- **INVION PRESENTS PHASE 2 DATA TO AMERICAN THORACIC SOCIETY**
- **DATA IS FROM STUDY OF INV102 (NADOLOL) IN SMOKING CESSATION**
- **INCREASED COUGH AND PHLEGM IDENTIFIED AS A BARRIER TO QUITTING**

Brisbane, Australia, and Delaware, United States, 20 May 2016: Australian drug development company Invion Limited (ASX: IVX) has presented data from its phase 2 clinical trial of INV102 (nadolol) to the Annual Meeting of the American Thoracic Society (ATS), held this week in San Francisco, USA.

The presentation outlined that in research by collaborators, INV102 (nadolol) has been shown to:

- uniquely and specifically block the beta arrestin pathway of beta 2 receptors on airway epithelial cells;
- prevent or treat goblet cell hyperplasia and mucous metaplasia in animal models of obstructive airway disease;
- act effectively when delivered to animals by inhaled route at 1/1000 oral dose; and,
- decrease airway hyper-responsiveness in mild persistent asthma in phase II clinical trials.

The key points of the presentation to the ATS of phase 2 smoking cessation data were:

- INV102 (nadolol) was safe and well-tolerated in the treated population of patients (with or without chronic bronchitis) trying to quit smoking, having been previously unable to quit;
- 62/ 69 patients achieved full dose of 100mg/day of nadolol;
- positively, there was no differentiation in the safety profile of patients treated with nadolol versus placebo;
- the data showed a statistically significant improvement in mucus protein MUC5AC v placebo, which rebounded after drug cessation;
- the study showed a trend towards reduction in daily cigarette use that would translate from a pack per day to less than 2 packs per week over 8 weeks, a relatively short period (p= 0.138);
- the study provides a clear pathway forward for the further development of oral and inhaled nadolol, including endpoints for evaluation and study designs; and
- the study supports a next study either in smoking cessation or the treatment of the broader population of patients with chronic bronchitis.

Dr Mario Castro, Professor of Medicine and Pediatric, Washington University School of Medicine, St Louis, said: "This proof of concept study using nadolol to help patients with cough that smoke is very encouraging. We saw a trend towards less cigarettes smoked while on nadolol and a significant reduction in a mucus protein, MUC5AC. There are very few medications that help smokers quit - this represents a potential major advance for them."

Invion's Executive Vice President R&D and Chief Medical Officer, Dr Mitchell Glass said: "Taken together with the clinical, biomarker and biopsy data which will be available later this year from the NIH-sponsored phase 2 study in mild asthma (NIMA), we should gain a clear picture of the impact of nadolol on airway diseases.

"During the session, Dr Castro and I were gratified to note that in response to a question from the moderator, virtually every cessation expert in the room confirmed that increased cough and phlegm are identified as a barrier to quitting by patients.

"We believe these results continue to not only support the implementation of phase 3 programs for the oral compounds, but also confirm inhaled INV102 (nadolol) as a target for chronic airway diseases including asthma, COPD and cystic fibrosis."

Invion is actively pursuing license and co-development partners for the INV102 franchise.

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About Invion Limited
Invion is a life sciences company focussed on the development of treatments for major opportunities in respiratory and autoimmune disease. Invion has three drug assets in development across four development programs. Invion is an ASX listed company (ASX:IVX), with operations in Brisbane, Australia and Delaware, USA.

- **INV102 (nadolol)** is a beta adrenergic biased ligand targeted to reverse mucous metaplasia in the airway epithelium treat chronic inflammatory airway diseases. In Q4 2015, Invion reported that data from a 155 patient phase 2 study of oral INV102 in smoking cessation demonstrated good safety and that treated patients were more likely to stop smoking completely or dramatically reduce the number of cigarettes smoked. Feasibility for an inhaled version of the drug to potentially treat COPD and cystic fibrosis is well-progressed with 3M Drug Delivery Systems, and toxicological studies have commenced. In addition, a phase 2 study of oral INV102 in mild asthma patients funded by the US NIH is fully recruited and will complete dosing in 1H 2016.

- **INV104 (zafirlukast)** is a leukotriene receptor antagonist (LTRA) that reduces inflammation, constriction of the airways, and the build-up of mucus in the lungs. An FDA-approved oral therapy, Invion is, through a joint development and licensing agreement with Hovione Scientia Limited, developing a proprietary dry powder formulation of the drug for the development of INV104 (zafirlukast) as a potential inhaled therapy for asthma.

- **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 reported final data from its phase 2 clinical trial in lupus patients in Q3 2015. 30mg and 100mg iv twice weekly showed reduced response to stimulation by LPS after 1 month of dosing. These data, which reflect relevant activity at the target cell type in patients with a target (autoimmune) disease, has formed the foundation of partnering discussions for this program.