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**UPDATE ON INVION's PHASE II STUDY OF INV103 (ala-Cpn10) IN LUPUS PATIENTS**

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- **DATA FROM FIRST TWO COHORTS RECEIVED AND ANALYSED**
- **GOOD SAFETY CONTINUES TO BE DEMONSTRATED**
- **INVION HAS PROCEEDED TO HIGHER DOSE COHORTS IN ONGOING PHASE II TRIAL**

Invion Limited (ASX: IVX) is pleased to advise that it has received interim data from its phase II clinical trial of INV103 (ala-Cpn10) in patients with Systemic Lupus Erythematosus (SLE).

Data from the first two cohorts has been analysed. In the first cohort, patients received a twice-weekly intravenous (iv) dose of either 10mg INV103 (ala-Cpn10) or placebo. In the second cohort, patients received a twice-weekly intravenous dose of 30mg INV103 (ala-Cpn10) or placebo.

Data analysed included a broad range of serum biomarkers, blood chemistries, adverse drug events, anti-drug antibodies, vital signs, and signs and symptoms of lupus.

Safety data from the first two cohorts of the study have demonstrated a safety profile supportive of testing higher doses in the ongoing phase II trial. Data from both cohorts has shown no pattern of adverse events.

In the first cohort, in which mild lupus patients received 10mg iv twice weekly, neither serum biomarkers nor stimulated cells showed any statistically significant pattern of response to INV103 (ala-Cpn10). In the second cohort, also in mild lupus patients, serum biomarkers showed no statistically significant cohort-wide response to treatment, due to baseline values at or near the normal range.

Based upon the safety profile generated from these results, the protocol has been advanced to dosing patients with mild lupus at 100mg iv twice-weekly, which represents a 10-fold increase over the highest dose used in previous clinical trials of ala-Cpn10.

Executive Vice President R&D and Chief Medical Officer, Dr Mitchell Glass, said:

"It is not unexpected that lupus patients with mild disease may not have a baseline abnormality in these biomarkers, and hence cannot show a response to treatment. It was important for us to establish this safety profile in mild lupus patients, and now we look forward to leveraging this understanding into the final cohorts of the study - which include significantly higher doses of INV103, and also patients with more severe disease."

"While we will continue to collect valuable safety and pharmacokinetic data in mild patients, results to date have allowed us to open a dialogue with the FDA to enable us to study SLE patients with more severe disease, including the renal disorder associated with SLE. Patients with more severe lupus have higher levels of the biomarkers that we are examining and accordingly we would hope to see amelioration of these important biomarkers. We believe that the response from the final cohorts of this study will be pivotal for both regulatory strategy and possible partnering for INV103."

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**About INV103 (ala-Cpn10)**

INV103 (ala-Cpn10) is a modified version of a naturally occurring human protein. It has been proposed as a founding member of the Resolution Associated Molecular Pattern (RAMPs) family - a critical component of prevention of autoimmunity. Data to date includes dose response reduction in biomarkers of inflammation including serum IL-6, MCP1, TNF and IL-1 and a strong safety profile in greater than 250 patients. INV103 (ala-Cpn10) has composition of matter protection in all the major markets.

**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 biased ligand) 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. Invion is an ASX listed company (ASX:IVX) with its clinical headquarters in Delaware, USA.