

FDA PROVIDES MANUFACTURING CLEARANCE FOR PHASE III TRIAL OF ANTI-CANCER DRUG

Key points:

- Receives green light from the Food and Drug Administration (FDA) to manufacture PI-88 for upcoming Phase III trial
- Manufacturing in-house saves Progen approximately AUD\$7.8 m in outsourcing fees
- Successful FDA meeting forms basis for New Drug Application (NDA) Chemistry Manufacturing and Control (CMC) section submission

Brisbane, Australia 29 November 2006. Progen Industries (ASX: PGL; NASDAQ: PGLA) today announced it has received notification from the U.S. FDA that the appropriate CMC procedures have been put in place to progress its anti-cancer drug PI-88 to Phase III clinical trials.

This notification follows Progen's End-of-Phase II CMC meeting with the FDA, held on 24 October, and gives Progen the "green-light" to manufacture PI-88 for its upcoming Phase III clinical trial. Manufacturing the first step of PI-88 in-house saves Progen approximately AUD\$7.8 million in outsourcing fees to a contract manufacturing organisation.

Progen's facility in Darra will manufacture the first step in the process, while a large U.S.-based contract manufacturing company has been contracted to produce the final active ingredient (API), PI-88. Up to 150,000 doses of PI-88 will be manufactured in advance of the Phase III trial starting in mid-2007.

The End-of-Phase II CMC meeting plays a critical part in the rapid development of drugs with the FDA. At the meeting, the details on the specifications, stability and release procedures for the active ingredient and the final product were reviewed and discussed. No issues were identified that would delay the manufacture of the Phase III product. Holding this meeting now avoids manufacturing related delays for the Phase III trial and forms the basis for proceeding efficiently to submitting PI-88's CMC section of the NDA with the FDA.

The first step of manufacturing PI-88 will continue to be carried out at the Progen TGA cGMP (Therapeutic Goods of Australia, current Good Manufacturing Practice) certified facility. Following the positive meeting with the FDA, Progen now has PI-88's manufacturing and quality control schedule defined, and will fill excess capacity by renewing contract manufacturing services for the pharmaceutical and biotechnology industries.

Justus Homburg, Progen's Chief Executive Officer, commented: "The manufacturing division at Progen has worked very hard to ensure that our Company meets world class standards. The successful outcome of this meeting is a direct result of their skills and dedication. We intend to use these skills to win further contract manufacturing revenue for the division with the excess capacity now created."

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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 cancer and other serious diseases.

Progen's three key areas of focus are:

- **Clinical Development** - *via* a focused clinical trial program involving its two 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 biopharmaceutical products to global standards.

Keywords - Progen, cancer, PI-88, CMC, manufacturing, Justus Homburg

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

End of Year Financial Results	www.progen.com.au/?page=nepress2006.html
Preparing for Accelerated Development	www.progen.com.au/?page=nepress2006.html
Progen meets with FDA	www.progen.com.au/?page=nepress2006.html
New CEO	www.progen.com.au/?page=nepress2006.html
PI-88 mode of action	www.progen.com.au/?page=rep1-88.html
Progen's drug development pipeline	www.progen.com.au/?page=pihome.html
Progen Industries Ltd	www.progen.com.au

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