ASX / MEDIA ANNOUNCEMENT

20 December 2013

INVION LIMITED "SMOKING CESSATION" PHASE II STUDY: FDA HOLD

Invion Limited (ASX: IVX) today announced that the US Food and Drug Administration (FDA) has requested changes to the protocol for its "smoking cessation" clinical study that have resulted in a halt to enrolment (clinical hold) while Invion addresses the Agency's concerns around certain technical aspects of the protocol.

The rationale for the clinical hold appears to be to align the titration and termination criteria for the study in COPD patients with the criteria established in Invion's ongoing study of Nadolol in Mild Asthma (NIMA) patients ongoing under Invion's IND with the Division of Pulmonary, Allergy, and Rheumatology Products (DPARP).

Invion Chief Medical Officer, Dr Mitchell Glass said:

"We respect the FDA's rationale and of course, will comply with their request. While the two study populations are quite different, aligning the titration criteria will enable Invion to integrate the safety data from the two trials seamlessly, providing us with a more robust titration schedule for future studies whether in COPD or more severely asthmatic patients.

"Since responding to this requirement will generate a delay in recruitment, Invion is adding clinical trial sites to minimise the impact on the availability of interim results and study completion," he said.

About INV102 (nadolol)
INV102 (nadolol) is a beta blocker currently marketed as a safe and effective treatment for high blood pressure and migraine. Demonstrated to have unique anti-inflammatory capabilities, INV102 is being repurposed by Invion to treat chronic inflammatory airway diseases (e.g. asthma and COPD). Invion has an issued patent on the use of INV102 (nadolol) as a method of treating airway diseases. Invion's development strategy for INV012 is broad and includes oral and inhaled formulations - the current protocols in asthma and chronic bronchitis (smoking cessation) are for oral drug, the inhaled program will target chronic bronchitis and cystic fibrosis. Preclinical data to date confirms nadolol as a *beta adrenergic inverse agonist*. Two phase II clinical trials are completed, showing 80% positive response against an objective endpoint, acceptable safety, dose-related reduction of airway hyper-responsiveness. Invion's current phase-II asthma trial is funded by US NIH in excess of $USD4M, an exciting validation by one of the most prominent medical research bodies in the world. The phase II chronic bronchitis (smoking cessation) program is targeting increased smoking cessation, reduced airway inflammation, and decreased peri-operative complications in patients with pre-existing COPD in registered quit smoking programs. Further details of this clinical trial can be found at www.clinicaltrials.gov with the identifier: NCT01825122.

About Invion Limited
Invion is a life sciences company focussed on the development of treatments for major opportunities in respiratory disease and autoimmune disease. The Group has three drug assets in development, and three phase II clinical trials, regulated by the Food & Drug Administration (FDA), currently underway in the United States. **INV102 (nadolol)** a beta blocker (*beta adrenergic inverse agonist*) currently used to treat high blood pressure and migraine, is being repurposed to treat chronic inflammatory airway diseases, including asthma and chronic obstructive pulmonary disease (COPD). **INV104 (zafirlukast)** is a *leukotriene receptor antagonist* (LTRA) or *anti-leukotriene* that reduces inflammation, constriction of the airways, and the build-up of mucus in the lungs. **INV103 (ala-Cpn10)** is a modified, naturally occurring human protein which has been proposed as a founding member of the Resolution Associated Molecular Pattern (RAMPs) family hypothesised to maintain and restore immune homeostasis. Invion is an ASX listed company (ASX:IVX), with its clinical headquarters in Delaware, USA.

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