

**INVION AND HOVIONE SIGN  
JOINT DEVELOPMENT AND LICENSING AGREEMENT  
FOR INHALED ZAFIRLUKAST**

- **Hovione Scientia Limited committing to a cost-profit sharing co-development and licensing partnership with Invion to develop and manufacture inhaled INV104 using Hovione's proprietary inhaler**
- **Invion to oversee clinical development with first studies expected to begin Q2 2016**
- **First inhaled non-steroidal anti-inflammatory to treat asthma**

**Brisbane, Australia and Wilmington, Delaware, United States 27 July 2015:** Australian drug development company Invion Limited (ASX: IVX) has secured a commitment from Hovione Scientia Limited, an international pharmaceutical company expert in inhalation development and manufacturing, to progress development of inhaled INV104 (zafirlukast) as a potential new treatment for asthma.

Invion and Hovione will collaborate to develop the proprietary novel technology – a dry powder formulation of the compound INV104 (zafirlukast) delivered by Hovione's inhaler.

Under the terms of the agreement, Hovione will provide expertise on chemistry, particle engineering, formulation, device and GMP manufacturing to develop and manufacture Zafirlukast Dry Powder Inhaler (DPI), which will be delivered using its proprietary device.

The collaboration extends from fully integrated scale-up and manufacture of phase appropriate cGMP Zafirlukast Dry Powder Inhaler for non-clinical and clinical studies to further secure for Hovione the exclusive rights to manufacture commercial supplies of Zafirlukast DPI.

Invion will oversee all non-clinical and clinical development and is moreover responsible for regulatory submissions. As consideration for Hovione's licensing and supply the finished drug product, Invion will pay an annual royalty to Hovione on total net sales of Zafirlukast DPI.

Zafirlukast is differentiated from other products being re-purposed for inhalation, given the extensive clinical database illustrating both its safety and efficacy. The collaboration has overcome the major impediment to reformulation and development of INV104 by producing a formulation devoid of banned propellants.

Invion has received agreement from the FDA to proceed in an accelerated development of the novel formulation and device. The collaboration has made excellent progress towards a stable formulation, paving the way for the development of INV104 as a novel non-steroidal anti-inflammatory for use in moderate to severe asthmatics.

Invion Chief Executive Officer and Managing Director Dr Greg Collier said this agreement was a 'win-win' for both companies and pivotal to Invion's plan to rapidly progress development of INV104.

He acknowledged Hovione's integrated inhalation development expertise and extensive knowledge of device development and noted the drug in oral formulation had an established safety and efficacy profile.

"This drug has already been administered to more than 4 million people to treat respiratory conditions," he said.

"We are reformulating this compound for inhalation and remain confident that delivering this compound directly into the lung in this manner will provide superior benefit and bypass any problems associated with systemic delivery.

"Hovione is the right partner to help us capitalise on this highly promising commercial opportunity."

Carla Vozzone, Hovione's Senior Director of Product Development and Licensing is delighted that Hovione's science in inhalation development and manufacturing is the conduit for Invision's INV104 program.

"Hovione has built through the years a profound and unique skill set in APIs, particle engineering, formulation and devices, being able to approach inhalation development holistically. Hovione's ability to manufacture all components of the drug product in the same location and solve problems within the same team accelerates development", she said. Carla Vozzone recognized that the co-development partnership entered with Invision illustrates Hovione's goal of repurposing drugs through alternative delivery routes with the aim of increasing its safety profile and patient compliance.

"Aligning Hovione's knowledge in inhalation with Invision's clinical expertise builds synergies for a winning proposition", she said.

INV104 is a leukotriene receptor antagonist (LTRA) which works by blocking the action of leukotrienes in the lungs, thereby preventing inflammation and narrowing of the airways.

An oral version of the drug marketed as a generic and by Astra Zeneca as 'Accolate®', is a first-in-class anti-leukotriene and treatment for asthma. All oral prescriptions of the drug come with a side effect warning.

Early data indicates INV 104 has an attractive safety and efficacy profile when delivered by inhalation at <1% of the oral dose.<sup>i</sup>

Invision has an exclusive, worldwide licence to develop and commercialise all inhaled formulations and applications of *zafirlukast*.

The global market for asthma therapeutics is in excess of \$22 billion per year.<sup>1</sup>

#### About Invision Limited

Invision 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 (nadolo) 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. Invision is an ASX listed company (ASX:IVX), with its clinical headquarters in Delaware, USA.

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<sup>1</sup> AstraZeneca Annual Report 2014 – Respiratory, Inflammation and Autoimmunity

**About Hovione**

Hovione is an international company with over 50 years' experience in the development and compliant manufacture of Active Pharmaceutical Ingredients and Drug Product Intermediates. With four FDA inspected sites in the U.S., China, Ireland, and Portugal, the company focuses on the most demanding customers, in the most regulated markets. The company also offers branded pharmaceutical customers services for the development and compliant manufacture of innovative new drugs, is able to support highly potent compounds and offers proprietary product development and licensing opportunities for drug products. In the inhalation area, Hovione is the only independent company offering such a broad range of services. Hovione is a member of [Rx-360](#), EFCG, IPAC-RS and participates actively in industry quality improvement initiatives to lead new global industry standards. [www.hovione.com](http://www.hovione.com)

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<sup>i</sup> Nathan, RA, Glass, M, Minkwitz MC. Inhaled ICI 204,219 blocks antigen induced bronchoconstriction in subjects with bronchial asthma. CHEST: 1994; 105(2): 483-488