

Progen Licensee Gains Approval for Phase III Clinical Trial

Brisbane, Australia, 19th April 2011. Progen Pharmaceuticals Ltd (ASX:PGL; OTC:PGLA) are pleased to announce that its licensee, Medigen Biotechnology Corporation, has had their application for a PI-88 Phase III clinical trial in hepatocellular carcinoma (HCC) approved by the Taiwan Food and Drug Administration (TFDA).

This study is designed to confirm the efficacy and safety of PI-88 in the adjuvant treatment of HCC after surgical resection. The Phase II study results for the same indication were published in 2009 in the Journal of Hepatology, a world-renowned peer-reviewed journal. The clinical merit of PI-88 was demonstrated as a satisfactory safety and tolerability profile was concluded from the Phase II study. The aim of the current Phase III trial is to assess a larger patient population to solidify the evidence for New Drug Application (NDA) in the future.

The Phase III, randomised, placebo-controlled, multinational trial will enrol approximately 500 subjects globally (with the majority of patients enrolled from Asia). Disease-free survival will be employed as the primary endpoint for efficacy assessment. Other endpoints such as time to recurrence, tumour recurrence rate and overall survival will be measured as secondary endpoints. The study is expected to conduct in Taiwan, South Korea, China, Hong Kong and some countries in Europe with high HCC prevalence. Trial sites approved by the TFDA to recruit patients include National Taiwan University Hospital, Chang-Gung Memorial Hospital-Linkou, Taipei Veterans General Hospital, China Medical University Hospital, Taichung Veterans University Hospital, Changhua Christian Hospital and National Cheng-Kung University Hospital. Two more hospitals in southern Taiwan are expected to participate in the study at a later date. The expected First-Patient-In timeline is targeted for Q2 2011.

"We are delighted that Medigen has made such strong progress with the PI-88 Phase III regulatory process and we look forward to the continued development and commercialisation of PI-88. This approval will trigger the first milestone payment to Progen." said Sue MacLeman, Chief Executive Officer, Progen Pharmaceuticals Ltd.

PI-88 is one of the Centre for Drug Evaluation's Critical Path Index Projects designated by the TFDA to expedite the NDA process. PI-88 has the potential to be approved for HCC treatments in an adjuvant setting should favourable clinical efficacy and safety results be concluded from this Phase III study.

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. www.progen-pharma.com

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