

**INVION OPTIMISES PHOTODYNAMIC THERAPY DRUG AND LASER  
READY FOR 2020 HUMAN TRIALS**

**Highlights**

- High purity IVX-PDT cancer drugs developed based on Photosoft Technology.
- Topical formulation of IVX-PDT developed for skin cancer and shown to be well-tolerated in pre-clinical studies.
- Clinical research site and Principal Investigator selected for skin cancer study, to commence H1 CY2020.
- Laser equipment designed, manufactured and received.
- Multiple significant events over coming months, including development activities for solid cancer indications

**MELBOURNE (AUSTRALIA) 30 September 2019:** Invion Limited (ASX: IVX) (“Invion” or “the Company”) provides an update on its research and development plans for its Photo-Dynamic Therapy (PDT) product *IVX-PDT*, based on Photosoft™ technology.

Invion has continued to optimise the *IVX-PDT* cancer drug and the associated manufacturing process with the aim of generating a high purity compound which addresses all regulatory and clinical requirements and can be manufactured at large scale, allowing for efficient market supply.

The additional effort has led to the development of IVX-P03, a higher purity version of IVX-P02. Further optimisation and definition of *IVX-PDT* and the manufacturing process will be undertaken in late 2019 to ensure regulatory and clinical acceptance.

This includes laboratory studies to ensure that the same drug compound can be used in a variety of forms for various cancer types. The fully-optimised version of *IVX-PDT* will be used in clinical studies, the first of which, in Basal Cell Carcinoma (BCC), is scheduled to commence in H1 CY2020.

**First indication focus: BCC**

The first target indication for Invion’s product, BCC, is a common type of skin cancer which is typically managed by surgery. While surgery is effective in most cases, it can lead to scarring. Thus, there is demand for new treatment options which are both effective and non-scarring.

Invion is developing a topical product – known as *IVX-SKIN* – as a new treatment option for BCC. Working with Melbourne-based formulation experts, Formulytica, a gel formulation has been developed with the aim of effectively delivering the drug into the skin. The gel formulation has been formally tested in animal topical safety studies and was well-tolerated.

For the skin cancer clinical studies, Queensland-based clinical investigator Veracity Clinical Research has been selected. Veracity has run many skin cancer studies and has prior experience with PDT treatment.

Experienced dermatologist Dr Lynda Spelman has agreed to be the Principal Investigator for the study. The Human Ethics Committee Application for the Phase 1b study in BCC is expected to be submitted in early 2020 with the study scheduled to commence in H1 CY2020. Other potential skin indications such as Actinic Keratosis will follow the BCC study.

**Additional topical applications**

In addition, Invion plans to leverage the availability of a gel formulation of *IVX-PDT* to look at other topical cancers, via interaction with expert scientists, doctors and research institutes.

In support of the various pre-clinical and clinical studies including the BCC study, Invion commissioned the development and supply of laser light source devices from the Guilin Xingda Photoelectric Medical Device Co. Ltd, built to Invion's exacting specifications. A number of LAS-1 devices have subsequently been received, have passed acceptance testing at Invion and are in use in the pre-clinical studies.

### **Other cancer opportunities**

In anticipation of the availability of the optimised *IVX-PDT* drug at end 2019, Invion is investigating the potential application of an IV formulation in solid cancers, such as mesothelioma and lung cancer.

Discussions with cancer experts have highlighted the need for better treatment options and clinical plans are in development. Invion's current collaboration with the Hudson Institute of Medical Research is a model for future similar engagements.

Invion anticipates that it will have further market updates on this development in the coming months.

The work at the Hudson is focussed on ovarian cancer and Dr Andrew Stephens, Group Head of the Ovarian Cancer Biomarkers Research Group, and his team are currently optimising the treatment conditions associated with use of Photosoft™ technology for tumour ablation.

Craig Newton, Invion's incoming CEO, said "Strong progress has been made in 2019 to ensure that the right drug form and the right laser equipment are available for use in multiple cancer types. Clinical development across a range of topical and solid cancer indications will be the focus in 2020, in collaboration with highly-credentialed cancer experts".

More details on the skin cancer human trials and other near-term milestones can be found in the accompanying updated investor presentation.

**ENDS**

### **Investor enquires**

Managing Director & CEO, Dr Greg Collier

T: +61 3 9081 6005

E: [investor@inviongroup.com](mailto:investor@inviongroup.com)

### **About Invion**

Invion is a drug delivery company that is leading the global research and development of Photosoft™ technology for the treatment of a range of cancers. Invion holds the Australia and New Zealand license rights to the Photosoft™ technology. Research and clinical trials are funded by the technology licensor, The Cho Group, via an R&D services agreement with the Company. Invion is listed on ASX (ASX:IVX).

### **About Photodynamic Therapy (PDT)**

Invion is developing Photosoft™ technology as an improved next generation Photodynamic Therapy. PDT uses non-toxic photosensitisers and visible light in combination with oxygen to produce cytotoxic-reactive oxygen that kills malignant cells, shuts down tumours and stimulates the immune system. A potential alternative to surgery, and in contrast to radiotherapy and chemotherapy which are mostly immunosuppressive, PDT causes acute inflammation, expression of heat-shock proteins, and invasion and infiltration of a tumour by leukocytes.

**Invion Limited** ABN 76 094 730 417

722 High Street, East Kew, VIC 3102 Australia

P: +61 3 9081 6005 W: [www.inviongroup.com](http://www.inviongroup.com)