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INVION ENTERS INTO GLOBAL LICENCE AGREEMENT FOR INHALED ZAFIRLUKAST

- **Invion announces it has licenced intellectual property to develop inhaled zafirlukast, to be known as INV104**
- **Zafirlukast is currently marketed by AstraZeneca as Accolate, an oral leukotriene receptor antagonist for the treatment of asthma**
- **INV104 to be developed as inhaled, non-steroidal, anti-inflammatory treatment for asthma**
- **Invion EVP R&D and CMO Dr Mitchell Glass led development of oral Accolate to FDA approval**

Clinical-stage drug development company Invion Limited (ASX:IVX) today announced the execution of a licence agreement with Accolade Pharma LLC for intellectual property to develop inhaled formulations of *zafirlukast* for the treatment of asthma and other respiratory conditions.

The agreement provides Invion with an exclusive, worldwide licence to develop and commercialise all inhaled formulations and applications of *zafirlukast*. A licence fee of \$500,000 is payable by Invion to Accolade Pharma LLC over a 12 month period commencing January 2014.

Zafirlukast is a *leukotriene receptor antagonist* (LTRA) or *anti-leukotriene* that blocks the action of the cysteinyl leukotriene receptors to reduce inflammation, constriction of the airways, and the build-up of mucus in the lungs.

The oral formulation of *zafirlukast*, currently marketed as a generic drug as well as by AstraZeneca as Accolate, has recently become available in the public domain due to the expiry of its original patents. Accolade Pharma LLC has created a patent strategy and strategic opportunities to develop non-oral formulations of the drug, aimed at reducing side effects and increasing effectiveness.

Invion aims to develop INV104 for novel inhaled indications using the FDA's abbreviated 505(b)(2) regulatory pathway.

Invion's CEO, Dr Greg Collier said, "Invion is delighted to announce this licence agreement. The introduction of *zafirlukast* into our portfolio as INV104 complements Invion's existing pipeline of inflammatory and respiratory disease treatments. INV104 represents a potential new inhaled, non-steroidal, anti-inflammatory treatment for asthma, which, similar to INV102 uses a drug with an existing safety profile."

"The development of INV104 will utilise existing knowledge, skills and competencies in the Invion clinical team, while strengthening Invion's development pipeline and asset commercialisation opportunities.

"Having been used in over four million people, there is a large safety database for this drug, and as we know, there continues to be a large unmet need for more effective and accessible asthma therapies. Having the INV102 (nadolol) and INV104 (*zafirlukast*) inhaled programs running in parallel means we can leverage IP and strategic efficiencies to the benefit of the Invion portfolio," he said.

Dr Mitchell Glass, Invion's Executive Vice President of R&D and Chief Medical Officer, led the development and submission of Accolate for Zeneca (now AstraZeneca) to its FDA approval letter in 1998, and is a substantial shareholder of Accolade Pharma LLC.

Key terms of the licence

Licensee	Invion Limited
Licensor	Accolade Pharma LLC, a Delaware USA private company (which is a related party of Invion by virtue of Dr Mitchell Glass' relationship with the Licensor).
Term	Until the last to expire of the Intellectual Property Rights in the Licensed IP.
Licensed IP	All information including data, contacts, contracts and other arrangements in connection with zafirlukast, owned or controlled by Accolade Pharma LLC.
Fees	The total Fee is AUD\$500,000. The Fee will be paid by way of equal monthly payments, for a period of 12 months, commencing on 16 January 2014. In the event that the Licensee has net cash in excess of AUD\$10 million during the 12 month period, then the Licensee may accelerate these payments.
Royalties	20% of the Net Sales received by the Licensee in connection with the development and commercialisation of zafirlukast. Net Sales include the gross amount invoiced by or on behalf of Invion less customary deductions.

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About INV104 (zafirlukast)

INV104 (zafirlukast) is a *leukotriene receptor antagonist* (LTRA) or *anti leukotriene* that works by blocking the action of leukotrienes, which are chemicals released by the body as part of the inflammation response. In the lungs, leukotrienes cause the muscles lining the airways to contract, thereby making the airways narrower. They also cause inflammation of the lining of the airways, which results in increased mucus production and further narrowing of the airway. By blocking the actions of leukotrienes, *zafirlukast* prevents the increased mucus production, inflammation and narrowing of the airways that occurs in asthma - this helps prevent asthma attacks from occurring. *Zafirlukast* is currently used as a regular oral treatment to prevent asthma attacks, rather than to treat them. The oral version of this drug is a first-in-class anti-leukotriene, which has shown in seven clinical trials an attractive safety and efficacy profile when delivered by inhalation at <1% of the oral dose. Invion is developing an inhaled version of the drug.

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, and three phase II clinical trials, regulated by the Food & Drug Administration (FDA), currently underway in the United States. **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 shown to reduce interleukin-6 (IL-6), a marker of autoimmune inflammation and a key marker in the chronic inflammatory disease, lupus. Invion is an ASX listed company (ASX:IVX), with its clinical headquarters in Delaware, USA.