

INVION COMPLETES ENROLMENT IN ITS PHASE II TRIAL OF ORAL INV102 (NADOLOL) IN SMOKING CESSATION

- Protocol designed to examine the effect of INV102 in patients with chronic bronchitis who are enrolled in validated smoking cessation programs
- Key clinical and regulatory milestone reached for oral INV102 program
- Recently released interim data showed impact on biomarkers of inflammation, underpins advancing inhaled INV102 program

Brisbane, **Australia**, **2 February 2015**: Invion Limited (ASX: IVX) is pleased to announce full enrolment in its phase II clinical trial of INV102 (nadolol) in patients with chronic cough or established COPD who are trying to quit smoking but have failed multiple times previously.

Patients with chronic bronchitis or a smoker's cough may have a harder time quitting smoking and are more likely to be incapacitated or die from lung disease. Invion's smoking cessation protocol is designed to examine the effect of INV102 (nadolol) in patients with chronic bronchitis who are enrolled in validated smoking cessation programs. The primary objective is to evaluate the efficacy of INV102 in improving rates of smoking cessation over a 10-12 week treatment period.

Dr Mitchell Glass, Executive VP of R&D and Chief Medical Officer said: "Completing enrolment in our Phase IIb smoking cessation study is a key milestone for Invion since this is the regulatory and commercial target for oral INV102. Completion of enrolment enables us to plan for dedicated resources to analyse the study and to prepare for our End of Phase II meeting with the FDA as well as other key regulatory agencies during the second half of 2015.

"The positive interim data that we recently released validates our approach for treating the airway epithelium even in the face of ongoing insult, such as cigarette smoking. We will be exploring whether these airway effects relate to successful quitting within this population of patients, who have failed so often previously."

"We have been pleased that nearly all patients to date have tolerated titration to a maintenance dose and have remained enrolled in a smoking cessation program. We know that patient treatment and follow-up should be completed early in the third quarter, at which time we will undertake the intensive analysis of data from the trial, including smoking cessation, biomarkers of airway inflammation and remodelling, and the correlations of these effects with drug treatment and dose.

"Safety and tolerability of INV102 in these patients, together with the previously reported results from the NIH-sponsored study of nadolol in mild asthma (NIMA), strongly support our development of inhaled INV102 for the long-term treatment of chronic airway diseases, including COPD, severe asthma and cystic fibrosis.

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ASX / MEDIA ANNOUNCEMENT



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.