

## Progen Update on Phase 3 Clinical Program for PI-88 in Liver Cancer

**Brisbane, Australia. 2 November 2007:** Progen Pharmaceuticals Limited (ASX: PGL; NASDAQ: PGLA) today announced that in light of the recent Fast Track designation awarded to PI-88 for the prevention of tumour recurrence following curative resection of primary liver cancer and in order to commence the Phase 3 program as rapidly as possible, the Company will no longer continue with the Special Protocol Assessment process.

The Company has used the Special Protocol Assessment (SPA) process to obtain valuable FDA feedback on specific elements of our trial design. By incorporating this feedback into the trial design and with Fast Track designation for the assessment of delaying tumour recurrence following curative resection, Progen is confident that its Phase 3 trial meets the FDA requirements for approval under the Fast Track designation.

Justus Homburg, Progen's Chief Executive Officer, commented: "We will avail ourselves of the additional FDA access that the Fast Track designation affords us as we proceed towards trial completion. With the FDA feedback we have received to date and Fast Track designation, it is now time to lock trial design and prepare to commence patient recruitment."

The Phase 3 double-blinded placebo-controlled trial is scheduled to be run in countries in North America, Europe and Asia. Approximately 600 patients with post-operative primary liver cancer will be enrolled in the trial. The benefits of this trial design include the treatment of more patients than the Phase 2 program, which strengthens the clinical and statistical significance of the data. Patients will be treated for a longer period of time potentially prolonging the time to recurrence. The double-blinded, placebo-controlled nature of the trial will ensure the best possible data under the most rigorous of conditions.

We remain on track to enroll the first patient into the Phase 3 trial before year's end. An Asian investigators' meeting has been held in Thailand, the North American investigators' meeting is being held this week and one is planned for Europe in the coming weeks. In addition, key sites have submitted the protocol for ethics approval and regulatory submissions have been filed in key countries.

**About Progen:** Progen Pharmaceuticals Limited is an Australian-based globally focused biotechnology company committed to the discovery, development and commercialisation of small molecule therapeutics primarily for the treatment of cancer.

**About PI-88:** PI-88 is one of a new class of multi-targeted cytostatic cancer therapeutics. It is a novel anti-cancer compound with a first-in-class mechanism as a heparan sulfate mimetic. Its anti-tumor activity is based on inhibition of two biological processes – angiogenesis (the growth of new blood vessels) and metastasis (the spread of cancer to other sites) – critical to the growth and progression of cancer. In a Phase 2 trial in post-resection liver cancer, 160mg of PI-88 demonstrated a 25% improvement in the primary endpoint of disease-free rate at 48 weeks and 78% improvement in secondary endpoint of disease-free survival.



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