60 Degrees Pharmaceuticals (60P) Achieves First Global Product Launch Milestone by providing new Malaria Prevention Medicine, Kodatef® (tafenoquine succinate), to Australia

60P partners with Biocelect to provide product to the Australian traveler's market

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60 Degrees Pharmaceuticals (60P) and its Australian distribution partner Biocelect Pty Ltd, began commercialising the new malaria prevention medicine, Kodatef® (tafenoquine succinate). The two organisations announced today that the first shipments of **Kodatef** have arrived and are now available to customers in Australia.

In September 2018, the Therapeutic Goods Administration (TGA) approved **Kodatef** for the prevention of malaria in adults 18 years of age and above for up to 6 months of continuous dosing. The approval marked the first time in more than 20 years that the TGA had approved a new drug for the prevention of malaria. Malaria remains widespread in many countries, including Australia's near neighbors.

"The first shipments of **Kodatef** into the Australian market represent an exciting and important milestone for 60P and our partner, Biocelect," said Doug Loock, Vice President of Global Commercial Operations at 60 Degrees Pharma. "We know that the threat of malaria is growing in a number of areas around the globe. It is gratifying to be part of the effort to protect individuals from this life-threatening disease when they are travelling to malaria endemic areas. We look forward to continuing to build on today's success."

"In **Kodatef**, the travel medicine community now has an antimalarial option that provides protection in all of the malaria endemic zones," said Karl Herz, Managing Director of Biocelect. "We remain committed to serving the Australian travel market with new and exciting products and today we took our first step to doing so."

Kodatef has the potential to protect Australian travelers from the devastating and life-threatening effects of malaria. Approximately 700-800 Australians contract malaria every year, largely through foreign travel, and suffer severe symptoms that generally require hospitalization and which, without treatment, can be fatal.

After an initial loading dose prior to travelling, **Kodatef** is to be taken once a week, with only one dose required on return from the malaria-affected region. This convenience may make it more likely that travellers will adhere to the drug regimen. For **Kodatef** dosing information, refer to the regimen below or the **Kodatef (tafenoquine succinate)** Approved Product Information. You may also refer to the Kodatef (tafenoquine succinate) Product and Consumer Medicine Information Licence.

60P plans to launch a similar product under a different brand name in the United States during summer 2019.

Important Safety Information

Dosing regimen for KODATEF® (tafenoquine succinate)

Loading Dose	Before travelling to a malarious area	200 mg (two of the 100 mg tablets) once daily for three days.
Maintenance Dose	While in the malarious area	200 mg (two of the 100 mg tablets) once weekly – start seven days after the last loading dose.
Final (Terminal) Dose	In the week following exit from the malarious area	Single 200 mg dose (two of the 100 mg tablets) 7 days after the last maintenance dose.

Individuals need to complete the full course of KODATEF including loading and terminal doses. If leaving the malarious area before the start of the maintenance regimen, a single terminal dose should be taken 7 days after the last dose of the loading regimen.

Contraindications: KODATEF should not be administered to:

- Individuals with G6PD deficiency or unknown G6PD status due to the risk of haemolytic anaemia.
- Pregnancy and Lactation.
- Subjects with current or history of psychosis.
- Known hypersensitivity to tafenoquine, other 8-aminoquinolines, or any other component of KODATEF formulation. Due to the long half-life of tafenoquine (up to 17 days), hypersensitivity reactions may be delayed in onset and/or duration.

Special warnings and precautions for use:

G6PD enzyme deficiency

G6PD deficiency should be excluded before prescribing KODATEF due to the risk of haemolytic anaemia in patients with G6PD deficiency. Physicians need to be aware of residual or unrecognised risk of haemolysis due to limitations of the G6PD tests. In clinical trials, declines in haemoglobin levels have been reported in patients with normal G6PD enzyme levels. Monitor patients for clinical signs or symptoms of haemolysis. Advise patients to discontinue KODATEF and seek medical attention if signs of haemolysis occur.

Psychiatric Effects

In patients receiving KODATEF in clinical trials, adverse psychiatric reactions included sleep disturbances (2.5%), depression/depressed mood (0.3%), and anxiety (0.2%). KODATEF was discontinued in one subject with a reported adverse reaction of suicide attempt (0.1%) deemed unrelated to KODATEF by the Investigator. Subjects with a history of psychiatric disorders were excluded from the pivotal clinical study (trial 033) supporting the use of KODATEF for prophylaxis of malaria. Serious psychiatric disorders such as psychosis and depression have been associated with some quinoline anti-malarial agents. KODATEF should not be used in

subjects with a history of serious psychosis or current psychotic symptoms, delusions or hallucinations. If psychosis or other serious psychiatric events occur while taking KODATEF, urgent medical advice should be sought.

Haematological effects

Haemoglobin decreases by 0.66 g/dL have been frequently reported in clinical trials of KODATEF. Asymptomatic elevations in methaemoglobin, characteristically increases to >1% but below 10% (a level associated with hypoxia), have been observed in the clinical trials of KODATEF. Discontinuation of KODATEF treatment is recommended if signs and symptoms of methaemoglobinaemia occur, followed by medical advice and appropriate medical therapy.

Gastrointestinal effects

Gastrointestinal effects including diarrhoea (13% of subjects), vomiting (4%), and gastroesophageal reflux disorder (2%), occurred at a greater frequency in KODATEF - treated subjects than in placebo subjects in clinical trials. Administration of KODATEF with food may ameliorate these gastrointestinal effects.

Use in hepatic impairment

KODATEF pharmacokinetics have not been studied in patients with hepatic impairment. Patients with serum levels of ALT >60 U/L and total bilirubin levels >2.0 mg/dL were excluded or infrequently entered in the pivotal clinical trials (mean ALT = 28 U/L, SD=12; mean total bilirubin = 0.5 mg/dL, SD=0.3).

Use in renal impairment

KODATEF pharmacokinetics have not been studied in patients with renal impairment. Patients with serum creatinine >1.8 mg/dL were excluded from the pivotal clinical trials. Use in the elderly Clinical trials did not include sufficient numbers of subjects 65 years of age and over to determine if they respond differently than younger subjects.

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Paediatric use

Safety and effectiveness in children have not been established.

Effects on laboratory tests

The use of KODATEF may influence the results of certain laboratory tests including biochemical parameters of the liver and kidneys and haematology parameters. These changes, which are expected due to the oxidative nature of 8-aminoquinoline drugs, generally remain within the normal laboratory range of each parameter. Biochemical parameter changes may include mild ALT elevations (> 60 U/L) and serum creatinine elevations > 1.8 mg/dL. Change in haematology parameters, may specifically include a reduction of haemoglobin > 0.66 g/dL and

methaemoglobin increases to >1%. Methaemoglobin does not increase to as much as 10%, a level associated with hypoxia.

INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS
KODATEF may inhibit drug transporters in the kidney. Since inhibition of these transporters may lead to increased exposure to medications that they excrete, when KODATEF is coadministered with procainamide, it may be advisable to re-evaluate the safety and/or efficacy of procainamide. Tafenoquine inhibited the in vitro transport of [14C] metformin via OCT2, MATE1, and MATE2-K. Clinical predictions indicate there may be a potential, but low risk of lactic acidosis in subjects who receive tafenoquine and metformin concomitantly, due to an increased exposure to metformin arising from this interaction.

Treatment with Other Potentially Haemolytic Drugs
Drugs including dapsone may cause haemolysis in G6PD-normal individuals. It is possible that dapsone in combination with KODATEF might cause haemolysis in G6PD-normal individuals. If dapsone is co-administered with KODATEF, monitor urine for dark colour and perform periodic checks of hematocrit.

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 U.S. Centres for Disease Control and Prevention (CDC). Malaria cases among travellers returning to the U.S. have been trending upwards.

About Kodatef (tafenoquine succinate)

Tafenoquine is an 8-aminoquinoline chemically derived from primaquine, with activity against all types of malaria. It was first synthesized by scientists at WRAIR in 1978. The TGA approval was a culmination of more than 30 years of research and development with the USAMRMC, from the discovery of tafenoquine at WRAIR through the current collaboration between 60P and USAMMDA. Further information is available on www.biocelect.com.

About Biocelect
Biocelect is all about “Building Pathways to Patients”. Being Sydney based, Biocelect is 100% Australian and family owned and is a company that sources, in-licences and commercialises biopharmaceutical, device and in vitro diagnostic products that address unmet medical needs of patients and customers in Australia, New Zealand and the South Pacific region. In Australia, Biocelect has just registered its first specialty prescription product, **Kodatef** with the Australian Therapeutic Goods Administration. The first prescription product with a new active ingredient for malaria prophylaxis in Australia in 20 years. Preparations for the launch of **Kodatef** are now underway. Being an agile company, we can provide a range of bespoke partnering solutions for companies wanting to distribute their products in Australia and the region. Biocelect has an experienced and seasoned team with many years of experience in the global pharmaceutical, device and in vitro diagnostic markets. Biocelect also has the ability to draw on the extensive capability of its sister company, Biointelect, including Biointelect’s deep knowledge of market

evaluation and market access in Australia and internationally. This allows Biocelect to provide the functions of a bigger company, with an experienced team of people. Hence ensuring the success of the product in the region and ultimately meeting the needs of patients and customers. For further information on Biocelect or **Kodatef** please contact us at info@biocelect.com

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 U.S. Department of Defence. The company also collaborates with prominent research organizations in the U.S. and Australia. In addition, 60P has been funded by Knight Therapeutics Inc. (TSX:GUD) a Canadian specialty pharmaceutical company. 60P is headquartered in Washington D.C., with a subsidiary in Australia. For more information about Kodatef (tafenoquine succinate) visit www.biocelect.com. In August 2018, 60P received U.S. FDA licensure and marketing approval for Tafenoquine under a different brand name; for more information visit the company's website, 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.

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