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Progen Industries Limited
16 Benson Street
Toowong, Queensland 4066

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Progen Industries Limited announced earlier today preliminary data for the Phase 2 trial evaluating PI-88 for the treatment of patients with liver cancer following surgical removal of the tumour. What are the main findings of the preliminary data?

CEO Justus Homburg

In this trial, we are assessing PI-88's ability to treat liver cancer in patients who have had tumours surgically removed with the intention of PI-88 delaying the recurrence of the disease, and giving the patient a longer, disease-free life.

There are really two main findings of the preliminary data analysis.

First, we saw a 76 percent improvement in the time to tumour recurrence or disease-free survival for patients in the 160mg PI-88 dose group compared with patients in the untreated group.

This means that about 80 percent of the untreated patients were disease free at 17 weeks. This time was extended by 13 weeks (76 percent) to 30 weeks in the patients treated with 160mg of PI-88. This encouraging trend in the time to recurrence is particularly important because it is these data that we will use to guide the design of our Phase 3 trial endpoint.

Second, from this 30-week data, the chance of remaining disease-free increased from 65 percent in the untreated dose group to 79 percent in the 160mg dose group.

While this analysis was not part of the per-protocol statistical analysis plan, these data are in fact statistically significant at a probability value of 0.05 based on a one-tailed

test. Typically, a phase 3 trial has a much larger patient population and is designed to produce data statically significant at a probability level of 0.05 or lower based on a two-tailed test.

We see this result as very promising for the product. This is the first PI-88 data that we have had in a large randomised trial; where patients have been treated with our product, along with patients having received no treatment allowing us to directly compare the benefit of PI-88. This is very encouraging news for liver cancer patients and potentially for patients of many other cancers and is a significant milestone in PI-88's development.

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How does an absolute improvement of in disease-free rate of 14 percent and a 76 percent improvement in the time to recurrence compare with other approved cancer drugs?

CEO Justus Homburg

We believe it compares very favourably. First let me point out that the median time to recurrence (50th percentile) is normally used when assessing trial data of this nature. As I said before the preliminary data we have is at the 80th percentile point. Having said this though, Genentech's Herceptin was approved by the FDA on the 16th of November this year, not based on median time to recurrence but instead based on absolute improvement in disease-free rate at 3.5 years. Herceptin showed an absolute improvement of 12 percent for breast cancer patients following resection of the tumorous tissue (75.4 percent versus Herceptin treated 87.1 percent). Herceptin also prolonged the time to recurrence by approximately 33 percent in this patient population.

Of course, the data we have released on PI-88 has been collected from a much smaller sample size than has been used in registration trials for approved drugs. Nonetheless, the data generated for PI-88 in liver cancer compare very favourably with other registered compounds. This gives us the confidence we need to initiate a much larger Phase 3 registration trial.

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What approved products are currently available for liver cancer patients and how might PI-88 affect their treatment and care?

CEO Justus Homburg

It's a very severe disease with few treatment alternatives. There aren't any approved standard-of-care treatments for liver cancer patients who've had their tumours surgically removed. Typically, patients are followed up periodically after their surgery but do not receive any further treatment until their disease recurs.

Clinicians typically try a variety of chemotherapies, radiation, ablation or liver transplant, but the one year and three year survival rates for patients with disease recurrence is typically only 65 percent and 35 percent respectively, and patients quality of life deteriorates rapidly.

With approximately 625,000 new liver cancer cases worldwide in 2002 and over 600,000 deaths due to the disease the same year, this cancer has a very high mortality rate. The goal with PI-88 is to provide the opportunity for liver cancer patients who've had their tumour surgically removed to stay disease free much longer; enjoy a higher quality of life and live longer. Every day a patient remains disease free has an enormous impact on that patient's mental and physical well-being.

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What are the implications of the higher drop out rate experienced for the 250mg dose compared with the 160mg dose arm of the trial?

CEO Justus Homburg

This type of dose-related dropout is typical in pharmaceutical development. In each cancer indication we have trialed PI-88, we have different doses and schedules depending on the tolerability of patients with the particular disease. Just like any other product, we have known for some time that at higher dose rates PI-88 can be difficult for some patients to tolerate. This trial was designed with two different doses to ensure that we could find a dose that was best tolerated in this predominantly Asian indication. This trial has identified that the 160mg was a better tolerated dose and as such it gives us a strong rationale for this dose selection for our Phase 3 trial. Earlier this year, we shared our safety data with the FDA and they did not raise any concerns regarding the safety profile of PI-88.

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When do you expect to announce the final results of the trial?

CEO Justus Homburg

The entire process involves data checking, verification and processing. We have announced the preliminary data today as the last patient has now completed the trial. The data we announced today is for all patients at the 30-week time-point of the 48-week study. Once the full database is verified and processed, it will be locked and the analysis of the entire 48 weeks is conducted. Finally, the completed study report will be written and submitted to the regulatory agencies. We expect this process to be completed in the first calendar quarter 2007 with final 48-week data available early in the second quarter.

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What is the likelihood that final results differ significantly from today's preliminary results?

CEO Justus Homburg

The 30-week data we have analysed now is the first formal measurement of the performance of PI-88 in this patient population. These 30-week data will remain unchanged in the final analysis.

The final analysis will also include additional data for the final 18 weeks of the trial (i.e. up to 48 weeks). Importantly, it will also give us an indication of what happens to patients in the treated group, when they are taken off PI-88 at week 36.

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You are planning to conduct the Phase 3 post-resection liver cancer trial using a Special Protocol Assessment (SPA) with the US Food and Drug Administration (FDA). How are you progressing with the SPA and when do you expect it to be completed? What is the benefit to Progen of the SPA process?

CEO Justus Homburg

We've started the SPA process and expect to complete it in the second quarter of 2007, prior to the commencement of the Phase 3 trial.

The benefit is that it locks down all of the relevant components of the Phase 3 liver cancer trial and specifically defines the results needed to gain marketing approval from the FDA. It gives us and our contract research organisation a very clear understanding of how to execute this trial in all the relevant details.

With an SPA in place, we've reduced to a minimum the uncertainty associated with regulatory approval. Provided we adhere to the protocol and obtain the desired end-point agreed with the FDA, subsequent regulatory approval is then a very high probability.

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What are the implications of the preliminary Phase 2 data for the SPA process?

CEO Justus Homburg

The most important implication is the benefit to liver cancer patients. We're now in a position to design endpoints for the Phase 3 study based on these 30-week data and that gives the drug a better probability of successful registration.

A very important point is that the data from the Phase 2 trial is crucial in encouraging the participation of investigators and clinics in the Phase 3 study. Enrolment of patients is a key determinant to the timelines of our Phase 3 trial, and the more information we have that can be provided to physicians and clinics, the better off we will be.

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As at 30 June 2006 cash on the balance sheet was A\$15.87 million. Given the increase in costs associated with advancing to Phase 3 trials with PI-88, what are the options for funding the ongoing development program?

CEO Justus Homburg

A Phase 3 trial isn't cheap and we'll be announcing our plans to raise the necessary capital soon. We've been planning this study for over the past six months and discussing it with half a dozen international contract research organisations. On top of this we need to fund the ongoing development of the second generation PI-88 which is likely to be in human trials in 2008.

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Are you still planning to license the product or will you take it to market yourselves?

CEO Justus Homburg

In the past, Progen has considered partnering an important path to PI-88 commercialisation. We are on the cusp of moving towards a level of commercial success that changes the relevance and nature of our partnering opportunities.

We will pursue all paths to commercialisation including licensing opportunities, partnering or independent marketing, and any combination thereof. We are very aware of the potential commercial upside of PI-88 and now it's all about making sure the product gets into the marketplace as quickly as possible. We'll aggressively pursue all relevant opportunities while maximising the value that's inherent in PI-88 for all of our stakeholders.

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How have you shaped the Company's strategy since being appointed as CEO in March this year? What will be your priorities for 2007?

CEO Justus Homburg

I've joined a remarkable team of professionals and all of us are totally committed to bringing about effective solutions for cancer patients by following a critical path in everything we do. Over the past seven or eight months we've begun the planning and preparation for a multinational Phase 3 trial and started producing sufficient quantities of PI-88 for all of our ongoing and planned trials. We've also consolidated the goals in our discovery and pre-clinical compounds. It's been a remarkable period for the entire team.

We'll be driving as hard as we possibly can to get this Phase 3 trial underway, and we'll accelerate the development of our other compounds in the discovery and pre-clinical phases of development. We anticipate being in a position to increase the value of Progen via a range of opportunities including possible in-licensing opportunities or merger and acquisition opportunities that leverage all of our core capabilities and transform ourselves into a globally competitive sustainable biotechnology company.

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Thank-you Justus

For further information on Progen Industries Limited, visit www.progen.com.au or call Sarah Meibusch on +61 7 3842 3333.

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