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MD on PAT-SM6 Clinical Trial Progress



Open Briefing interview with MD and CEO Dr. Marie Roskrow

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Patrys Limited (ASX: PAB) is an Australian biotechnology company focused on the development of natural human antibodies as therapies for cancer and other major diseases. Patrys has a deep pipeline of anti-cancer natural human antibodies that enable both internal development and partnering opportunities.

In this Open Briefing[®], Dr. Marie Roskrow discusses:

- Clinical advancement of the Company's lead anti-cancer compound PAT-SM6
- Strong safety profile of PAT-SM6 and encouraging efficacy signals
- Operational update and investor activity

Record of interview:

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Patrys Limited (ASX: PAB) is currently undertaking a Phase I/IIa clinical trial of PAT-SM6 as a novel therapy for the rare blood cancer multiple myeloma. What is the current status of this trial?

MD and CEO Dr. Marie Roskrow

The trial is for patients with relapsed and multi-drug resistant multiple myeloma. These patients have failed all currently marketed drugs and so they have a very poor prognosis. The trial has been ongoing for almost a year, with nine patients treated so far and we're now recruiting the final cohort of three patients (total of 12 patients). Among those already treated, there is convincing evidence that PAT-SM6 is active in patients with end-stage disease who are resistant to other marketed therapies. In addition, two multi-resistant patients have experienced stable disease post treatment with PAT-SM6. These are highly promising results in patients that are very sick and have run out of therapeutic options. There is also significant demand for new multiple myeloma drugs. Existing therapy relies on the use of multiple drugs, with patients prone to developing resistance to these and suffering a relapse of disease. The five-year survival rate for multiple myeloma is less than 30%.

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Side-effects of treatment are a significant area of focus for physicians and for patients, and dose-limiting toxicities can undermine the therapeutic usefulness of anti-cancer drugs in particular. What can you say about the side-effect profile of PAT-SM6?

MD and CEO Dr. Marie Roskrow

PAT-SM6 represents a new approach to anti-cancer medicine that, to date, is remarkable for the absence of side-effects. The drug is based on a naturally occurring human antibody and, in fact, no serious adverse side-effects have been reported among trial participants. Compare this to common side-effects of conventional multiple myeloma therapy including blood clots, which pose a risk of heart attack or stroke, or an underperforming immune system which places a patient's life at risk from common infections. We foresee that because PAT-SM6 will not have that type of toxicity profile you will be able to combine the

product with anything else that is on the market without adding to the side-effect profile - that is a very powerful thing for patients that are already extremely sick.

The low toxicity profile is attributed to the highly selective nature of PAT-SM6 which does not bind to normal cells in the body and is only going to bind to, and kill, cancer cells. PAT-SM6 is an antibody that is generated naturally by the human immune system and which is thought to protect most healthy people against developing cancer. Patrys has a proprietary process that is able to systematically capture and identify antibodies with high anti-cancer potential, and then produce them in commercial quantities.

Use of these anti-cancer antibodies as a therapeutic represents a new and highly targeted approach to cancer therapy. In general terms, conventional cancer therapies all have toxic profiles of varying degrees. They may be effective at killing off cancer cells however they also attack normal cells, causing damage that can hamper vital functions of the body such as the immune system.

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Patrys recently received orphan drug designation for PAT-SM6, granted by the European Medicines Agency (EMA), what is the significance of this for the drug development process?

MD and CEO Dr. Marie Roskrow

European regulators have recognised the potential of PAT-SM6 in multiple myeloma, granting it orphan drug status. This provides a more rapid progress through regulatory approvals processes as well as a range of support mechanisms such as; access to funding schemes and other financial incentives, ten years of market exclusivity for multiple myeloma and scientific advice and protocol assistance by the EMA to optimise drug development.

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Patrys is developing a suite of cancer therapy agents, which are progressing through various stages of testing and development. Does PAT-SM6 remain your key focus and what is the status of the rest of Patrys' drug candidates?

MD and CEO Dr. Marie Roskrow

Preclinical trials indicate PAT-SM6 also has wide applicability to multiple cancer types. An earlier Phase I trial of PAT-SM6 in melanoma patients showed the drug's activity was highly localised to the tumour site and – again – there were no signs of serious side-effects. The Company's most mature product is PAT-SC1, which has been shown to provide treated gastric cancer patients with a 10 year survival benefit and which is now being prepared for out-licensing. Patrys is also developing PAT-LM1 which has also shown wide applicability to an array of cancer types.

We are focusing most of our resources on PAT-SM6.

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You reported just over \$5m cash at June 30, is this sufficient to complete the PAT-SM6 trial and will Patrys need to raise capital in the near future?

MD and CEO Dr. Marie Roskrow

We do have sufficient capital to complete our current Phase I/IIa clinical trial for PAT-SM6 and we are constantly evaluating our capital requirements with a view to advancing our most promising products as quickly as possible. We currently have a number of attractive opportunities for PAT-SM6 and, as the trial advances through the final stages, we will be considering all of our options which will determine cash requirements. We hope to be in a position to update shareholders in the coming months.

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There has been significant price volatility for microcap companies on the ASX over the past year and it appears Patrys has also experienced this. Why do you think this is the case and how does this impact Patrys?

MD and CEO Dr. Marie Roskrow

We have seen significant swings in our price which has been very frustrating, particularly considering that our progress this year has been excellent and the PAT-SM6 trial results are looking really promising. I think there are a number of contributing factors and we agree with your observations that microcap companies are generally experiencing volatility.

Our efforts and resources are focussed on this important multiple myeloma trial for PAT-SM6 which means less activity on our other programmes along with a reduction in road shows and promotion this year. Patrys has provided regular positive updates on the trial at the completion of each cohort (each containing three patients). We recognise that some shareholders would like to see higher news flow but we also believe that the significance of these promising results from the trial have not been recognised by the market. Our focus on the task at hand however ensures that we are giving Patrys and its shareholders the best opportunity for a more stable and positive share price in the future.

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What is coming up for Patrys that shareholders should be aware of?

MD and CEO Dr. Marie Roskrow

Last week we presented at the Bio Investor Forum in San Francisco. This Forum is an international biotech investor conference focused on early and established private companies as well as emerging public companies. As well as presenting we also had good demand for one-on-one meetings. Patrys is also participating in the Australia Invest Conference in Melbourne on 28-29 October which is expected to attract in excess of 300 investors from Australia and overseas. We expect to be in a position to announce the completion of the multiple myeloma trial this quarter and publish final results in the first quarter of 2014. Finally, we have been invited to present data generated to date from this trial at the 55th ASH Annual Meeting and Exposition, to be held in December, which is one of the major cancer conferences in the world.

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Thank you Marie.

For more information about Patrys, visit www.patrys.com or call Dr Marie Roskrow on (+61 3) 9670 3273

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