and malaria caused an estimated 429,000 fatalities.[4]

"We see Priority Review, following our Fast Track Designation, as a validation of the importance of this therapy. TQ will provide a significant improvement over currently available therapies. TQ has the advantage of a convenient weekly dosing regimen which will help travelers comply and protect themselves from malaria parasite(s) while in endemic regions of the world" said Geoffrey Dow, Ph.D., CEO, 60 Degrees Pharmaceuticals.

Dr. Dow further commented that "receiving priority review expedites the review of Tafenoquine and indicates that the product potentially fulfils the statutory requirements for a priority review voucher (PRV). Receiving a PRV would assist 60P in acquiring needed resources to launch Tafenoquine."

In 2014, 60P entered into a cooperative research and development agreement with the U.S. Army Medical Materiel Development Activity to develop Tafenoquine, which was discovered at the Walter Reed Army Institute of Research. 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

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through internal research and commercial partnerships.

An analysis of five clinical trials to assess the safety and tolerability of Tafenoquine has recently 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. 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] 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

[4] CDC. 2017. Malaria Facts. https://www.cdc.gov/malaria/about/facts.html

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