ASX / MEDIA ANNOUNCEMENT

INVION
Targeting inflammation

INVION SUCCESSFULLY COMPLETES PHASE 2 STUDY OF INV102 (NADOLOL) TO AID SMOKING CESSATION

- **Completed Phase 2 trial data demonstrates INV102 treated smokers were more likely to stop smoking completely or dramatically reduce the number of cigarettes smoked**
- **Data demonstrates that INV102 is a safe and effective treatment for patients with chronic bronchitis who are enrolled in smoking cessation programs**
- **Invion is preparing an FDA submission during Q4 2015 for End of Phase 2 Meeting request**
- **New data paves the way for INV102 to be developed as a novel inhaled treatment for chronic airway diseases including asthma, COPD and cystic fibrosis**

Brisbane, Australia, and Delaware, United States, 4 October 2015: Australian drug development company Invion Limited (ASX: IVX) will immediately pursue further development of its novel respiratory drug INV102 (nadolol) following the successful conclusion of a Phase 2 clinical trial in patients trying to quit smoking.

Summary data from the randomised, double blinded, placebo controlled study released today shows smokers administered INV102 were more likely to stop smoking completely, or dramatically reduce the number of cigarettes smoked.

In addition, INV102 reduced key biomarkers MUC5AC and ERK1 in collected sputum samples - supporting Invion's hypothesis that INV102 has a novel mechanism of action directly targeting epithelial cells lining the airway.

The Company regards these data as strong confirmation of the development strategy for both oral and inhaled INV102 for the treatment of airway disease.

Data from the study released today shows:

- INV102 was safe and well tolerated, and Invion's proprietary titration scheme enabled patients to reach efficacious doses
- Trial subjects treated with INV102 were more likely to achieve abstinence at the conclusion of dosing (12/62, 19.3%) compared to those administered placebo (7/59, 11%)
- More patients treated with INV102 achieved a >70% reduction in cigarettes smoked compared with placebo treated patients (38/62 on INV102 and 21/59 on placebo)
- Two key markers of the beta arrestin pathway - ERK1 and MUC5AC – which are necessary for the activation of mucous metaplasia in the airway, showed the most robust changes. MUC5AC levels were reduced by 82% in INV102 treated patients, compared to 54% in placebo subjects. ERK1 levels were reduced by 47% for INV102 compared with 27% for placebo.

There will be ongoing analysis of the clinical data generated from this trial to examine which patients responded to INV102 therapy and if this correlated with any of the several biomarkers measured in the sputum samples collected.

The aim of the further analysis will be to determine if the company can generate further IP around predicting patient response to INV102, and also determining the best patient groups to be selected for Phase 3 trials.

The study was conducted on 155 patients at multiple US trial sites, including Washington University. All patients had tried to quit smoking multiple times but were defeated by chronic "smoker's cough" resulting from the build-up of mucus in the lungs following the last cigarette. The trial was designed to evaluate the efficacy of INV102 in improving rates of smoking cessation over a 10-12 week treatment period.

INV102 is hypothesised to work via the inhibition of a cellular pathway (the beta arrestin pathway) that causes cells lining the lungs to change from normal to mucus-producing cells. This mechanism is completely different from drugs presently approved and indicated either for smoking cessation or the treatment of chronic respiratory disease.

Invion Chief Medical Officer Dr Mitchell Glass said the underlying pathology common to all respiratory diseases was the change in the airway epithelium lining the lung.

He commented: "These positive Phase 2 data validate our approach for directly treating the airway epithelium even in the face of ongoing insult, such as cigarette smoking. This is the first indication that epithelial damage can be treated directly by a drug. There are currently no approved drugs capable of treating the change in the airway epithelium and these results pave the way for a potentially novel and better way of treating chronic airway diseases."

Dr Glass said patients with chronic bronchitis or a smoker's cough frequently experienced difficulties quitting smoking and were more likely to be incapacitated or die from lung disease.

"This is an enormous global health problem and in this indication alone, INV102 represents a substantial commercial opportunity. A therapy which can reduce or eliminate smoker's cough, a common barrier to quitting smoking, could be life changing for patients."

"We are proposing to the FDA that an End of Phase 2 meeting be convened early in 2016, to move this drug into Phase 3 development."

Invion Managing Director and Chief Executive Officer Dr Greg Collier said these trial data not only support further development of INV102 as a novel therapy for smoking cessation, but validate the expeditious development of an inhaled version of the drug for other chronic respiratory disorders.

"Investors should note that this smoking cessation study is our 'short path to market' strategy," he said.

"Crucially, these results will underpin our broader agenda -- to immediately develop this drug as a first in class treatment for chronic airway conditions like asthma, COPD and cystic fibrosis where there is a substantial unmet medical need and commercial opportunity."

The smoking cessation drug market is predicted to be $3.8 billion by 2016. While nicotine focused therapies comprise the bulk of the existing market, they do not address lung healing. INV102 represents an opportunity to add-on and expand an existing market.

The global market for respiratory drugs is estimated to reach $47.1 billion by 2017.

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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, three phase II clinical trials and two clinical feasibility programs currently underway. **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 operations in Brisbane, Australia and Delaware, USA.