

INVION COMPLETES DOSING IN KEY PHASE II CLINICAL TRIAL OF ORAL INV102 (NADOLOL) IN SMOKING CESSATION

- ***Release of clinical trial data anticipated in Q32015***
- ***Potential new treatment for chronic respiratory diseases including asthma, COPD and cystic fibrosis***
- ***Substantial unmet medical need for new respiratory disease treatments - \$34B global market opportunity***

Brisbane, Australia and Delaware, United States: 29 June 2015: Invion Limited (ASX: IVX), an Australian drug development company, is pleased to announce that it has completed dosing in INVSC001: "Efficacy and safety of beta-adrenoceptor inverse agonist, nadolol, in smoking cessation of patients with pre-existing COPD".

This double-blind, randomized, placebo-controlled Phase IIB clinical trial, is being performed in the United States under an Invion-sponsored Investigational New Drug (IND) application.

This is an important milestone ahead of the release of headline study data, expected in Q3 2015.

The trial is designed to provide further testing of three hypotheses concerning the effects of INV102 (nadolol) on the airway epithelium:

- the impact of nadolol on biomarkers of airway inflammation, β -arrestin pathway activation and abnormal mucus production;
- the safety and efficacy of nadolol as an aid to smoking cessation in patients with increased cough and sputum (phlegm) production who have repeatedly failed to quit; and
- the correlation of biomarkers of airway healing with cigarette smoking reduction or cessation, in order to optimise the nadolol regimen and patient selection for planned phase III clinical trials.

Results from this trial could pave the way for an entirely new approach to the treatment of chronic respiratory diseases like COPD, cystic fibrosis and severe asthma and could provide novel intellectual property if correlations provide insights to safety or efficacy linking nadolol usage to specific profiles of biomarkers.

An interim examination of data has already provided highly encouraging data and important insights into this population of difficult to treat cigarette smokers.

As announced on 19 January 2015, interim analysis of biomarkers from sputum in patients in the trial showed improvement in inflammatory markers and β -arrestin pathway activation in patients treated with nadolol v placebo regardless of smoking status.

Further, Invion and the Principal Investigator of the study, Dr Mario Castro of Washington University, St Louis, reported that patients with cough and sputum who continued to smoke had essentially the same abnormalities in their sputum at baseline, thereby enlarging the target population for commercialisation of oral nadolol.

Invion's Chief Medical Officer Dr Mitchell Glass said that completion of dosing was an important milestone. "This means that safety and tolerability of titration has been established in this vulnerable

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population – there is no indication that patients who received nadolol versus placebo were adversely affected."

"All existing data from previous nadolol studies have validated Invion's novel approach to treating the airway epithelium, even in the face of ongoing insult like cigarette smoking."

Dr Glass concluded, "The team at Invion is actively engaged in validating the extensive data set to enable the forthcoming statistical analyses."

The global market for new respiratory disease treatments is estimated at \$34 billion, with the smoking cessation drug market estimated at \$2.4 billion in 2012. Nicotine replacement therapy is the bulk of the existing market, however these therapies do not address lung healing. There is a substantial untapped market for a therapy that can work to heal lungs in concert with efforts to break nicotine addiction.

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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.