

### **PI-88 Melanoma Phase II trial Commenced**

**Brisbane, Australia Wednesday, January 21, 2003.** Progen Industries Limited (ASX: PGL, NASDAQ: PGLAF), a progressive Australian oncology drug discovery and development company, announced the commencement of a new Phase II clinical study of its lead anti-cancer compound, PI-88 with two patients starting treatment this week.

Following the successful completion of a PI-88 Phase I dose ranging trial in advanced cancers, the company has begun a multi-center Phase II melanoma clinical trial that will be conducted in the following U.S. and Australian clinical centers: University of Colorado Health Sciences Center (Denver, USA); Sir Charles Gairdner Hospital (Perth, Australia); Princess Alexandra Hospital (Brisbane, Australia); The Alfred Hospital (Melbourne, Australia) and The Queen Elizabeth Hospital (Adelaide, Australia).

Rob Don, Progen's VP of R&D commented "PI-88 has been well tolerated by patients in the Phase I trial. We have also seen positive signs that PI-88 has retarded tumor growth in over 40% of the melanoma patients for periods lasting up to 30 months. These are particularly encouraging data, as all patients in this trial have advanced cancers, have previously failed to respond to standard surgical, radiation and chemotherapeutic regimens, and they have limited treatment options left available to them."

The completed Phase I study was designed to evaluate the safety, pharmacokinetics and biologic effects of PI-88 self-administered subcutaneously on four consecutive days per week by patients with various advanced cancers. Experimental dosing ranged from 80 mg to 315 mg with 250 mg selected as the optimal dose according to the study protocol. Forty-two patients were enrolled (median age 55) [range 19-77]. One of the aims of the study was to determine the DLT (Dose-limiting toxicity) and this was observed at the 315 mg dose level. Three patients had DLT and other toxicities were minor and self-limiting. One patient had a partial response, and another 12/40 evaluable patients, have maintained stable disease for three months or longer. These results included 8/19 melanoma patients.

This Phase II clinical trial in advanced melanoma patients is the first of three new PI-88 Phase II trials that will be initiated in the near future. The other Phase II trials scheduled are; respectively, the evaluation of PI-88 in combination with Taxotere® (docetaxel) for the second-line treatment of advanced non-small cell lung cancer (NSCLC) and, PI-88 as an adjuvant single agent therapy in post-operative liver cancer patients. The latter trial will be conducted by Medigen Biotechnology Corporation (Taiwan).

Progen's Managing Director, Lewis Lee, said today "This launch marks an important milestone in our clinical trial program. PI-88 has been extensively evaluated for safety, tolerability and signs of efficacy in our Phase I trials, and the cumulative data collected to date provides a good level of confidence required to launch the next series of Phase II trials. Our clinical program has been validated by the participation of several of Australia's premier research hospitals, and the reputable University of Colorado Health Sciences Center in the United States. Ultimately, our goal is to add a new therapy for oncologists to aid the treatment of cancer."

## About Melanoma

Melanoma is the most deadly form of skin cancer. The incidence of this disease is increasing by approximately 4% annually in the US. In 2002, almost 54,000 cases of malignant melanoma were diagnosed in the US. Every year about 1000 people die from melanoma in Australia, which has the highest rate of skin cancer in the world. Melanoma is the number one cause of cancer death in women aged 25 to 30. For more information on melanoma please visit:

[http://www.nci.nih.gov/cancer\\_information/cancer\\_type/melanoma](http://www.nci.nih.gov/cancer_information/cancer_type/melanoma)

## About PI-88

Our lead product candidate, PI-88, is one of a new class of multi-targeted cancer therapeutics inhibiting both angiogenesis or tumor promoting factors such as Vascular Endothelial Growth Factor, Fibroblast Growth Factors 1 and 2, and heparanase, an enzyme implicated in metastasis (tumor spread). PI-88 is currently being studied in phase II clinical trials in the U.S. and Australia under an active Investigational New Drug application, or IND, with the United States Food and Drug Administration, or FDA.

## About Progen:

Progen Industries Limited is an Australian based globally focused biotechnology company committed to the discovery, development and commercialisation of small molecule pharmaceuticals for the treatment of various diseases.

Progen's three key areas of expertise are:

- **Clinical Development** *via* a comprehensive clinical trials programme involving its two lead compounds – PI-88 and PI-166.
- **Drug discovery** projects focusing on the development of potent, selective inhibitors of carbohydrate-protein interactions, which are implicated in many disease processes.
- **Commercial Services** manufacturing of biopharmaceutical products to global standards.

**Keywords** - Progen, cancer, PI-88, Phase I, phase II, clinical trials

## Web links to recent news and other information about Progen:

Focus on cancer: Divestment of Lifesciences  
AGM 2003 Managing Directors Presentation  
New Placement Terms Announced  
Progen Secures Share Placement  
Good Financial Results Bolster Strategy  
Achieves Efficacy Endpoint Phase II Trial  
Additional Results Support Trial Program  
PI-88 mode of action  
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<http://clinicaltrials.gov/ct/show/NCT00068172?order=1>  
<http://www.centerwatch.com/patient/studies/stu49833.html>

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.