

## US FDA Fast Tracks PI-88 for the Treatment of Post Resection Liver Cancer

**Brisbane, Australia. 24 September 2007:** Progen Pharmaceuticals Limited (ASX: PGL; NASDAQ: PGLA) announced today that its investigational anti-cancer drug PI-88 has been awarded Fast Track status by the U.S. Food and Drug Administration (FDA). The fast track designation has been granted to PI-88 for the prevention of tumor recurrence following curative liver resection in patients with hepatocellular carcinoma (HCC, primary liver cancer).

Under the FDA Modernization Act of 1997, the fast track program is designed to facilitate the development and expedite the regulatory review of new drugs that demonstrate the potential to treat serious or life-threatening diseases where there is an unmet medical need. The Fast Track designation will enable Progen to file a New Drug Application (NDA) on a rolling basis as data becomes available. This permits the FDA to review the different components of the Drug Master File as they are completed in advance of receiving the final submission.

Mr Justus Homburg, Progen's CEO commented "This designation will speed the process of bringing this potentially clinically very important drug to patients with liver cancer. The FDA decision to award fast track status to PI-88 was based on recent Phase 2 clinical data and the high unmet need for treatments for patients with resectable primary liver cancer. The key Phase 2 study showed that PI-88 has the potential to improve the time a patient remains disease free following surgery. As we enter the final stages of clinical development and commence a multinational Phase 3 trial, we look forward to collaborating closely with the FDA to expedite the development and approval of PI-88."

Conservatively, over half a million new cases of HCC are diagnosed worldwide each year, making it the fifth most common cancer and the third major cause of deaths due to cancer worldwide. The most common causes of HCC are related to chronic infection with hepatitis B and C (HBV, HCV). Due to late disease diagnosis, currently only about 25% of patients are eligible for surgery and half of those patients will have their disease recur within 12-15 months. No products have been approved by the FDA to prolong the time a patient remains disease free following surgery.

The fast track designation is fully aligned with Progen's Phase 3 trial design. The double blinded, placebo-controlled Phase 3 trial will be powered for the primary endpoint of disease-free survival determining if PI-88 can prevent early recurrence following curative hepatic surgery. The trial will begin later this year and targets 600 patients with liver cancer post resection, in more than a dozen countries.

**About Progen:** Progen Pharmaceuticals Limited is an Australian-based globally focused biotechnology company committed to the discovery, development and commercialization 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, 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. These results, combined with positive feedback from the FDA, provide Progen with confidence in the potential of PI-88 for this

indication and we are therefore aggressively pursuing its development towards registration and commercialization.

**Progen Information:**

Justus Homburg  
Progen Pharmaceuticals Limited  
T: +61 7 3842 3333  
E: justush@progen-pharma.com

Noreen Dillane  
Progen Pharmaceuticals Limited  
T: +61 7 3842 3333  
E: noreend@progen-pharma.com

**Media and Investor Relations Australia:**

Rebecca Piercy  
Buchan Consulting  
T: +61 2 9237 2800 / +61 422 916 422  
E: rpiercy@bcg.com.au

Rebecca Wilson  
Buchan Consulting  
T: +61 417 382 391  
E: rwilson@bcg.com.au

**Media Relations USA:**

Robert D. Stanislaro  
Financial Dynamics  
T: 212-850-5657  
E: robert.stanislaro@fd.com

**Investor Relations USA:**

Evan Smith  
Financial Dynamics  
T: 212-850-5606  
E: evan.smith@fd.com

This press release contains forward-looking statements that are based on current management expectations. These statements may differ materially from actual future events or results due to certain risks and uncertainties, including without limitation, risks associated with drug development and manufacture, risks inherent in the extensive regulatory approval process mandated by the United States Food and Drug Administration and the Australian Therapeutic Goods Administration, delays in obtaining the necessary approvals for clinical testing, patient recruitment, delays in the conduct of clinical trials, market acceptance of PI-88, PI-166 and other drugs, future capitals needs, general economic conditions, and other risks and uncertainties detailed from time to time in the Company's filings with the Australian Stock Exchange and the United States Securities and Exchange Commission. Moreover, there can be no assurance that others will not independently develop similar products or processes or design around patents owned or licensed by the Company, or that patents owned or licensed by the Company will provide meaningful protection or competitive advantages.