

— **INVION ANNOUNCES SUCCESSFUL MEETING WITH FDA TO PROGRESS DEVELOPMENT OF INV102**

Brisbane, Australia and Delaware, United States, 4 April 2016: Australian drug development company Invion Limited (ASX:IVX) is pleased to advise that it has met with the Division of Anesthesia, Analgesia, and Addiction Products (DAAAP) of the US Food and Drug Administration (FDA) to discuss Phase 3 plans for development of oral nadolol as a treatment for patients with COPD who cannot quit cigarette smoking.

Written and oral communication fully supports Invion's proposals for further manufacturing in conjunction with Phase 3 development. In addition, the FDA confirmed that the animal toxicology package is complete. The Company and the FDA engaged in a highly productive dialogue on the design and regulatory target of the Phase 3 plan for oral INV102. In meeting directly with senior FDA officials, Invion team members were able to explain the role that airway healing can play in enabling these patients to quit, by reducing cough and phlegm. Invion was able to place the smoking cessation program into the context of treating COPD.

Executive Vice President R&D and Chief Medical Officer, Dr Mitchell Glass said, "We are pleased that the FDA has confirmed our plans for INV102 as a treatment for patients with established chronic bronchitis who cannot quit smoking due to increased cough and sputum production.

"Our discussion, based on their in-depth review, reflected their deep interest in our program and their shared desire to see us succeed in enabling these patients to quit by ameliorating symptoms that have precluded previous quit attempts.

"We welcome their recommendations, which will focus and strengthen our registration program without causing delay."

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About Invion Limited

Invision is a life sciences company focussed on the development of treatments for major opportunities in respiratory and autoimmune disease. Invion has three drug assets in development across four development programs. Invion is an ASX listed company (ASX:IVX), with operations in Brisbane, Australia and Delaware, USA.

- **INV102 (nadolol)** is a beta adrenergic biased ligand targeted to reverse mucous metaplasia in the airway epithelium treat chronic inflammatory airway diseases. In Q4 2015, Invion reported that data from a 155 patient phase 2 study of oral INV102 in smoking cessation demonstrated good safety and that treated patients were more likely to stop smoking completely or dramatically reduce the number of cigarettes smoked. An End of Phase 2 Meeting with the

FDA was held in 1Q 2016. Feasibility for an inhaled version of the drug to potentially treat COPD and cystic fibrosis is well-progressed with 3M Drug Delivery Systems, and toxicological studies have commenced. In addition, a phase 2 study of oral INV102 in mild asthma patients funded by the US NIH is fully recruited and will complete dosing in 1H 2016.

- **INV104 (zafirlukast)** is a leukotriene receptor antagonist (LTRA) that reduces inflammation, constriction of the airways, and the build-up of mucus in the lungs. An FDA-approved oral therapy, Invion is, through a joint development and licensing agreement with Hovione Scientia Limited, developing a proprietary dry powder formulation of the drug for the development of INV104 (zafirlukast) as a potential inhaled therapy for asthma.
- **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 reported final data from its phase 2 clinical trial in lupus patients in Q3 2015. 30mg and 100mg iv twice weekly showed reduced response to stimulation by LPS after 1 month of dosing. These data, which reflect relevant activity at the target cell type in patients with a target (autoimmune) disease, has formed the foundation of partnering discussions for this program.