ASX / MEDIA ANNOUNCEMENT

Targeting inflammation

INVION COMPLETES CLINICAL TRIAL OF INV103 (ALA-CPN10) IN LUPUS PATIENTS

- **Invion completes study of INV103 (ala-Cpn10) in patients with systemic lupus (SLE)**
- **Study designed to test safety and biochemical effect of materially higher doses than previous studies**
- **Data from patients' cells show positive effect after one month of dosing**
- **Study supports larger, longer trials of Cpn10 in patients with autoimmune diseases**
- **Company to focus on partnering the drug asset**

Brisbane, Australia and Wilmington, Delaware, United States 17 August 2015: Australian drug development company Invion Limited (ASX: IVX) has completed its Phase II clinical trial entitled "Double-blinded, randomised, placebo-controlled study to investigate the safety, tolerability, pharmacokinetics, and biochemical activity of intravenous Cpn10 administration in subjects with SLE (NCT01838694)".

The Company's decision to complete the trial is based on the review of safety and biochemical markers of effect in 28 subjects across four cohorts, which show that the study has met its objectives and supports the continued development of INV103 (ala-Cpn10) in longer and larger trials in patients with autoimmune diseases.

Three sets of data were reviewed from subjects who received twice-weekly doses of 10, 30 or 100mg of ala-Cpn10, or placebo. The adverse events and clinical chemistry profiles showed that increasing the dose 10-fold over levels used previously in the development of the drug asset could be achieved safely.

Serum biomarkers of vascular inflammation were too variable in all cohorts to draw absolute conclusions about biological effect.

However significant data were derived from extracting white blood cells from patients before and after certain doses and stimulating these cells (peripheral blood monocytic cells or PBMCs) to produce inflammatory signals. PBMCs are hypothesized to play a critical role in autoimmune diseases.

Subjects in the first cohort, who received 10mg intravenously twice-weekly for four weeks, showed no consistent effect on stimulated PBMC production of 3 key cytokines (IL-1Beta, IL-6 and TNF-alpha) measured at two time points.

In contrast, subjects in the second cohort (30mg intravenously twice-weekly for four weeks) showed a consistent decrease in production of all three cytokines measured at the same two time points in stimulated PBMC.

Data from the third cohort (100mg intravenously twice-weekly for four weeks) support findings from the second cohort, although, like the placebo data, had some variability.

Executive Vice President R&D and Chief Medical Officer, Dr Mitchell Glass, said, "We are pleased that the data from this trial support the dose escalation that has underpinned the strategy for ala-Cpn10.

"Although we report the data here as means, the data are quite variable as is to be expected from PBMC assays. However we are pleased at the consistency of the responses.

"INV103 (ala-Cpn10) will need scale-up and longer term toxicology to extend these findings from one month to longer term studies in larger groups of subjects.

"We will be providing these data to potential partners in the near term, with a view to partnering the program."

FOR MORE INFORMATION CONTACT

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About the results

Subjects in the first cohort, who received 10mg intravenously twice weekly for 4 weeks showed no consistent effect on stimulated PBMC production of 3 key cytokines (IL-1β, IL-6 and TNFα) measured at 2 time points: from 6 hours after the first dose to 6 hours after the last dose (Visit1 v Visit 9: -18%TNFα; -1% IL-1β; +2.8% IL-6), and at 6 hours after the final dose compared to pre-dose levels after stimulation (+227 to +987%). In contrast, subjects in the second cohort showed a consistent decrease in all 3 cytokines measured at these 2 time points: V1 v V9 -35% TNFα –38.5% IL-1β and -42.5% IL-6. At visit 9, from 6 hours after the final dose compared to pre-dose levels after stimulation, effects were -62% (TNF), -66% (Il-1) and -73% (IL-6). Data from the third cohort support the data from the second cohort, although, like the placebo data, had some variability, including one patient who received 100mg iv twice weekly for 4 weeks but had no response, to a placebo subject who had profound (99%) decreases in stimulated cytokine production from visit 1 to Visit 9.

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) 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.