MEDIA RELEASE

Submits formal request for pre-IND meeting with US FDA

Melbourne Australia 12 February 2019 – Invictus BioPharma Ltd., the Company commercialising an innovative new non-invasive and direct drug and vitamin delivery platform, submitted a formal request on Friday, 8 February 2019, to the US Food and Drug Administration (FDA) for a pre-investigational new drug (pre-IND) consultation.

The submission outlines the rationale behind the company's drug development program aimed at developing potential new therapies for non-alcoholic fatty liver disease (NAFLD), non-alcoholic steatohepatitis (NASH) and pancreatic cancer.

Consultation with the FDA is expected to be completed in the next two months and Invictus will update shareholders on the outcomes of the process as it progresses.

The submission will outline the proposed pathway by which Invictus will develop two drug candidates, one targeting NAFLD/NASH and the other targeting pancreatic cancer based on its patented transmucosal drug delivery platform.

The pre-IND submission proposes two protocols for two Phase II proof of concept clinical studies for NAFLD/NASH and pancreatic cancer respectively. It outlines how a direct and non-invasive method for delivering tocotrienols would improve the bioavailability of the drug to potentially provide an efficacious treatment for NAFLD/NASH and pancreatic cancer. The submission will address safety and toxicity from animal and clinical studies. It also sets out the GMP manufacturing methods developed for the drugs.

Chairman of Invictus BioPharma Scientific Advisory Board and Chief Scientific Officer, Dr David Kingston said, "Receiving guidance from the FDA in relation to our drug development program is critical as the US is a high priority market for all of our drug candidates".

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A number of published clinical studies using orally administered tocotrienols to address NAFLD and NASH have shown promise and animal studies have shown that tocotrienols have the potential to target pancreatic and other cancers in a novel way.

It is estimated between 75 million to 100 million people in the US are affected by NAFLD/NASH with the number affected increasing. There are currently no medicines approved for the treatment of NAFLD/NASH which are associated with a range of other diseases including insulin resistance and the metabolic syndrome, hyperlipidaemia, diabetes and high blood pressure.

The majority of pancreatic cancer diagnoses are at the advanced stages and consequently it is the fourth leading cause of cancer-related deaths in the US, claiming an estimated 44,000 lives each year. Invictus BioPharma intends to apply for Orphan Drug status for its pancreatic cancer drug candidate when it opens an IND prior to US-based clinical studies. There are currently a number of medicines and radiotherapy approved for the treatment of pancreatic cancer but they mostly produce relatively short lived remissions.

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About Invictus BioPharma Ltd.

Invictus BioPharma Ltd. is an Australian public unlisted biotechnology company developing and commercialising novel dietary supplements and prescription medicines based on natural products (tocotrienols) which have wide therapeutic potential, including: Delayed Onset Muscle Soreness, muscle recovery, exercise endurance, Non-Alcoholic Fatty Liver Disease (NAFLD), Non-Alcoholic SteatoHepatitis (NASH), pancreatic cancer, hyperlipidaemia, hypertension and diabetes. Invictus BioPharma owns and controls patent and other intellectual property rights for novel approaches to non-invasively delivering tocotrienols directly to the target tissues. The Company has a product development program for evidence-based nutraceuticals and a clinical development program for prescription medicines. For more information see: www.invictusbiopharma.com