

FDA ACCEPTS INVION PROPOSAL TO PROGRESS DEVELOPMENT OF INHALED NADOLOL TO TREAT CHRONIC RESPIRATORY DISEASES

- **Pre-IND meeting confirms company's regulatory and clinical strategy for inhaled INV102 (nadolol)**
- **3M formulation and device accepted**
- **Proposed toxicology program confirmed and underway**
- **Proposal for Phase 1 studies accepted**
- **Regulatory targets include COPD, severe asthma and cystic fibrosis**

Brisbane, Australia, 23 March 2015: Invion Limited (ASX: IVX) has received a positive response in an important pre-IND meeting with the US Food and Drug Administration (FDA), enabling further development of novel compound INV102 (nadolol) as a potential new inhaled therapy to treat chronic airway diseases like asthma.

This is a critical development milestone and demonstrates that FDA regulatory authorities have now examined and approved Invion's clinical strategy for inhaled nadolol, as well as the associated drug delivery hardware – a proprietary pressurised metered dose inhalation technology developed by global manufacturing collaborator 3M Drug Delivery Systems. Further, the FDA has accepted Invion's two Phase 1 study outlines and proposed toxicology program.

The successful meeting has also confirmed Invion's development program by:

- Accepting Invion's chemistry and manufacturing plan, which is ongoing at 3M Drug Delivery Systems;
- Confirming that the proposed toxicology program is necessary and sufficient;
- Agreeing the outline and objectives of Phase 1 studies; and
- Agreeing the targets for inhaled INV102 (nadolol), based on understanding the unique mechanism of action upon the airway epithelium.

Invion Chief Medical Officer and Executive VP of R&D, Dr Mitchell Glass, said that the pre-IND meeting had provided a clear and straightforward roadmap for the development of inhaled nadolol to treat chronic inflammatory airway diseases.

"We are enthusiastic about the results of our pre-IND meeting. We have confirmed and clarified the path forward for the inhaled formulation of INV102 to provide lifelong treatment of chronic airway diseases," he said.

"This is a key development milestone. The FDA is aware of the recent positive interim data from Invion's smoking cessation study of oral INV102, which provided clinical target validation for using this drug to treat the airway epithelium directly.

"Importantly, Invion is allowed to leverage results from ongoing studies with oral nadolol to provide safety, efficacy and exposure data that will expedite inhaled nadolol development."

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 chronic obstructive pulmonary disease (COPD).

Recent interim data from a Phase 2 trial of oral nadolol in smoking cessation was highly encouraging, demonstrating the compound's efficacy on four key biomarkers associated with lung inflammation.

The global market opportunity for new treatments for these diseases is in excess of \$35 billion.

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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.