Company Update

Open Briefing interview with MD and CEO Dr. Marie Roskrow

Patrys Limited
Suite 614, Level 6 Equitable House
343 Little Collins Street
Melbourne VIC 3000

Patrys is an ASX listed company focused on the development of a completely new type of product for the treatment of cancer – natural human antibodies. These natural human antibodies potentially offer the promise of increased potency coupled with greater safety as compared to existing cancer treatments.

Patrys has several clinical and preclinical development programs.

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

- The planned Phase Ib/IIa clinical trial of PAT-SM6, for the treatment of multiple myeloma, a common form of blood cancer;
- Progress on out licensing PAT-SC1 for the treatment of gastric cancer; and
- Updates on the development of PAT-LM1 and the company's preclinical programs.

Record of interview:

PAT-SM6

openbriefing.com
Patrys recently released details of the upcoming planned clinical trial for PAT-SM6 for the treatment of the blood cancer, multiple myeloma. Can you tell us what is the current status of that trial?

MD and CEO Dr. Marie Roskrow
The upcoming planned trial is a Phase Ib/IIa trial of our antibody PAT-SM6, to be used in combination with existing treatments - carfilzomib and dexamethasone - in patients with multiple myeloma (MM) who are refractory and/or intolerant to bortezomib, a currently-marketed proteasome inhibitor. We are on track to start this trial, as planned, by the end of 2014.

As we referred to in our ASX release of 25 August 2014, the GMP manufacturing of the PAT-SM6 product which is used in the trial is tracking well. This is important, as we need to be able to produce enough product for use in the trial. Scaling up manufacturing to quantities needed for a trial - and eventually commercial quantities - is a crucial and often complex element of the process.

You may also recall that Onyx Pharmaceuticals (a subsidiary of Amgen), which owns carfilzomib is committed to providing quantities of the drug needed in the study. As a partner, we need to engage with them throughout the process and in this regard discussions are ongoing. The trial synopsis has now been approved by Onyx, and with that we are able to submit the full trial protocol to the Paul Ehrlich Institut (PEI) – the German federal institute for vaccines and biomedicines. This is the regulatory body that will give the final approval to commence the trial in Germany.

While this regulatory review process is still underway, we have started working with the clinical sites in Germany to prepare them for the commencement of the trial. The successful execution of a clinical trial is highly reliant on the quality of interactions and cooperation amongst a large group of people; and this trial is no different – there are many different departments and professionals involved in the preparations.

openbriefing.com
You announced back in November 2013 that you would be commencing this trial at the end of 2014, why does the planning for a clinical trial take so long?

MD and CEO Dr. Marie Roskrow
There's an enormous amount of planning and preparation to be undertaken on a number of elements before a clinical trial commences so this has taken much of our focus. This work includes designing the full trial protocol and having it approved –by an external party (Onyx) as well as the regulatory body, hiring external parties such as the Contract Research Organisation (CRO), getting the clinical trial sites ready and manufacturing the product to be used in the trial. Although we have undertaken clinical trials involving PAT-SM6 previously, this is the first in which PAT-SM6 will be used in combination with other drugs. This adds multiple layers of complexity both at the design stage and with the logistics. There are many additional considerations, such as safety, dosing schedules and routes of administration when using drugs in combination, each of which requires meticulous care.

In addition we (Patrys), along with the clinicians at the University of Würzburg, are doing much of the work ourselves and thus have limited resources compared to some other organisations. In our planning, we were also realistic about the fact that dealing with an external partner – especially a large pharmaceutical company – can protract the process. All of the parties involved are interacting and working well together and we are pleased with the progress made to date.

We appreciate that along the way there is not a lot to report back to shareholders with regard to trial planning progress, but this is certainly not a reflection of the level of activity underway to advance to commencement of the trial.

openbriefing.com
The trial is projected to take 15 – 18 months – why will it take this long?

MD and CEO Dr. Marie Roskrow
We are aiming to progressively recruit up to 24 patients across two centres. We have based this time frame on our experience with our previous trial of PAT-SM6 where it took 12 months to recruit 12 patients at one single site. Therefore, we believe this is a realistic estimate of the maximum time required for recruitment but as already noted recruitment and the trial will be ongoing during this period.

We also have strict eligibility criteria - not every patient with advanced MM can be included. For a patient to be eligible for this trial they need to be resistant or intolerant to bortezomib (velcade). Carfilzomib can be toxic in some patients as well, finding patients who are able to tolerate carfilzomib is an additional requirement. This means that the patients will need to be in a reasonable condition health wise. Hence finding patients is not as straightforward as one may expect. In order to increase the rate of recruitment into our study we will be recruiting from two clinical centres in Germany. Both Würzburg and Dresden are "centres of excellence" and see many MM patients.

Clinical trials are both a science and an art. It is really important to select the "right" patients. This is not always straightforward but it is critical in order to increase the probability of the trial having a valid and reliable positive outcome.

openbriefing.com
As investors, what news can we expect as this planned trial progresses?

MD and CEO Dr. Marie Roskrow
As detailed in our announcement on 25 August 2014, this will be a two-stage trial. In the first stage, a total of nine patients will be recruited and treated. As each patient proceeds through the trial, their individual data is collected and analysed. To proceed to stage two of the trial, we need to see that more than two of these nine patients have responded clinically with at least a partial response. If this is not the case, the trial will be terminated at that point.

Once we have received and analysed the data from the first nine patients in stage one, we will release that information to our investors. At this point we will know – and be able to inform investors – if the trial will progress to stage two. It is difficult to predict the duration of stage one so, currently, we are not able to provide a reliable estimate of when this data will be reported.

Assuming that the trial enters stage two, recruitment of the additional fifteen patients will commence.

If the trial proceeds to stage two, then we will be releasing data at appropriate intervals giving updates on safety and observed clinical responses.

openbriefing.com
If the trial is successful (i.e. hits the primary and secondary endpoints) what is the future plan for PAT-SM6?

MD and CEO Dr. Marie Roskrow
As we have always stated, our plan would be to out-license PAT-SM6 to a major biotech / pharmaceutical company. Developing any cancer drug is expensive and we would need a partner with deep pockets and a good understanding of the MM market and monoclonal antibodies. In the first instance we would be looking for a "plain vanilla" licensing deal with an upfront payment, milestones and eventual royalties on sales, however, we would be open to other deal structures as well.

At this stage, we do not intend to engage in detailed discussions with prospective partners until the trial has progressed into stage two. If the clinical data is good, we would commence detailed discussions prior to finalising the trial. There are many major biotech / pharmaceutical companies with an interest in MM. Although it is a niche indication, it's a multi-billion dollar market and expected to expand significantly over the next ten years. Companies are always looking for novel therapies particularly those that can be combined with existing treatments on the market in a safe and effective way. If the planned clinical trial is successful then it is highly likely that there will be significant interest in PAT-SM6.

openbriefing.com
With PAT-SM6 in clinical development, how important is it to continue to do preclinical work as well?

MD and CEO Dr. Marie Roskrow
Preclinical work helps us to both generate new data that supports and informs our clinical programmes, and to find potential new anti-cancer targets or disease indications which could ultimately be incorporated into our development programme and intellectually property portfolio.

To give you some specific examples, we are currently undertaking preclinical studies with PAT-SM6, such as investigating the effect of the compound in an animal model of MM. We are also looking at the effect of PAT-SM6 in various MM cells when given in combination with other drugs currently on the market. When looking for a commercial partner for PAT-SM6 we need to make sure that we have the best preclinical data package possible, therefore making it an attractive candidate to a wide range of major biotech / pharmaceutical companies.

Similarly, the preclinical programme being undertaken in collaboration with CSIRO, to explore the possibility of producing Patrys' IgM antibodies in the CHO system, is very important to our commercialisation plans. Currently we manufacture using the PER.C6® cell system, but the CHO cell system is more commonly used by many large pharmaceutical and biotechnology companies, and the ability to produce our antibodies in this system could enhance our attractiveness to potential partners.

One of our other preclinical programmes focusses on genetically engineering T cells through the introduction of a chimeric antigen receptor (CAR). This is a very "hot" area of research currently, with many major pharmaceutical and biotechnology companies engaged in CAR research and numerous clinical trials using these modified T cells now underway. The reason we are quite interested in this area is that it is acknowledged by experts in the field that engineered T cells need to be directed against novel anti-cancer targets. All of Patrys' IgM antibodies in both clinical and preclinical development are directed against novel anti-cancer targets. Therefore, in this CAR project, parts of these IgM antibodies will be utilised to generate the genetically engineered T cells which, in turn, will attack and kill cancer cells expressing the novel target.

Our preclinical programmes are also important in continuing to gather intellectual property which will bring value to shareholders and generate awareness of the Patrys portfolio amongst potential future licensing partners.

PAT-SC1

openbriefing.com
Is Patrys still searching for a partner for this product and when can we expect a result?

MD and CEO Dr. Marie Roskrow
We are continuing the out-licensing campaign which has focused on Japan, China, South Korea and India, all regions where gastric cancer has a higher incidence, than in Western countries.

This has taken longer than initially anticipated requiring the engagement of consultants across multiple regions to help address the language, cultural and regulatory differences. This all adds considerable complexity. We have also found that many companies we have been in discussion with do not make decisions quickly and generally their internal review processes are very protracted.

There are some other barriers: PER.C6® is not used in these regions, so if partners want to manufacture the antibody themselves they will need to use an alternative production system, such as CHO. As mentioned previously, this is the subject of one of our preclinical programmes. We expect to have further updates on this programme around December 2014, and accordingly would not expect any developments on licensing any time prior to this.

openbriefing.com
What resources is Patrys putting into this programme?

MD and CEO Dr. Marie Roskrow
We are very focussed on the out- licensing campaign. The consultants we have engaged are highly aligned with Patrys' desired outcomes and we have been very conscious to ensure that expenditure on this programme is prudent and targeted towards a successful outcome.

PAT-LM1

openbriefing.com
What is currently happening with the PAT-LM1 programme?

MD and CEO Dr. Marie Roskrow
We have successfully completed the process development for this product and are now moving into the scale-up portion of the development / manufacturing plan. With the large-scale development of PAT-SM6 being performed at the same Gallus facility in the USA, scale-up of LM1 has been slowed down in order to free up the facilities and personnel for the PAT-SM6 programme. That obviously takes priority because of the planned trial.

openbriefing.com
What clinical indications are you looking at for this antibody?

MD and CEO Dr. Marie Roskrow
We continue to focus our research on haematological malignancies, but we are also exploring other indications which have a significant unmet medical need, orphan indications and niche markets, such as brain tumours.

Corporate Questions

openbriefing.com
You raised cash last year at a price of 5 cents per share. Since that time the share price has declined significantly. Why do you think this is?

MD and CEO Dr. Marie Roskrow
Like our shareholders we are very frustrated with the current share price. Throughout the year we have continued to meet our targets but unfortunately there has been limited news flow. It is worth noting that the decline in price has occurred on relatively low volumes and is driven more by speculative traders. Our major shareholders continue to support us and have actually been net buyers of our shares.

As news flow improves the Company is committed to timely, transparent and effective communication with its shareholders and the investment community. Patrys recognises that the continued support of its major shareholders and the investment community is fundamental to its success.

We are also entering a particularly exciting period for the sector, with a number of companies reporting Phase II data in the coming six months, demonstrating that there are opportunities for investors to realise a return on investment at this stage of development.

openbriefing.com
Thank you Marie.

For more information about Patrys, visit www.patrys.com.