

**INV102 (ORAL NADOLOL) DATA PRESENTED TO  
AMERICAN THORACIC SOCIETY MEETING IN DENVER, COLORADO**

- **PRINCIPAL INVESTIGATORS PRESENT IMPORTANT INTERIM BIOMARKER DATA FROM THE ONGOING PHASE II SMOKING CESSATION STUDY**
- **DATA SHOW THAT NADOLOL CAN BE SAFELY ADMINISTERED TO SMOKERS TRYING TO QUIT**
- **DATA SUPPORT TREATMENT OF COPD PATIENTS AND SMOKERS WITH CHRONIC COUGH AS SINGLE POPULATION – INCREASING THERAPEUTIC AND MARKET OPPORTUNITY**

**Brisbane, Australia and Delaware, United States, 19 May 2015:** Australian respiratory technology company Invion Limited (ASX: IVX) has presented data from a trial of lead compound INV102 (oral nadolol) to international medical experts at a prestigious US pulmonary conference.

Trial investigators have shown delegates at the American Thoracic Society (ATS) meeting that an ongoing Phase 2 study of Invion's INV102 as an aid to smoking cessation has confirmed Invion's hypothesis that patients with chronic cough due to cigarette smoking could be studied as a single population based on biomarker results, whether or not they had evidence of airflow obstruction.

Earlier results from this study indicated that key signs of respiratory inflammation could be reduced in as little as four weeks of treatment versus placebo.

Lead study investigators Dr Mario Castro and Geneline Sajol from Washington University further noted that oral nadolol could be safely administered to smokers experiencing chronic cough and not just patients diagnosed with chronic obstructive pulmonary disorder (COPD).

Dr Castro said study protocols had been amended following trial initiation to include patients without a formal COPD diagnosis. This had provided investigators with a novel opportunity to compare sputum biomarkers in smokers both with and without diagnosed airflow obstruction.

"On examining baseline biomarkers, we found no difference in COPD versus non-COPD subjects," he said.

"What this essentially means is that we now believe we can safely target the smoking population with or without diagnosed COPD, because of the similarities in airway inflammation.

Nadolol is a beta blocker (beta adrenergic biased ligand) currently used to treat high blood pressure and migraine. Invion is repurposing the drug to treat chronic inflammatory airway diseases, including asthma and COPD.

The global market opportunity for treatments for asthma, COPD and smokers cough is estimated at \$34 billion.

The smoking cessation drug market is estimated at in excess of \$2 billion. Nicotine-focussed therapies comprise the bulk of the existing market, yet these therapies do not address lung healing. Oral nadolol presents an opportunity to add-on and expand this existing large market.

#### **About the study design**

Invion's study design into this difficult to treat population uses the Company's proprietary approach to titration of INV102 to a maximally tolerated dose up to 100mg/day, maintenance treatment for eight weeks and down titration over two weeks, with follow-up 3 months later for a total of 6 months per subject.

Biomarkers included evaluation of expectorated cells ("differential"), markers of inflammation (IL-6 and IL-8), beta arrestin pathway activation (ERK1 and ERK2) and normal and abnormal mucus proteins ("mucins": MUC1, MUC5AC, and MUC5B).

Interim data from this trial was reported in January 2015. The blind-broken analysis showed clinically relevant changes in four biomarkers of inflammation in INV102 (nadolol) treated patients compared to placebo. The study was fully enrolled in January, 2015 and is due to report data in Q3 2015.

#### **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, and three phase II clinical trials, regulated by the Food & Drug Administration (FDA), currently underway in the United States. 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) 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 its clinical headquarters in Delaware, USA.

#### **FOR MORE INFORMATION CONTACT**

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