

Incitive's Lead Compound ICV0019 completes Toxicology Studies

Key points:

- ICV0019 is not toxic at doses used in disease animal model trials.
- ICV0019 acute tolerated dose (ATD) and maximum tolerated dose (MTD) for three routes of administration are significantly greater than therapeutic levels required for animal trials.

Brisbane, Australia. 11 March 2008: Incitive Ltd (ASX code: ICV) today announced they have completed two preliminary toxicology studies on their lead compound ICV0019. The two studies determined the ATD and MTD doses for ICV0019 in healthy mice, and showed that ICV0019 is not-toxic at the therapeutic levels used in animal trials.

Mr Donald Home, Incitive Managing Director said the company had completed two key milestones in proving that the lead compound is both safe and capable of being scaled up for manufacturing in readiness for clinical trials.

Mr Home said, " ICV0019 is currently in trial in a number of efficacy models to determine the level of effectiveness in treating important diseases. These are important steps in preparation for entering human clinical trials," he added.

Incitive has worked on the production of ICV0019 through the course of 2007, and has now demonstrated that its lead compound can be reproducibly manufactured in large quantities on a regular basis. This is a significant step forward for the company.

The current studies reported in this announcement indicate that ICV0019 shows no adverse clinical symptoms when given at certain doses, via three different routes, including oral administration and over extended periods.

More about the ATD and MTD Study:

The ATD is defined as the highest dose administered in a 24 hour period that does not induce weight loss in an animal in excess of 15% of the original body weight, or cause death or severe morbidity, at any time in the study. The three routes of administration chosen for this study were intravenous (i.v.), intraperitoneal (i.p.) and oral.

- For the i.v. route of administration the ATD was determined as 30 mg/kg as this was the highest dose that fulfilled the requirements of the study. Doses of 40 mg/kg were toxic to the mice tested.
- For the i.p. route of administration the ATD was determined as 20 mg/kg as this was the highest dose that fulfilled the requirements of the study. Doses of 30 mg/kg i.p. were toxic to the mice tested.



- For the oral route of administration the ATD was not determined as no toxicity was observed in animals administered 40 mg/kg, the highest dose level administered to mice.

The MTD is defined as the highest dose administered in a 24 hour period that does not induce weight loss in an animal in excess of 15% of the original body weight, or cause death or severe morbidity, at any time in the study. This daily dose is repeated for seven consecutive days. The three routes of administration chosen for this study were intravenous (i.v.), intraperitoneal (i.p.) and oral.

- For the i.v. route of administration the MTD was determined as 8 mg/kg when given daily and 12 mg/kg when given on alternate days. The mice were unable to receive higher doses i.v. due to necrosis of the tail vein.
- For the i.p. route of administration the MTD was determined to be 8mg/kg. The mice were unable to receive higher doses due to inflammation and necrosis at the injection site.
- For the oral route of administration the MTD was determined to be 32 mg/kg. At 40mg/kg one mouse lost >15% body weight, no other adverse events were noted in this group.

These results confirm that ICV0019 should be safe and well tolerated in future trials. The current dose of ICV0019 used in disease animal model trials is less than 10 mg/kg by oral administration.

About Incitive Limited

Incitive Ltd is a publicly-listed life science company that aims to be a leader in the development of drugs that treat inflammation and auto-immune diseases. The primary target markets are tissue/organ transplantation and autoimmune disease. Incitive's product pipeline is novel and based on over ten years of international peer-reviewed research. The lead products include protein drugs derived from natural sources and small molecules, all aimed to treat diseases in areas of unmet clinical need.

The lead compound, ICV0019, is a purified protease isolated from bromelain, an extract from pineapple stems. ICV0019 acts by blocking the MAP kinase pathway to inhibit T cell activation and is being developed at The Queensland Institute of Medical Research, the largest medical research institute in Australia. The small molecule program targets perforin, which is responsible for tissue damage during autoimmunity. The perforin technology is being developed at the Peter MacCallum Cancer Centre in Melbourne and the University of Auckland.

More information: www.incitiveltd.com



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