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INVION ANNOUNCES COMMENCEMENT OF PHASE II CHRONIC BRONCHITIS CLINICAL TRIAL

- INV102 phase II chronic bronchitis clinical trial initiated and enrolling patients
- Renowned pulmonary specialist and former chair of the American Lung Association, Dr Albert Rizzo is Principal Investigator on the trial
- Invion’s third phase II clinical trial runs concurrently with INV102 study in asthma funded by the NIH in excess of USD$4M, and INV103 study in lupus

Clinical-stage drug development company Invion Limited (ASX:IVX) is pleased to announce the initiation and commencement of patient enrolment in its phase II clinical trial of INV102 (nadolol) in patients with chronic bronchitis who are enrolled in a validated smoking cessation program.

To date, INV102 (nadolol) has been used in more than eight million people for the treatment of high blood pressure, migraine and chest pain. Invion is repurposing this drug and targeting it to the treatment of chronic inflammatory lung conditions, including asthma and chronic obstructive pulmonary disease (COPD).

The randomised trial is being conducted at two centres in the United States, and up to 136 patients will be enrolled. The primary objective is to evaluate the efficacy of INV102 in subjects with chronic bronchitis in improving rates of smoking cessation over a 10-12 week treatment period. The primary outcome measure is the change from baseline in the average number of cigarettes smoked per day.

The Principal Investigator is Albert A. Rizzo, M.D. renowned pulmonary specialist, Chief of Christiana Care’s Pulmonary and Critical Care Medicine Section, and former Chair of the American Lung Association. Dr Rizzo is board-certified in internal medicine, pulmonary disease, critical-care medicine and sleep-medicine disorders.

Dr Greg Collier, Managing Director and Chief Executive Officer said: “The data generated from this trial will not only potentially advance a novel therapy for smoking cessation, but it will also add to the already strong data package in our wider asthma and COPD program. This is a very exciting time for this company.”

Dr Mitchell Glass, Executive VP R&D and Chief Medical Officer said: “Tobacco is a known or probable cause of at least 25 diseases, including cancers, heart disease, stroke, emphysema and other chronic lung diseases. People who smoke have higher rates of serious complications following surgical procedures, and about one in two regular smokers dies of a smoking related disease, reducing their life expectancy by 16 years on average. This is a significant global health problem and represents an enormous commercial opportunity. A therapy which can reduce or eliminate smoker’s cough, a common barrier to quitting smoking, could be life changing for patients.”

In 2011 the global market for asthma and COPD prescription drugs was valued at $34 billion, with a five year compound annual growth rate (CAGR) of 4.4%.
Initiation of the chronic bronchitis trial follows the commencement in Q1 2013 of Invion’s phase II study of INV102 in asthma patients which is funded by the US National Institutes of Health in excess of USD$4 million.

In early Q3 2013, Invion also announced the commencement of its phase II clinical trial of INV103 (ala-Cpn10) in patients with system lupus erythematosus (SLE or lupus).

Invion has two drug assets in three phase II clinical trials currently underway.

FOR MORE INFORMATION CONTACT
Managing Director and CEO: Dr Greg Collier. P: 07 3295 0506 investor@invion.com.au
Media / IR: Jane Lowe, Buchan Consulting P: 02 9237 2800 jlowe@buchanwe.com.au

About INV102 (nadolol)
Invion is repurposing an existing drug, nadolol, which has been used in more than 10 million people for the treatment of high blood pressure, migraine and chest pain, and targeting it to the treatment of chronic inflammatory lung disease. Invion has an issued patent on the use of INV102 (nadolol) as a method of treating airway diseases.

About the phase II clinical trial in patients with chronic bronchitis (undergoing smoking cessation)
The phase II clinical trial is a multi-centre, randomised trial that will enrol up to 136 subjects in two centres in the United States. The Protocol is entitled “Efficacy and safety of beta-adrenoceptor inverse agonist, nadolol, in smoking cessation of patients with pre-existing COPD.” The primary objective is to evaluate the efficacy of 10-12-week treatment with nadolol in patients with COPD to improve success rates for smoking cessation. The primary outcome measure is the change from baseline in the average number of cigarettes smoked per day. Further details of this clinical trial can be found at www.clinicaltrials.gov with the identifier: NCT01825122. The Principal Investigator is Albert A. Rizzo, M.D. renowned pulmonary specialist, Chief of Christiana Care’s Pulmonary and Critical Care Medicine Section, and former Chair of the American Lung Association. Dr Rizzo is board-certified in internal medicine, pulmonary disease, critical-care medicine and sleep-medicine disorders. Christiana Care headquartered in Wilmington, Delaware (USA) is a major teaching hospital and is recognised as a regional centre of excellence, having conducted 842 clinical research studies in 2011.

About Invion Limited
Invion Limited (ASX:IVX) has two drug assets in three FDA-regulated, phase II clinical programs targeting treatments for major market opportunities in inflammatory diseases, including asthma and COPD ($34B) and lupus (to $4B). INV102 (nadolol) is a beta blocker used in more than 10M people that is being repurposed to treat lung indications. The US NIH is funding the current asthma trial in excess of $4M, the trial in chronic bronchitis patients will run concurrently. INV103 (ala-Cpn10) is a modified naturally occurring human protein shown to reduce IL-6, a key marker in lupus. A phase II lupus trial is anticipated to commence under FDA IND in the near term.