ASX / MEDIA ANNOUNCEMENT

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INVION PROVIDES UPDATE TO US FDA
ON PHASE II STUDY OF NADOLOL IN MILD ASTHMA (NIMA)

- **INV102 (nadolol) SAFE AND WELL-TOLERATED IN BLINDED DATA TO DATE**
- **HIGH % OF PATIENTS TITRATING TO MAXIMUM POSSIBLE DOSE**
- **PATIENTS SHOW NO REQUIREMENT TO INCREASE RESCUE MEDICATION**

Invion Limited (ASX: IVX) is pleased to provide an update on blinded interim data from the US National Institute of Allergy and Infectious Diseases (NIAID) and National Institutes of Health (NIH) funded phase II clinical trial of INV102 (nadolol) in patients with mild asthma (NIMA trial).

Evaluation of blinded data received to date has revealed important information relating to the treatment of asthma patients with INV102 (nadolol), as well as the titration program designed to minimise bronchoconstriction and other negative effects of beta-blocker use in patients with airway hyper-responsiveness.

Evaluation of data from the first 21 patients to have completed the study has shown that:

1. Patients (n=19) have tolerated titration to their highest dose without severe adverse events;

2. Patients have shown no pattern of cardiovascular or respiratory effects during the four hours of observation required after each titration dose;

3. During initial titration and through the three months of stable daily dosing, patients demonstrated no requirement to increase rescue medication usage – provided either as a short-acting beta-agonist (SABA) or as an anti-muscarinic agent; and

4. No pattern of adverse events has emerged - a significant finding given that nadolol is currently contraindicated in patients with asthma due to risks associated with worsening bronchospasm.

Emerging data from the NIMA trial is relevant to the oral and inhaled INV102 (nadolol) programs currently underway, and Invion has provided an update to the US Food and Drug Administration (FDA) Division of Anaesthesia, Analgesia and Addiction Products (DAAAP) in support of a protocol amendment for its ongoing clinical trial in smoking cessation.

Executive Vice President and Chief Medical Officer, Dr Mitchell Glass, said:

"The use of beta-blockers in asthma is currently contraindicated due to safety concerns. We are therefore very encouraged that nadolol appears to be following the same pattern as seen in early carvedilol studies in chronic heart failure - that with careful titration to a maximum tolerated dose, side effects can be avoided, which is a prerequisite to reversing a contraindication. We will continue our studies of nadolol, which is the first and only drug specifically targeting the airway epithelium.

"Initial studies conducted by Dr Nicola Hanania, Associate Professor of Medicine at Baylor University, showed improvement in patients' airway hyper-responsiveness after nadolol use. These data from the current NIMA trial strongly reinforce that nadolol may be given safely and effectively to patients with asthma after dose titration.

"We are also encouraged as these data support our plan to develop inhaled nadolol for long-term treatment of moderate to severe asthma, which results in the same epithelial derangement seen in patients with smoker's cough, chronic bronchitis and cystic fibrosis.

Invion's phase II NIMA trial is being conducted with Principal Investigators at Baylor College of Medicine, Washington University and Duke University. The trial is due to complete in 2015.

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About INV102 (nadolol)
INV102 (nadolol) is a beta blocker (*beta adrenergic biased ligand*) currently used to treat high blood pressure and migraine that Invion is targeting as a therapy to treat chronic inflammatory airway disease including asthma, COPD and cystic fibrosis. Invion currently has two phase II clinical programs underway for oral nadolol – a 'smoking cessation' study assessing the effectiveness of INV102 in the smoking cessation of patients with COPD; and the 'NIMA' study of patients with mild asthma which is funded by the US National Institutes of Health. A collaboration with 3M Drug Delivery Systems is targeted to develop inhaled versions of this drug for asthma & COPD.

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. INV102 (nadolol), a beta blocker (*beta adrenergic biased ligand*) 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*) 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.