ASX / MEDIA ANNOUNCEMENT

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INVION LIMITED – CHANGES TO FDA REVIEWING DIVISION FOR SMOKING CESSATION CLINICAL TRIAL

Invion Limited (ASX: IVX) today announced that the US Food and Drug Administration (FDA) has transferred the protocol for the company's smoking cessation trial in patients with chronic bronchitis from the Division of Pulmonary, Allergy, and Rheumatology Products (DPARP) to the Division of Analgesia, Anesthesia and Addiction Products (DAAAP).

The DAAAP regulates Investigational New Drug Applications (INDs), New Drug Applications (NDAs), and Biologics Licensing Applications (BLAs) for prescription drugs and biologics intended for the prevention and treatment of nicotine addiction, amongst other indications.

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. Invion's smoking cessation protocol is designed to examine the effect of INV102 (nadolol) in patients with chronic bronchitis who are enrolled in a validated smoking cessation program. 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.

Executive Vice President and Chief Medical Officer Dr Mitchell Glass said, "INV102 is currently being developed under IND submitted to the DPARP, and the asthma program will remain with this division. The DAAAP will assign a new IND number for the smoking cessation protocol, and will utilise the standard 30 day IND review period. DAAAP will provide greater insight into smoking cessation drug development, and our excellent rapport with the Agency has resulted in open communication to ensure the smoothest possible transition between divisions."

"This transfer to the DAAAP has provided us the opportunity to utilise recent clinical research progress and strengthen the protocol by adding genotypic and phenotypic measures to the analysis. We will now be observing hereditary and non-hereditary variable responses to INV102 in the sputum of patients with chronic bronchitis, with the aim of supporting our two goals of enabling an end of phase II meeting for smoking cessation in COPD patients, and supporting our expedited development of inhaled INV102.

"We anticipate substantive interim data on this program in H1 2014," Dr Glass said.

FOR MORE INFORMATION CONTACT
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About Invion and INV102 (nadolol)
Invion is a clinical-stage life sciences company focussed on the development of treatments for major opportunities in the respiratory and inflammatory diseases markets including asthma and COPD ($34B) and systemic lupus erythematosus (lupus) (to $4B). Invion has three drug assets and three FDA-regulated, phase II clinical programs currently underway. INV102 (nadolol) is a beta blocker currently marketed as a safe and effective treatment for high blood pressure and migraine. Demonstrated to have unique anti-inflammatory capabilities, INV102 is being repurposed by Invion to treat chronic inflammatory airway diseases (e.g. asthma and COPD). Invion has an issued patent on the use of INV102 (nadolol) as a method of treating airway diseases. Invion's development strategy for INV012 is broad and includes oral and inhaled formulations - the current protocols in asthma and chronic bronchitis (smoking cessation) are for oral drug, the inhaled program will target chronic bronchitis and cystic fibrosis. Preclinical data to date confirms nadolol as a *beta adrenergic inverse agonist*. Two phase II clinical trials are completed, showing 80% positive response against an objective endpoint, acceptable safety, dose-related reduction of airway hyper-responsiveness. Invion's current phase-II asthma trial is funded by US NIH in excess of $USD4M, an exciting validation by one of the most prominent medical research bodies in the world. The phase II chronic bronchitis (smoking cessation) program is targeting increased smoking cessation, reduced airway inflammation, and decreased peri-operative complications in patients with pre-existing COPD in registered quit smoking programs.