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**ASX ANNOUNCEMENT**  
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## **BIONOMICS PRESENTS BNC105 PHASE II RENAL CANCER TRIAL BIOMARKER DATA**

- ***Progression Free Survival at six months by renal cancer patients increased from 36% to 60% for a patient group defined by four biomarkers***
- ***57% of patients had the four biomarkers***

Bionomics Limited (ASX:BNO, ADR:BMICY) today presented new important data from the DisruptOR-1 trial of BNC105 in patients with metastatic renal cancer at the European Society for Medical Oncology congress in Madrid, Spain. The data, presented by Dr Sumanta Pal, of the City of Hope Comprehensive Cancer Center in Duarte, CA, USA, emphasizes the plasma biomarker profile associated with favourable outcomes for patients treated with BNC105.

### **Four biomarkers are associated with patient response to BNC105 in combination with Afinitor (everolimus)**

Throughout the clinical trials of BNC105 Bionomics has analyzed a panel of blood biomarkers. This was done to detect changes resulting from the administration of BNC105 and to determine whether such changes can indicate BNC105 clinical benefit .

A most exciting aspect of this biomarker analysis has emerged from the randomised Phase II DisruptOR-1 trial. As reported in March, 136 patients were enrolled and segregated in two treatment arms (69 in the BNC105 + Afinitor arm and 67 in the Afinitor-only arm). The primary endpoint of the study was to improve Progression Free Survival (PFS) from 36% at six months in the Afinitor-only arm to 60% PFS in the BNC105+Afinitor arm. The initial data indicated that, in an unselected population, the proportion of PFS patients were similar between the two arms.

However, blood samples were obtained from 44 patients before and after treatment with BNC105 in the BNC105+Afinitor arm. This large sample size enabled statistical correlation of blood biomarker changes with disease status at six months of treatment. This correlation analysis revealed four biomarkers can be used to significantly enrich treatment success for this patient group treated with BNC105 plus Afinitor.

57% of patients were positive for the 4 biomarker signature, with 60% of these being disease free at six months.

In contrast, only 5% of the patients that were negative for the 4 biomarker signature were disease free at six months. It is noteworthy that for this sizeable patient group the 60% six month PFS primary endpoint target was achieved.

"This is the first time a biomarker signature associated with clinical outcomes for a VDA (BNC105) plus Afinitor has been reported for renal cancer patients," said Dr Pal, who is Co-Director of the Kidney Cancer Program at the Department of Medical Oncology & Experimental Therapeutics of the City of Hope Comprehensive Cancer Center. "These biomarkers should be further evaluated in future studies, within the frame of personalised medicine, to guide drug administration in those patients with the highest chances of benefiting from a significant clinical outcome."

This very important finding suggests that future studies may select renal cancer patients using this 4 biomarker signature to endeavour to demonstrate a much higher probability of benefiting from BNC105 (+Afinitor).

Future studies may also evaluate overall survival after five years and overall response rate of the combination of BNC105 monotherapy following Afinitor treatment.

Data collection and analysis on these parameters is continuing and will be reported in scientific presentations and publications as it becomes available.

A copy of the poster presented by Dr Pal can be downloaded from Bionomics' website.

#### FOR FURTHER INFORMATION PLEASE CONTACT:

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#### About Bionomics Limited

Bionomics (ASX: BNO) is biopharmaceutical company which discovers and develops innovative therapeutics for cancer and diseases of the central nervous system. Bionomics has small molecule product development programs in the areas of cancer, anxiety, memory loss and pain. Its oncology approach includes cancer stem cell therapeutics as well as vascular disruption in solid tumours. Bionomics partners include Merck & Co and Ironwood Pharmaceuticals.

Bionomics' discovery and development activities are driven by its four proprietary technology platforms: MultiCore®, a diversity orientated chemistry platform for the discovery of small molecule drugs; ionX®, a set of novel technologies for the identification of drugs targeting ion channels for diseases of the central nervous system; Angene®, a drug discovery platform which incorporates a variety of genomics tools to identify and validate novel angiogenesis targets (involved in the formation of new blood vessels); and CSC Rx Discovery™, which identifies antibody and small molecule therapeutics that inhibit the growth of cancer stem cells. These platforms drive Bionomics' pipeline and underpin its established business strategy of securing partners for its key compounds. Bionomics partners include Merck & Co and Ironwood Pharmaceuticals.

[www.bionomics.com.au](http://www.bionomics.com.au)

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