ASX / MEDIA ANNOUNCEMENT

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INVION ANNOUNCES INITIATION OF PHASE II ASTHMA TRIAL

Invion Limited (ASX:IVX), a clinical-stage drug development company targeting chronic inflammation, today announced the initiation of **"NIMA"**, a phase II clinical trial that is funded by the US National Institute of Allergy and Infectious Diseases (NIAID) to investigate the use of INV102 in patients with mild asthma.

The NIAID is part of the US National Institutes of Health (NIH), which are the primary agency of the United States government responsible for biomedical and health-related research. The NIAID is funding the **"NIMA"** trial via a cooperative agreement grant to Baylor University College of Medicine of approximately US$4.4 million.

INV102, also known as nadolol, has been used in more than eight million people for the treatment of high blood pressure, migraine and chest pain. Invion is repurposing nadolol and targeting it to the treatment of inflammatory lung disease, including asthma and chronic bronchitis.

This trial will provide valuable data around INV102's effect on airway responsiveness, a crucial part of assessing INV102's potential as a treatment for lung diseases such as asthma.

The global market for asthma and chronic obstructive pulmonary disease (COPD) prescription drugs was valued at $34 billion in 2011. This figure is increasing at a five year compound annual growth rate (CAGR) of 4.4%.[i]

Dr Mitchell Glass, Chief Medical Officer said, "The development of INV102 in chronic inflammatory diseases of the lungs is following the medical, regulatory and commercial precedent of the development of beta blockers for use in chronic heart failure."

"Once contraindicated, after careful titration beta adrenergic inverse agonists were shown to reduce mortality in all classes of chronic heart failure and have now become the standard of care. Using similar careful titration, INV102 is targeted to reduce airflow obstruction due to damaged airways and provide a safe and effective therapy for the treatment of asthma," Dr Glass said.

To date, two phase II clinical trials of INV102 have been completed which have demonstrated acceptable safety as well as dose-related reduction of airway hyper-responsiveness. Chronic INV102 dosing resulted in a reduction in airway hyper-responsiveness comparable to results achieved with inhaled corticosteroids for several weeks.

About the Study

"NIMA" for "nadolol in mild asthma" is a randomized trial that will enrol up to 60 subjects in three centres in the United States. Randomized subjects will receive either INV102 or placebo and will be progressively tested to the maximally tolerated dose of INV102 according to strict study criteria. The trial will measure endpoints including airway hyper-responsiveness, signs and symptoms, use of rescue medication (for example, inhalers) and, in a subset of subjects, airway evaluation of mucus and biomarkers collected during bronchoscopy. These will form a data set providing further information regarding INV102's mode of action. The primary objective of the study is to assess INV102's effect on airway responsiveness to inhaled methacholine (a common test in the assessment of lung conditions which induces narrowing of the airways). Secondary objectives include safety, signs and symptoms and biomarkers.

About INV102

INV102, a beta adrenergic inverse agonist also known as nadolol, has been used in more than eight million people for the treatment of high blood pressure, migraine and chest pain. Invion is repurposing nadolol and targeting it to the treatment of inflammatory lung disease, including asthma and chronic bronchitis. Long-term exposure to beta adrenergic inverse agonists block cellular changes induced by beta agonists, thereby inactivating the production of inflammatory cytokines and decreasing sensitization to airway challenges. Of the three *beta adrenergic inverse agonists*, INV102 has demonstrated the best inverse agonist activity in the airways. To date, two phase II clinical trials of INV102 have been completed which have demonstrated acceptable safety as well as dose-related reduction of airway hyper-responsiveness. Chronic INV102 dosing resulted in a reduction in airway hyper-responsiveness comparable to results achieved with inhaled corticosteroids for several weeks.

About Invion Limited

Invion Limited is a clinical-stage drug development company that targets chronic inflammation. Focussed on the development of treatments for major market opportunities in inflammatory diseases including asthma, chronic bronchitis and lupus, Invion has two phase II proprietary therapeutic candidates: INV102 – a repurposed beta adrenergic inverse agonist; and INV103 (Ala-Cpn10) – a modified natural immunomodulator.

FOR MORE INFORMATION CONTACT:

Corporate	Investor Relations	Media
Dr William Garner	Rebecca Wilson	Tom Donovan
Managing Director and CEO	Buchan Consulting	Buchan Consulting
Invion Limited	03 9866 4722	(03) 9866 4722
investor@invion.com.au	rwilson@buchanwe.com.au	tdonovan@buchanwe.com.au

[i] "*Global Markets for Asthma and COPD Drugs*". BCC Research, 2012.