

Progen Announces PI-88 Phase 2 Lung Cancer Results

Brisbane, Australia. 24 September 2007: Progen Pharmaceuticals Limited (ASX: PGL; NASDAQ: PGLA) today announced that the Phase 2 trial administering 250mg of PI-88 in combination with the chemotherapeutic agent docetaxel to patients with advanced non small cell lung cancer did not meet its primary endpoint of significantly improving the progression-free rate at six months compared to docetaxel alone. The trial also did not meet its secondary endpoints of improvement in time to progression, response rate, overall survival and quality of life measures.

The overall data from this trial suggests that no further investigation of PI-88 in combination with docetaxel in patients with non small cell lung cancer that have failed platinum based first line therapies is warranted. However, nine patients in the study switched to PI-88 after experiencing toxicity or disease progression with docetaxel monotherapy. The data for this patient group suggests a potential survival benefit that Progen intends to investigate further with, amongst others, the clinicians involved in this study.

"We are disappointed, first and foremost, for the patients with non small cell lung cancer that have disease progression following platinum based chemotherapy as treatment options are limited," said Justus Homburg, Progen's Chief Executive Officer. "The outcome of this study has no impact on our Phase 3 registration strategy for patients with post-resection liver cancer which we announced today has been granted fast-track status designation by the U.S. FDA."

"It is quite common for new drugs to show benefit in one patient group but limited benefit in another. To date, PI-88 has shown evidence of benefit in patients with melanoma, multiple myeloma and post-resection liver cancer. In particular, PI-88 may be more active for tumors that are at an earlier disease stage, such as has been demonstrated in the PI-88 Phase 2 primary liver cancer trial" added Homburg. "In that trial, patients were at high risk of disease recurrence but had no demonstrable disease present at the time of starting therapy with PI-88" he said. "We remain committed to the ongoing development of PI-88, especially given the exciting Phase 2 data seen in the primary liver cancer trial."

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.

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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.

Clinical Appendix

The following additional information is provided in accordance with the Code of Best Practice for ASX Reporting by Life Science Companies.

Trial Title: A Phase II Study of Docetaxel with PI-88 in Patients with Advanced Non-Small-Cell Lung Cancer

The Goal of the Trial:

The primary objective of the trial was to determine the safety and efficacy of PI-88 combined with weekly docetaxel administration as second-line therapy in patients with advanced non-small-cell lung cancer (NSCLC).

Investigators and Clinical Sites:

Principle Investigator:

Dr Nick Pavlakis - Royal North Shore Hospital,

Co-ordinating Investigators:

Dr Michael Boyer - Royal Prince Alfred Hospital,
Dr Craig Lewis - Prince of Wales Hospital,
Dr Fiona Abell - Newcastle Mater Misericordiae Hospital,
Dr Gavin Marx - Sydney Haematology and Oncology Clinics,
Dr Paul Mainwaring - Brisbane Mater Hospital,
Dr Marree Colosimo - Prince Charles Hospital,
Dr Keith Horwood - Princess Alexandra Hospital,
Dr Geoffrey Hawson - Nambour General Hospital,
Dr Ken Pittman - The Queen Elizabeth Hospital,
Dr Jeremy Shapiro - The Alfred Hospital,
Dr Craig Underhill - Border Medical Oncology, and
Dr Michael Millward - Sir Charles Gairdner Hospital.

Trial Efficacy Endpoints:

Efficacy was assessed via spiral CT scan of the chest after cycles 2, 3, 4 and 6 during treatment with docetaxel alone or in combination with PI-88, and after every second cycle during treatment with PI-88 alone. Objective responses, disease stabilization and disease progression were defined according to the US National Cancer Institute RECIST criteria (Response Evaluation Criteria in Solid Tumors). Where possible, all scans were assessed by an independent External Response Review Panel (ERRP), in accordance with established best practice, and the ERRP assessments were regarded as definitive in the calculation of all endpoints.

The primary efficacy endpoint:

- ▶ Non-progression rate at 6 months – the percentage of patients that have remained free from disease progression at 6 months according to the RECIST criteria.

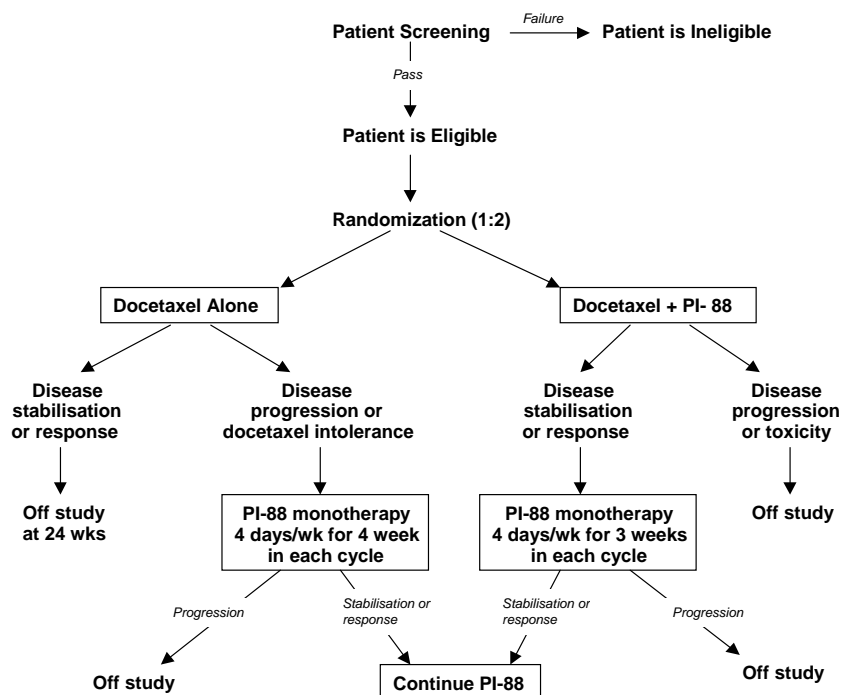
Secondary efficacy endpoints:

- ▶ Time-to-progression - The measure in weeks, from first treatment dose until the disease starts to get worse.

- ▶ Overall survival - The time from first treatment dose until death from any cause.
- ▶ Response rate - the percentage of patients whose cancer stays stable, shrinks or disappears after treatment according to the RECIST criteria.
- ▶ Quality of life – A measure of the effects of cancer and its treatment on the overall enjoyment of life. This is measured through patient surveys that measure aspects of an individual’s sense of well-being and ability to carry out various activities.

Methods:

Patients with relapsed IIIb/Stage IV NSCLC that has progressed during or after first-line radiotherapy or platinum-based chemotherapy and were suitable for second line therapy were recruited onto the trial. Eligible patients were randomised in a 1:2 ratio to receive either docetaxel alone (30 mg/m² IV on days 1, 8 and 15 of each 4-week cycle) or docetaxel at the same regimen plus PI-88 250 mg once daily for 4 consecutive days/week for three weeks in each cycle (days 1-4, 8-11 and 15-18). Individual patients in the combination arm for whom a response was observed in the initial treatment period had the option to receive further cycles of PI-88 treatment alone. Patients in the single-agent arm who show disease progression were also subsequently eligible to receive PI-88 treatment alone. Below is a diagrammatic representation of the study design:



The trial began in February 2004 and was conducted at 13 sites around Australia.

Results:

There were 35 evaluable patients in the docetaxel alone arm and 61 evaluable patients in the docetaxel + PI-88 arm.

Primary Endpoint Analysis - Non-progression rate at 6 months

The percentage of patients who remained progression free at the end of 6 months was 16.0% (from 0.0% to 32.8% at the 95% confidence interval) for the combination arm and 28.0% (from 8.7% to 47.2% at the 95% confidence interval) for the docetaxel only arm. The time to progression curves were compared using the Kaplan Meier log-rank method and the p value of 0.3997 showed no statistically significant difference between treatment groups.

Secondary Endpoint Analyses

Overall Survival

In the combination treatment group the probability of survival was 0.61 (from 0.48 to 0.73 at the 95% confidence interval) at 6 months and 0.25 (from 0.13 to 0.36 at the 95% confidence interval) at 12 months. In the docetaxel only arm the probability of survival was 0.65 (from 0.49 to 0.81 at the 95% confidence interval) at 6 months and 0.28 (from 0.12 to 0.44 at the 95% confidence interval) at 12 months. The overall survival curves were compared using the Kaplan Meier log-rank method and the p value of 0.7555 showed no statistically significant difference between treatment groups.

3rd line Monotherapy Arm Survival

Patients who were randomized to receive docetaxel only were compared according to whether they remained on docetaxel only therapy or changed to PI-88 as third line therapy. There were nine patients who changed to PI-88 third-line therapy. An analysis was performed considering only those patients from the docetaxel only arm who survived at least 8 weeks. The median overall survival of patients in the docetaxel arm was 34 weeks compared to 52 weeks in the combination arm. While the Kaplan-Meier survivor curve for this analysis shows a non-significant difference in survival rates between the treatment arms (p=0.4268 log-rank test) a potential trend towards benefit in this patient population warrants further investigation.

Other Secondary Endpoints

There were no statistical differences between the arms for response rate and quality of life measures.

Safety Analysis:

62 serious adverse events (SAEs) were reported in 50 patients in the study. Of these, 13 SAEs occurred in the docetaxel alone arm; 2 SAEs occurred in the PI-88 monotherapy (extension) arm; 38 SAEs occurred in the combination arm; and 3 SAEs occurred in screening patients. Considering the randomization of patients 1;2 (docetaxel:docetaxel+PI-88) these data indicate a marginal higher incidence of SAEs in the combination arm. Eight SAEs in 7 pts were considered related (possibly, probably or certainly) to PI-88; five SAEs (in 5 pts) were considered related to PI-88 and/or docetaxel; five SAEs (in 5 pts) were considered related to docetaxel. Adverse events (AEs) were generally mild to moderate in grade, with 5 patients withdrawn from the study due to PI-88-related AEs (mainly thrombocytopenia).

Arm	Event Term	Causality
Docetaxel Monotherapy Arm	Fevers, rigors & worsening dyspnoea	Possibly – docetaxel
Docetaxel Monotherapy Arm	Stomatitis	Probably - docetaxel
Docetaxel + PI-88 Arm	Stomatitis & dehydration	Certainly - docetaxel
Docetaxel + PI-88 Arm	Mucositis	Certainly - docetaxel
Docetaxel + PI-88 Arm	Fevers and rigors	Possibly - docetaxel
Docetaxel + PI-88 Arm	Drug reaction	Probably – PI-88 & docetaxel
Docetaxel + PI-88 Arm	Sudden death	Possibly – PI-88 & docetaxel
Docetaxel + PI-88 Arm	Multiple drug overdose with suicidal intent	Possibly – PI-88 & docetaxel
Docetaxel + PI-88 Arm	Diverticular disease with ruptured diverticulum	Possibly – PI-88 & docetaxel
Docetaxel + PI-88 Arm	Rash – right arm	Probably – PI-88 and/or docetaxel
Docetaxel + PI-88 Arm	Right pulmonary embolus	Possibly – PI-88
Docetaxel + PI-88 Arm	Right chest lump	Possibly – PI-88
Docetaxel + PI-88 Arm	Suspected right arm thrombosis	Possibly – PI-88
Docetaxel + PI-88 Arm	Injection site reaction	Probably – PI-88
Docetaxel + PI-88 Arm	Cardiac ischaemia / infarction	Certainly – PI-88
Docetaxel + PI-88 Arm	Left arm thrombosis	Certainly – PI-88
PI-88 Monotherapy Arm	ST elevated myocardial infarction	Possibly – PI-88
PI-88 Monotherapy Arm	Thrombocytopenia	Probably – PI-88

Implications of the Results:

A review of the literature suggests that the median time to progression in this patient group is approximately 3 months following treatment with either weekly or 3-weekly docetaxel. It is therefore anticipated that approximately 50% of patients will have progressive disease at the end of 3 months and 80% by 6 months. The non-progression rates shown in this trial (16% and 28%) are in line with historical data.

The data from this trial would suggest that no further investigation of PI-88 in combination with docetaxel in patients with non small cell lung cancer that have failed platinum based first line therapies is warranted.

While there is a trend towards an improvement in survival for those patients that received PI-88 following toxicity or progression on the docetaxel alone arm, it is difficult to draw a conclusion given the overall efficacy data between the two primary populations. The potential benefit identified in this third line population, may warrant further investigation of PI-88's activity in non small cell lung cancer patients that are refractory to docetaxel treatment.

Recent clinical data especially from the PI-88 trial in the post-resection primary liver cancer setting suggests the product demonstrates anti-angiogenic and anti-metastatic effects at earlier disease stages. Consistent with the positioning of other anti-angiogenic therapies in lung cancer, we do not rule out the possible use of PI-88 amongst patients undergoing first line treatments, when anti-metastatic and anti-angiogenic effects are more likely to impact disease progression. This is consistent with PI-88 current clinical development program in, primary liver cancer, prostate cancer and melanoma.