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Venus gets DCGI nod for phase III trial

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After thorough screening by the IND committee for the investigational New Chemical Entity (NCE) VRP1620, DCGI has found that the clinical phase I and phase II data from Venus Remedies as satisfactory and thus granted it permission to conduct phase III clinical trials on the molecule. The molecule is for early cancer detection and this leap will make Venus pioneers among the companies providing innovative solution for cancer detection.

Dr (Mrs) Manu Chaudhary, director, Research, Venus Medicine Research Centre (VMRC) said, "This NCE is based on selective tumor targeting because tumor-infiltrating blood vessels deviate morphologically and biochemically from normal vessels. VRP1620 specifically increases tumor blood flow and this property has been utilized to promote delivery of cancer detection contrast media to the site of tumors via blood stream."
It is a targeted delivery of diagnostic agent which enhances image quality to several 100 times, thus making it clearly differentiated. She further added that, "We can also differentiate between benign and malignant tumor because of its property to enhance image quality and very small sized tumors can also be traced. As of now, there is no such technology for early detection of small sized solid tumor available in the market across the globe and secondly, VRP1620 will help us in staging of tumors.
Our technology omits false negatives."

Venus Remedies had completed the phase I study at Postgraduate Institute of Medical Sciences (PGIMER), Chandigarh, conducted to find the maximum tolerable dose levels in breast cancer patients in 2010. Later, in April 2011, after DCGI approval, the phase II study of this molecule was conducted at multiple institutions throughout India including PGIMER, Chandigarh and Central India Cancer Research Institute, Nagpur, to establish the pharmacokinetic profile and preliminary efficacy of the drug. "Late stage diagnosis of breast cancer and solid tumors in general are a major cause of decreasing survival indices in our country. A diagnostic product like VRP1620 will surely go a long way in putting breast cancer patient ahead in time to receive better therapeutic benefits. I shall be looking forward to this novel drug performing in clinical practice," said Dr Ajay Mehta, director, Central India Cancer Research Institute.

Venus is planning to launch this NCE by the last quarter of 2013 in India for the first time globally. "We are excited about this NCE molecule, as this is our first-ever success in phase I and II and we look forward to meeting the otherwise unmet market need," said Mr Pawan Chaudhary, chairman and managing director, Venus Remedies.

In a recent report, the World Health Organization (WHO) has warned that there will be a cancer patient in each household in India by 2020. In India, the number of people suffering from cancer is expected to increase to 40 lakh by 2020, and the number of people dying of it each year is expected to rise to 11.5 lakh. In more than 70 percent of the cases, cancer is diagnosed at the advanced stages of the disease, which leads to a poor survival and high mortality rate. This NCE has huge potential and will provide a cutting edge in timely detection of cancer and has tremendous need specially in under developed and developing countries.