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Bionomics Limited (ASX: BNO) today released interim data of the Phase I trial of its anti-cancer agent, BNC105 at the American Society of Clinical Oncology Conference (ASCO). How conclusive are these interim results with respect to the safety and tolerability of the drug?

CEO & MD Deborah Rathjen

The results released at ASCO provide an overview of patient responses to BNC105 at dose levels of BNC105 which we know from animal studies caused vascular disruption activity within tumours. The data reported has provided a good foundation from which to make assessments of the safety and tolerability of BNC105 as the trial has continued.

The findings have been in line with our laboratory studies indicating that BNC105 has a greater than 10-fold therapeutic window – the difference between the effective dose and the dose which causes side-effects – relative to one of the leading benchmarked competitors. It therefore appears that the favourable profile of BNC105 observed in laboratory tests has translated to patients with advanced cancer. It is pleasing that no serious side effects other than fatigue and transient mucositis have been encountered at these dose levels.

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What additional work needs to be conducted before BNC105 can enter Phase II trials?

CEO & MD Deborah Rathjen

The current focus of the Phase I trial of BNC105 is the identification and confirmation of a recommended dose level to be administered to patients in future Phase II trials. This involved the recruitment of additional patients and a detailed analysis of the data being gathered. This work is in progress and once completed, we will be able to provide information on the recommended Phase II dose level and also define the planned Phase II trials of BNC105 in line with our previous projections.

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How relevant is the Phase I design for the structure of the Phase II trials?

CEO & MD Deborah Rathjen

The Phase I study design utilised by us is an accelerated two-stage design. In the first stage, one patient was evaluated at each dose level and these levels were rapidly increased. In the second stage, three patients were enrolled at each dose level. This trial design meant that we were able to rapidly reach relevant dose levels in cancer patients.

Subsequent Phase II trials of BNC105 will have a somewhat different design, which will vary according to the type of tumour being evaluated and whether BNC105 is being evaluated in combination with other cancer treatments or as a standalone treatment.

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You recently announced new data on the effectiveness of BNC105 on throat and lung cancers. You also mentioned in your recent newsletter that the next phase of BNC105 development will focus on one or two particular tumour types. Has the Phase I data provided any insight into the most likely targets? How will the tumour targets be selected?

CEO & MD Deborah Rathjen

BNC105 has demonstrated efficacy against all of the tumour types that have been studied in the laboratory to date, for example in lung, colon as well as head and neck cancer models. This indicates the significant commercial potential of BNC105 if successfully developed.

As our announcement of the Phase I data indicates, stable disease (halting of tumour growth) was seen in patients with mesothelioma and renal cell cancer and these tumour types are strong contenders for further clinical development of our drug.

Our team has undertaken a rigorous process of evaluation of settings for Phase II clinical trials of BNC105. This has included extensive input from cancer doctors in Australia and the US. We have considered the options for further development from both the clinical perspective as well as from a commercial perspective since our aim is to license BNC105 once we have Phase II data.

I have previously pointed to Erbitux[®] to indicate the potential commercial opportunity for BNC105 if successfully developed for the treatment of head and neck cancers and for the treatment of colon cancer which has spread to other parts of the body. Bristol-Myers Squibb sells Erbitux[®] in the US in partnership with Eli Lilly and Co whilst Merck KGaA sells the drug in other parts of the world. The US sales of Erbitux[®] in quarter 4, 2008 reported by Bristol-Myers were US\$182 million. In 2007, Merck KGaA reported sales of €470 million and recently reported a 20 percent rise in Erbitux[®] sales to €565 million in 2008.

By way of further example, renal cell cancer is the eighth leading cause of cancer death in the US and approximately 40 percent of sufferers are diagnosed with an advanced stage of the disease. Sutent[®] and Nexavar[®] are each approved for first line treatment of renal cell cancer.

Sutant[®], which was approved in 2006, is the market leader with market shares of between 40 percent and 60 percent in Europe depending on the country, and 59 percent in the US. Sales of Sutent[®] in 2008 by drug company Pfizer were US\$847 million worldwide. Nexavar[®] achieved US\$677.8 million in sales in 2008 and analysts anticipate sales of US\$850 million in 2009 and US\$1 billion in 2010.

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BNC210, your lead anti-anxiety compound has also recently passed the review by the ethics committee of the clinical trial centre and is approved to enter human clinical trials. What implications does the approval have for the structure of the BNC210 Phase I trials in Australia? What is the expected timeline for the Phase I trial?

CEO & MD Deborah Rathjen

The recent approval of BNC210 to enter Phase I clinical trial included review and approval of the proposed clinical trial protocol. The trial protocol proposed by Bionomics included an evaluation of the safety and tolerability of BNC210 in parallel with determination of blood levels of the drug.

I anticipate that the trial will get underway next quarter and will be completed by the end of this year.

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One of your main development projects is partnered with Merck Serono – the Kv1.3 inhibitor for multiple sclerosis. What is your strategy in relation to the development of BNC105 and BNC210?

CEO & MD Deborah Rathjen

Our commercialisation strategy for BNC105 is to look to license the program with Phase II data in hand. We believe that having positive Phase II clinical trial data will provide significant value uplift for deal-making.

With BNC210, our intention is to seek a partner once our Phase I trial has been completed later this year, as later stage trials will be lengthy and costly. The anxiety and depression markets are large, attractive markets. Translation of the favourable profile of BNC210 to humans – efficacy combined with a lack of

side-effects such as sedation and addiction - is an attractive commercial proposition that fills a significant unmet clinical need for patients with anxiety and depression.

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Thank you Deborah.

For more information about Bionomics Limited, please visit www.bionomics.com.au or call Dr Deborah Rathjen on (08) 8354 6101.

For previous Open Briefings with Bionomics Limited, or to receive future Open Briefings by e-mail, please visit www.corporatefile.com.au.

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Factors Affecting Future Performance

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