MEDIA RELEASE

Response received from FDA for Pre-IND Consultation for Phase II Clinical Study on Fatty Liver Disease and pancreatic cancer

Melbourne Australia 14 June 2019 – Invictus BioPharma Limited, the Company commercialising an innovative non-invasive direct drug and vitamin delivery platform, today announced the receipt of the FDA's response to its Pre-Investigational New Drug (Pre-IND) submission.

The response from the FDA broadly supports the preclinical and clinical development pathway proposed by Invictus BioPharma Ltd and provided helpful suggestions in the Company's preparations for an Investigational New Drug (IND) Application.

Invictus proposed a Proof of Concept Phase II Clinical Study to assess the efficacy of tocotrienols delivered sublingually *via* the Company's patented drug delivery platform on fatty liver disease (NAFLD/NASH). The FDA agreed with the Company's clinical development strategy in pursuing an abbreviated pathway for development, a 505(b)(2) pathway. In this response, the FDA also agreed with the Company's proposed strategy for GMP manufacture of its test materials and made some helpful suggestions regarding non-clinical toxicology studies which will be incorporated into the IND.

It is estimated that 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. Invictus BioPharma is addressing the oxidative stress caused by fatty deposits around the liver which in turn leads to the inflammation which in turn leads to the scarring of the liver (fibrosis). In this way, the Company is pursuing a powerful approach which potentially "switches off" the disease earlier than other approaches which target the individual inflammatory pathways.

Invictus BioPharma Scientific Advisory Board Chair and Chief Scientific Officer, Dr David Kingston said, "It was very pleasing to see the response from the FDA agreed in principle to our proposal for a Proof of Concept Phase II clinical study on NAFLD/NASH and did not propose any requirements which would substantively add time or cost to our plans to assess the efficacy of drugs based on our

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patented drug delivery platform for tocotrienols. This study will be very exciting in that the approach we have adopted is targeting a different part of the disease pathway than those used by other groups."

Invictus BioPharma Executive Chairman and Chief Executive Officer, Dr Glenn Tong said, "We are now in the process of finalising a Pre-IPO capital raising which will assist in progressing this fatty liver disease clinical study."

The Oncology Division of the FDA also agreed in principle with the proposed Proof of Concept Phase II clinical study in pancreatic adenocarcinoma (cancer) and invited Invictus BioPharma to discuss the entire development program with them. 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 which creates a great unmet need. Invictus BioPharma is addressing pancreatic cancer with a two-pronged approach *via* promotion of programmed cancer cell death (apoptosis) and inhibition of the spread of stem cell-like cancer cells which in turn promote the spread of cancer cells (metastasis).

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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