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ASX Release

PROGRAM UPDATE: ANAGRELIDE

Its potential role in cancer prevention

Key points:

- Cancer incidence escalating and becoming economic burden
- Identified need for Chemo-preventative strategy
- Platelets identified as potential cancer bio-marker
- Anagrelide a potential prophylactic cancer treatment in at risk individuals

PERTH, AUSTRALIA – 15 March 2019: SUDA Pharmaceuticals Ltd (ASX: SUD), a leader in oro-mucosal drug delivery, in addition to its update of 21 February 2019, provides the following update on its development of anagrelide, an anti-thrombotic agent, that has shown promise as a novel anti-cancer agent.

There have been a number of articles recently on the need for chemo-preventative strategies in cancer. With more than 14 million cases of cancer reported per year and estimated to reach nearly 22 million globally by 2030 (Bray *et al.*, 2015) the cancer burden and deaths from cancer are increasing worldwide. The escalating costs of diagnosing and managing cancer are clearly not sustainable and it is well recognised that treatment of cancer is becoming increasingly unaffordable as the incidence increases for a variety of reasons (aging population, environmental, chemical exposures etc). It is becoming more accepted that the only financially viable strategy would seem to be cancer prevention.

A recent paper by Serrano etal. (*Molecular Oncology; V13 Issue 3. January 2019*) drew an analogy between the potential of cancer chemo-prevention strategies and those used for risk reduction in cardiovascular disease. Serrano explains that therapeutic prevention is standard practice in cardiovascular disease (CVD) where use of antihypertensives, statins and antiplatelet drugs have contributed to a dramatic decline in mortality due to CVD over the past ~40 years. Serrano attributes the success in CVD prevention to the relatively straight forward relationship between the disease and related biomarkers. For example, high blood pressure or high low-density cholesterol (LDL) can be considered disease surrogate biomarkers.

There is now significant evidence to suggest that platelet count may afford a useful surrogate biomarker for cancer which could then point to the need for prophylactic intervention. Several recent reports have suggested that patients with high platelet counts should be tested for cancer and that GP's should be urged to think cancer when diagnosing thrombocytosis (Bailey et al 2017). Much of this thinking emanates from the now appreciated role of platelets in providing the angiogenic growth factors for the initial development of the primary tumour development and the part played by cancer cells in triggering the production of more platelets so propagating the process and establishing a potentially a fatal loop.

The use of platelets as surrogate biomarkers in cancer risk / diagnosis then poses the question of what chemo-prevention strategies could be utilised

We have previously explained that anagrelide could be complementary to many cancer treatments by reducing platelet numbers so minimising the proliferative and protective effect that platelets exhibit on metastatic cells, thereby potentially offering a novel and valuable first-in-class *treatment* option for cancer.

We have, however, not previously highlighted that it is this basic activity that could also render anagrelide suitable as a chemo-preventative product. SUDA's anagrelide patent already addresses the potential prophylactic use of anagrelide as a chemo-preventative agent. Identifying at risk patients and then providing prophylactic platelet lowering therapy with an anagrelide oral spray, may lead to an improved outcome for those patients. We believe that the potential value of prophylactic use of anagrelide in at risk patients could be immense if the statins and CVD are anything to go by.

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NOTES TO EDITORS:

About SUDA Pharmaceuticals Ltd

SUDA Pharmaceuticals Ltd (ASX: SUD) is a drug delivery company focused on oro-mucosal administration, headquartered in Perth, Western Australia. The Company is developing low-risk oral sprays using its OroMist® technology to reformulate existing pharmaceuticals. The many potential benefits of administering drugs through the oral mucosa (i.e.: cheeks, tongue, gums and palate) include ease of use, lower dosage, reduced side effects and faster response time. SUDA's product pipeline includes ZolpiMist™, a first-in-class oral spray of zolpidem for insomnia. ZolpiMist is marketed in the USA and SUDA has rights to the product outside of the US and Canada. SUDA has submitted a Marketing Authorisation Application to the Australian Therapeutic Goods Administration for ArTiMist®, its novel sublingual malaria treatment for children. In a Phase III trial, ArTiMist was shown to be superior to intravenous quinine. Other products in development include oral sprays for the treatment of: migraine headache; chemotherapy-induced nausea and vomiting; erectile dysfunction; PAH; epileptic seizures and pre-procedural anxiety; and cancer.

For more information, visit www.sudapharma.com

About blood platelets in cancer

Cancer survival across all solid tumour types has been shown to be related to the number of blood platelets a patient has, cells which are more usually associated with the clotting process. However, platelets are now known to provide essential growth factors that nourish cancer cells and enable them to take hold and develop into tumours. Hence, those patients with the highest platelet numbers are least likely to survive. This has been shown across a wide range of solid tumours including cancer of the brain, oral cavity, the head and neck, thyroid carcinoma, gastrointestinal cancers, pancreatic, hepatocellular cancer, colorectal cancer, cancer of the lungs and bronchus, cancer of the ovaries, endometrium, cervix, breast, prostate, kidneys, skin mesothelioma, melanoma and gallbladder.

About Anagrelide

The pharmacology of anagrelide enables the selective lowering of platelet numbers without significantly affecting clotting or the formation of other blood cell lines and, in this respect, is unique. Currently anagrelide is only available as a solid oral formulation and is used exclusively as an anti-thrombotic agent. The drug's fundamental limitation which precludes its use in the treatment of cancer is its cardio-stimulatory side-effect profile. These effects are known to be due to a highly potent cardio-excitatory metabolite of the drug, formed in large quantities during its initial passage though the liver after oral administration. The use of proprietary non-enteral formulation such as an oro-mucosal spray would minimise this first pass effect in the liver.