

## EMA Recommends Orphan Drug Designation for PI-88

**Brisbane, Australia. 15 August 2007:** Progen Pharmaceuticals Limited (ASX: PGL; NASDAQ: PGLA) today announced that the Committee for Orphan Medical Products (COMP) of the European Agency for the Evaluation of Medicinal Products (EMA) has adopted a positive opinion recommending the granting of orphan medicinal product designation for PI-88 for the treatment of hepatocellular carcinoma, or primary liver cancer.

The Committee's orphan medicinal products opinions are submitted to the European Commission for orphan designation determination. The orphan drug designation will become effective upon adoption of this recommendation by the European Commission. This is expected to occur before the end of the third quarter of 2007.

The EMA's orphan drug program is designed to promote the development of drugs to treat rare life-threatening or very serious conditions that affect no more than five in every 10,000 people in the European Union (EU). The designation provides EU market exclusivity for up to ten years in the given indication. Other potential benefits include: a reduction in fees associated with various aspects of the regulatory process, including the application for marketing approval, and EMA guidance in preparing protocols concerning studies relevant for approval.

PI-88 is part of a new class of multi-targeted cancer therapeutics inhibiting both angiogenesis (or tumour promoting) factors such as Vascular Endothelial Growth Factor (VEGF), Fibroblast Growth Factors (FGF) 1 and 2, and heparanase, a degrading enzyme implicated in metastasis (tumour spread). Progen will this year launch a multi-national two-armed, double-blinded placebo controlled Phase 3 trial using PI-88, with the primary endpoint of disease free survival, in patients with post-operative primary liver cancer. The goals of PI-88 treatment in this population are to reduce disease recurrence, prolong the time to recurrence (known as disease-free survival time) and improve the overall survival time of patients after tumour resection. Additionally, the Company is currently conducting a Phase 2 trial in patients with melanoma, the other indication in which we have received U.S. FDA orphan drug designation, with results from this trial expected during the second half of 2008.

Mr Justus Homburg, Chief Executive Officer of Progen commented: "While the incidence of primary liver cancer in the European Union is relatively low, with over half a million new cases elsewhere in the world, it is a disease of significant global relevance. We are honored by the Committee's decision and support in our efforts to develop PI-88 for liver cancer."

**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.

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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.