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# PG545 Phase 1 Clinical Trial Successfully Completes Second Patient Cohort

**Brisbane, Australia, 22 September 2014.** Progen Pharmaceuticals Ltd ("Progen" or "the Company") (ASX: PGL, OTC: PGLA) is pleased to announce that it has completed assessment of the second patient cohort in its PG545 Phase 1 clinical trial. Progen together with an independent medical monitor and the co-ordinating investigators have reviewed the safety data from this cohort and have agreed to progress to the next dose level of PG545.

Each patient in the second cohort received once-weekly 50mg doses of PG545. No dose limiting toxicities were reported from the group following at least four weeks of treatment. Accordingly, the recruitment of the third cohort of three patients has commenced. Each of the patients in the third group will receive 100mg doses of PG545 at once-weekly intervals.

The study is entitled "an open-label, multi-centre Phase I study of the safety and tolerability of IV infused PG545 in patients with advanced solid tumours". The study is expected to enrol approximately 25 advanced cancer patients.

The primary objective of the study is the determination of the maximum tolerated dose (MTD) as defined by significant dose limiting toxicity (DLT).

The secondary objectives are:

- Assessment of the safety and tolerability of PG545 following multiple doses in subjects with advanced solid malignancies;
- To estimate pharmacokinetic parameters of PG545 and explore pharmacokinetic/pharmacodynamic relationships; and
- To document any anti-tumour activity observed with PG545

The clinical trial is being carried out at three sites in Australia.

## **ENDS**

#### **About Progen Pharmaceuticals Ltd**

Progen Pharmaceuticals Limited is a biotechnology company committed to the discovery, development and commercialization of small molecule pharmaceuticals primarily for the treatment of cancer. Progen has built a focus and strength in anti-cancer drug discovery and development. <a href="https://www.progen-pharma.com">www.progen-pharma.com</a>

#### **About PG545**

PG545 is a new multifunctional anti-cancer drug designed to target the tumour microenvironment and developed in-house by Progen Pharmaceuticals. PG545 has been demonstrated in a variety of cancer models to slow the growth rate and/or destroy cancer cells directly, block the growth of new blood vessels within tumours (angiogenesis), stop the spread of cancer (metastasis), and modulate specific immune cells known to interact with cancer cells. These complementary mechanisms are uniquely targeted by PG545 to block key processes in cancer development and represent a novel approach to the treatment for several cancer types.

### For more information:

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This 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, amongst others, 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, PG545, and other drugs, future capital needs, general economic conditions, and other risks and uncertainties detailed from time to time in the Company's filings with the Australian Securities 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.