

18 July 2013

INVION ANNOUNCES COMMENCEMENT OF PHASE II CLINICAL TRIAL IN LUPUS

- **INV102 phase II clinical trial initiated and enrolling for patients with SLE (lupus)**
- **Commencement follows acceptance by the FDA of Invion's IND**
- **Invion current has two phase II trials underway, including asthma study funded by NIH to \$4.4M**

Clinical-stage drug development company Invion Limited (ASX:IVX) is pleased to announce the initiation and commencement of patient enrolment in the company's phase II clinical trial of INV103 (ala-Cpn10) in patients with mild systemic lupus erythematosus ("SLE" or "Lupus").

The clinical trial which is being carried out at sites in Pennsylvania and Texas in the United States is being conducted under an FDA Investigational New Drug application (IND).

INV103 (ala-Cpn10) is a modified version of the naturally occurring human protein, chaperonin10. This study aims to generate data on the safety, tolerability, and efficacy of INV103 as a potential new therapy for lupus, with four groups (cohorts) of 8 patients each being treated under the study design.

With only one drug approved by the FDA for the treatment lupus over the last 50 years, a large gap currently exists for effective treatment therapies. This is an indication of the complexity surrounding this disease area, the drug market for which is expected to reach sales of over \$4 billion in the US and five major EU markets by 2020.

Invion CEO and Managing Director, Dr Greg Collier said "The commencement of the INV103 phase II lupus trial represents a major milestone for the company. The complex lupus treatment market has been clinically underserved, and positive data from this trial would deliver a promising lead on a potential future therapy."

"The FDA's acceptance of our IND for lupus means Invion is working under two INDs to develop two drug assets in three phase II clinical programs. This is a significant achievement by any measure for a company of Invion's size, however made even more so given we are less than 12 months into existence," he said.

The trial is expected to run for approximately 12 months, with safety and efficacy data from the first two cohorts available in approximately six months.

FOR MORE INFORMATION CONTACT: Jane Lowe, Buchan Consulting P: 02 9237 2800
jlowe@buchanwe.com.au

About INV103 (ala-Cpn10): Target Product Profile

INV103 (ala-Cpn10) is a modified version of the natural human protein, chaperonin10, which has biological activity ideally suited to the treatment of inflammation associated with autoimmune disease. IL-6 is a marker of vascular inflammation, and with INV103 clinical data to date that includes a significant reduction in biomarkers of

inflammation including serum IL-6, INV103 is targeted as a potential new therapy in the under-served lupus market. Lupus is a vascular inflammatory disease that leads to chronic inflammation, antibody production, and tissue damage. The disease occurs more commonly in women and increases risk of other health problems including heart disease, kidney disease and osteoporosis.

About the Clinical Trial Protocol

The Protocol is entitled a “Double-blinded, randomized, placebo-controlled study to investigate the safety, tolerability, pharmacokinetics, and biochemical activity of intravenous Cpn10 administration in subjects with SLE.” The Protocol Number is IVXCpn001. The primary objective is to evaluate the safety, tolerability and efficacy of four-week treatment with Cpn10 in subjects with mild SLE. The adverse event profile and safety laboratory parameters will be monitored throughout the study. The primary outcome measure is the reduction from baseline serum IL-6 levels at the end of active dosing, comparing treatment to placebo cohort. Dose escalation is planned from 10mg IV twice weekly (the highest dose used to date) to greater than 100mg IV twice weekly as tolerated. Further details of this clinical trial can be found at www.clinicaltrials.gov with the identifier: NCT01838694.

About the Clinical Trial sites and Investigators

The Altoona Center for Clinical Research (ACCR) is a privately owned, 40,000 square foot state-of-the-art research and group private practice facility located in Duncansville, Pennsylvania. ACCR is dedicated to providing quality clinical research with the highest standards of patient safety. Over 740 studies have been completed at the center for at least 100 different Sponsors and CRO's. The Center was founded in 1991 by Alan J. Kivitz, MD, CPI. Dr. Kivitz is a Certified Physician Investigator and a member of the Osteoporosis & Arthritis Investigator Networks. Dr Kivitz and his team of rheumatologists have a combined 48 years of clinical research experience. All four physicians are Board Certified in Rheumatology and Internal Medicine. The Metroplex Clinical Research Center (MCRC) is a privately owned multi-specialty clinical research and group private practice facility located in Dallas, Texas. MCRC was founded in 1984 by rheumatologists Roy M. Fleischmann, M.D. and Stanley B. Cohen, M.D., who have 50 years combined clinical research experience and are recognized thought leaders on the subjects of research and treatments for rheumatic diseases. MCRC's clinical team includes 10 board-certified physicians as well as a designated Phase I team of critical care professionals, and have completed more than 1,000 Phase I-IV clinical trials.

About Invion Limited

Invion is a clinical-stage drug development company focussed on the development of treatments for major opportunities in the inflammatory diseases market including asthma and COPD (\$34B)ⁱ and lupus (to \$4B)ⁱⁱ. The company's strategy is for the cost-effective development of its assets to late phase II before negotiating commercial partnerships. Invion has two phase II proprietary therapeutic candidates: INV102 (nadolol), a beta blocker being repurposed to treat inflammatory lung conditions; and, INV103 (ala-Cpn10), a modified human protein being targeted to the treatment of autoimmune inflammation. These assets are in phase II clinical programs in chronic bronchitis (smoking cessation), asthma and systemic lupus erythematosus (lupus). Invion's strategic partners include the United States National Institutes of Health (NIH) which is funding the phase II asthma program in excess of \$4 million (non-dilutive). This is an exciting validation by one of the most prominent medical research bodies in the world.

ⁱ Respiratory and Inflammation, AstraZeneca Annual Report, 2011; Smoking Cessation Drugs: World Market Prospects 2012-2022, Visiongain Reports 2012 ; Healthcare Finance, Bloomberg Brief, 13 August 2012; Full-Year and Fourth-Quarter 2011 Financial Results, Merck & Co.

ⁱⁱ Datamonitor: Systemic Lupus Erythematosus Market Forecast, 22 August 2011; Decision Resources: Systemic Lupus Erythematosus, 2012