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Bionomics Limited (ASX: BNO) today announced it had identified a safe dosage for Phase II clinical trials of BNC105, its novel vascular disrupting agent (VDA) for the treatment of solid tumour types, and that it has contracted Hoosier Oncology Group Inc. ("HOG") to conduct a Phase II trial to evaluate the efficacy of BNC105 in renal cell carcinoma. Bionomics also recently initiated a Phase I clinical trial for BNC210, its potential blockbuster anti-anxiety drug. To what extent have these events reduced the risks in getting BNC105 and BNC210 to commercialisation?

CEO & MD Deborah Rathjen

In less than two years we've been able to progress two newly discovered compounds into human clinical trials. This illustrates not only the capacity of our powerful drug discovery engine to generate high value drug candidates, but also the disciplined approach we employ to effectively execute the transition of drug candidates into the clinic.

With the Phase I clinical trial of BNC210 now commenced, and our latest announcement that BNC105 is about to enter Phase II trial in renal cell cancer in the US, we've de-risked both programs. Our strategy in the development of both BNC105 and BNC210 is very commercially oriented, and targets specific commercialisation points as we have previously outlined.

Identifying a dose for the BNC105 renal cancer trial and having one of the top US cancer groups engaged in the further clinical development of BNC105 has overcome a near-term risk for our lead drug candidate. BNC105 now has a clear path.

In choosing renal cancer as the setting for the initial Phase II trial of BNC105, we're seeking to respond to the need for new and effective treatments for this cancer. If BNC105 shows efficacy in the treatment of renal cell cancer, the development program offers a rapid path to a blockbuster market which is attractive to potential licensees.

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You've selected a dose of 12.6mg/m² for Phase II trials of the BNC105. Why has this dose level been selected? Why has renal cancer been selected as the cancer type to be studied in the next clinical trial of BNC105?

CEO & MD Deborah Rathjen

This dose was chosen because it was well tolerated by patients and rapidly achieved the plasma drug levels required for the vascular disruption effect of BNC105 from a single intravenous injection. Critically, this dose level is more than adequate to meet our current thoughts on the development and commercialisation of BNC105.

In considering therapeutic settings for the Phase II development program we went through a process of evaluating all solid tumour types, the current standard of care and where new developments in therapy for those cancer types may move to in the next few years, as well as the clinical need for new therapeutic approaches and the path to market. We also considered the available preclinical data on BNC105. Experts in Australia and the US were consulted as part of the process and have assisted greatly.

The net result of these analyses gave us a short list of five cancer types which were most attractive to target in our Phase II program for BNC105 and renal cancer – noting that a patient with renal cell cancer in the phase I study had shown evidence of inhibition of tumour growth (stable disease) - was one of those. We also saw that renal cell cancer was a strong market opportunity. To illustrate this, I can point to two drugs - Sutent[®] and Nexavar[®] - which are both approved for the first line treatment of renal cancer. Worldwide sales of Sutent[®] were US\$847 million in 2008 whilst reported sales of Nexavar[®] were US\$677.8 million. Sales of Nexavar[®] are anticipated to grow to US\$850 million in 2009 and US\$1 billion in 2010.

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Why did you choose the Hoosier Oncology Group ("HOG") to conduct the trial? What is HOG's expertise in this area?

CEO & MD Deborah Rathjen

The HOG has been working as a consortium to evaluate new treatments for cancer for a considerable period of time. Around 16 different cancer centres throughout the US are involved in the consortium.

HOG is well credentialed and has experience with Afinitor[®], a new agent that's recently been approved by the US Food and Drug Administration (FDA) for the treatment of renal cancer. By using HOG and its outreach through the different oncology centres in the US, we should be able to attract a large number of renal cancer patients to our trial relatively quickly. HOG is currently running trials across a lot of tumour types – bladder, breast, colorectal, lung,

ovarian and prostate, but it doesn't have a renal cancer trial on its agenda at the moment which is a plus for us.

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You've indicated that you're also considering additional Phase II clinical studies of BNC105 in other forms of cancer. What cancers are under consideration and what will be the key determinants of any decision to go ahead with additional trials?

CEO & MD Deborah Rathjen

We have a number of criteria for making these selections, based on the studies we've done to date in animal models of cancer and data we've released and presented at conferences around a broad range of tumour types. All that information as outlined earlier is playing a role in our selection of the cancer types for additional clinical trials of BNC105.

Identifying a rapid path to market has been a strong factor in our thinking and one of the key reasons we selected renal cancer. Amongst the other types of cancers we're looking at is mesothelioma. In our Phase I trial we saw a patient with mesothelioma have stable disease for 22 weeks at 8.9mg/m². This is a tumour type that's of strong interest to us and it's a large problem in both Australia and the US. In addition, we are also considering other cancer types including head and neck, ovarian and non-small cell lung cancer as potential Phase II clinical trial settings.

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The primary objective of your Phase I clinical trials of anti-anxiety drug BNC210 is to evaluate the safety, tolerability and pharmacokinetics of BNC210 with a secondary objective of conducting a preliminary evaluation of its effects on the central nervous system using visual analogue scales. How important will the effect on the central nervous system be for the future development of BNC210?

CEO & MD Deborah Rathjen

This study seeks to evaluate the effects of BNC210 on various parameters of mood, for example the level of anxiety that subjects in the trial express both before and after they've received BNC210. We'll also use scoring methods to evaluate whether there's any hint of some of the side effects associated with other drugs in the marketplace.

Phase I studies are not designed to inform us a great deal about the efficacy of compounds but they can give an indication of any difficulties such as safety issues or unexpected side effects. We've overlaid these normal elements of a Phase I trial with some elements that will give us early suggestions of BNC210's potential effects on the central nervous system. We expect BNC210 to be effective in the central nervous system because changes in the central nervous system are what underlie most anxiety disorders.

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The trial design is in accordance with International Conference on Harmonisation (ICH) standards. What significance will this have for the development of BNC210?

CEO & MD Deborah Rathjen

This will mean that the data gathered from the trial will be acceptable to the major regulatory bodies around the world: not only Australia's Therapeutic Goods Administration (TGA), but also the US FDA for example. Further, the adoption of ICH standards, which are recognised internationally, will facilitate future discussions with potential partners, thereby enhancing the commercial value of the project.

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What is the expected timeline for the Phase I trial and do you intend to update the market on interim results?

CEO & MD Deborah Rathjen

The Phase I trial comprises two components. At the completion of the initial component of the trial we'll inform the market of the status of the trial before moving on to the second component. We expect the trial as a whole will be completed before the end of this calendar year.

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Can you comment on how the recent developments could be expected to impact the partnering prospects for BNC105 and BNC210?

CEO & MD Deborah Rathjen

We expect recent developments to positively impact partnering prospects. The clinical trial programs for BNC105 and BNC210 are designed to maximise the value of the data obtained and have been specifically designed to meet international standards.

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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

This announcement contains "forward-looking" statements within the meaning of the United States' Private Securities Litigation Reform Act of 1995. Any statements contained in this press release that relate to prospective events or developments, including, without limitation, statements made regarding BNC105, BNC210 and its' drug development programs are deemed to be forward-looking statements. Words such as "believes," "anticipates," "plans," "expects," "projects," "forecasts," "will" and similar expressions are intended to identify forward-looking statements. There are a number of important factors that could cause actual results or events to differ materially from those indicated by these forward looking statements, including risks related to our available funds or existing funding arrangements, a further downturn in our customers' markets, our failure to introduce new products or technologies in a timely manner, regulatory changes, risks related to our international operations, our inability to integrate acquired businesses and technologies into our existing business and to our competitive advantages, as well as other factors. Subject to the requirements of any applicable legislation or the listing rules of any stock exchange on which our securities are quoted, we disclaim any intention or obligation to update any forward-looking statements as a result of developments occurring after the date of this announcement.