ASX / MEDIA ANNOUNCEMENT

Targeting inflammation

INVION PHASE 2 SMOKING CESSATION DATA: RESULTS OF ONGOING ANALYSIS

- **Ongoing analysis confirms headline data on safety profile: analysis of adverse events shows no difference between active treatment and placebo groups**

- **Nadolol treatment significantly decreased MUC5AC levels compared to placebo treatment confirming improvements in mucous metaplasia**

Brisbane, Australia and Delaware, United States, 17 November 2015: Australian respiratory technology company Invion Limited (ASX: IVX) is pleased to announce additional results from the ongoing analysis of the company's Phase 2 clinical trial of INV102 (nadolol).

The ongoing analysis, which forms part of the pre-specified statistical analysis plan (SAP), demonstrates that treatment with INV102 (nadolol) shows a statistically significant effect on biomarker MUC5AC independent of an effect on markers of inflammation.

MUC5AC, which is one of the major biomarkers reflecting mucous metaplasia in airways, was statistically significantly decreased from baseline to the end of maintenance at visit 8 in an analysis of all subjects who completed titration. MUC5AC and other biomarkers are being analysed further to determine whether baseline levels or biomarker responses during treatment define a more targeted population for Phase 3 studies.

This ongoing data analysis has contributed to submission of an abstract to the 2016 American Thoracic Society (ATS) annual meeting.

The combination of safety, tolerability of titration as reflected by the majority of subjects reaching the top dose of 100mg/ day, cigarette reduction and biomarker effects, have provided a strong basis for the recently submitted request for an End of Phase 2 Meeting with the US FDA.

Invion Chief Medical Officer Dr Mitchell Glass said "The ongoing data analysis continues to indicate an interaction between this key marker, MUC5AC, and the ability of patients to quit smoking who have previously failed to quit due to chronic cough. We are also continuing to analyse smoking reduction or cessation as a function of baseline levels or changes in other biomarkers.

"Although our Phase 2 study was necessarily complex, our Phase 3 study design will likely be more straightforward. Based on our results from eight weeks of dosing in the present study, we will focus our FDA discussions on achieving and maintaining abstinence over a longer dosing period in this difficult to treat population. We have already developed our diary cards, data management processes and criteria for selecting sites with large numbers of appropriate patients enrolled in validated smoking cessation programs.

"We believe these results not only support the implementation of a Phase 3 program to achieve smoking cessation in patients, but also confirm inhaled INV102 (nadolol) as a target for chronic airway diseases including asthma, COPD and cystic fibrosis. In inhaled INV102 studies, we will continue to evaluate biomarkers for prognostic value of safety or efficacy and response to therapy.

INV102 (nadolol), a beta blocker with inverse agonist and biased ligand activity, is being developed as a potential treatment to aid smoking cessation in patients with chronic cough due to its demonstrated effect in murine models in reducing goblet cell metaplasia and airway inflammation. It is hypothesised

to work via the inhibition of a cellular pathway (the beta arrestin pathway) that is pivotal in causing cells lining the lungs to change from normal to abnormal mucus-producing cells.

FOR MORE INFORMATION CONTACT

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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. **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. Invion is an ASX listed company (ASX:IVX), with operations in Brisbane, Australia and Delaware, USA.