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BNC105 effective in treating cancer

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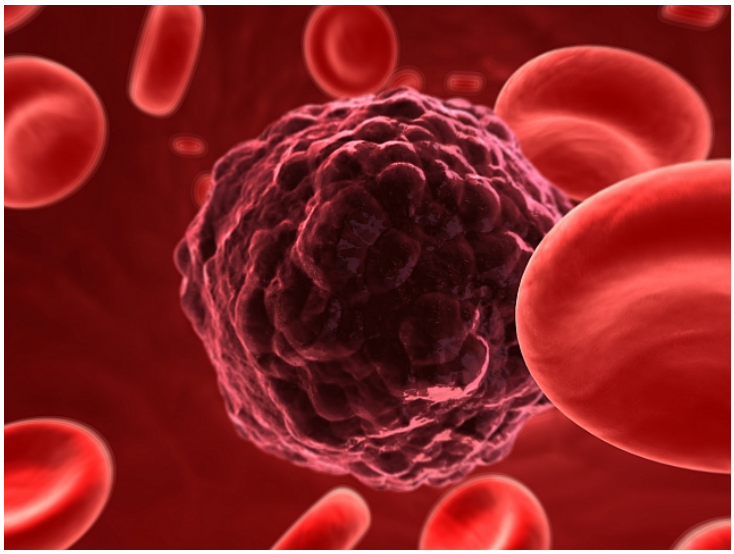
BNC105 in combination with Novartis' Afinitor is effective in treating renal cancer



Singapore: Bionomics is going to present clinical trial data from its ongoing US trial of BNC105 in patients with metastatic renal cancer and the completed Australian trial in patients with mesothelioma, at the annual American Society for Clinical Oncology (ASCO) meeting in Chicago, Illinois. BNC105 is a novel, proprietary compound being developed by Bionomics as a vascular disruption agent (VDA) for treatment of solid tumours.

Renal Cancer Trial
Bionomics's renal cell carcinoma (RCC) trial is a multi-center phase II clinical trial of BNC105 in combination with everolimus (Afinitor) being conducted in patients with progressive metastatic version of the cancer. Afinitor is an mTOR inhibitor, which is used as a treatment after patients have failed therapy with tyrosine kinase inhibitors (TKI), such as Sutent. Afinitor, which was approved by the FDA for the treatment of renal cancer in 2009 and is marketed by global pharma company Novartis, had recorded sales of $850 million in 2011. The phase II component of the study is currently underway and more than 30 US-based clinical trial sites have been activated to date.

The primary objective of the phase I component of the clinical trial was to examine the safety and tolerability of BNC105 in combination with Afinitor. Twelve patients were enrolled to the phase I component. Five patients have completed over 10 cycles of treatment and two patients continue to remain on treatment.

The results indicate that the recommended dose of Afinitor is well tolerated when combined with the previously identified phase II dose level of BNC105 of 16 mg/m², supporting the use of both Afinitor and BNC105 at their full dose levels. Plasma pharmacokinetic analysis of drug levels indicated no interaction between BNC105 and Afinitor, confirming the compatibility of the drug combination.

Mesothelioma Trial
This single arm phase II trial conducted by the Australasian lung cancer clinical trials group and the NH&MRC Clinical Trials

Center, enrolled patients progressing after first line chemotherapy with pemetrexed (Alimta) and cisplatin. Thirty patients were enrolled into the trial with one patient showing an objective response. Thirteen patients were classified as having stable disease according to RECIST for mesothelioma. BNC105, at a dose of 16mg/m² was well tolerated, a finding that is consistent with clinical experience to date.

Statistically significant changes were observed in candidate biomarkers which are consistent with the vascular activity of BNC105. These include changes in MIP-1beta (p=0.0023), IL-8 (p=0.0007), IL-10 (p-0.0018), TNFR2 (p=0.0001) and IL-16 (p=0.0037). In addition mesothelin levels, a potential marker for mesothelioma, in the patient showing an objective response achieved a decrease to less than 75 percent of baseline after one treatment cycle.

Two additional patients with stable disease similarly achieved decrease in mesothelin to less than 75 percent of baseline. The objective tumour response, safety profile and tolerability of BNC105 warrant further research into its integration with established chemotherapy regimens.