



## **Technology In-Licensing – A Case Study**

### **Background**

*From past 2 decades Venus Remedies Limited (VRL), has worked to discover, develop and commercialize medications to advance the care of patients suffering from life-threatening diseases in areas of unmet medical needs.*

*VRL is actively involved in In-Licensing and Out-Licensing of technologies across globe. A case is presented wherein Technology is sourced from outside India i. e. USA and developed to detect solid tumor (Breast Cancer).*

### **Identifying Need Gap**

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% of the cases cancer is not diagnosed at the advanced stages of the disease, which leads to a poor survival and high mortality rate.

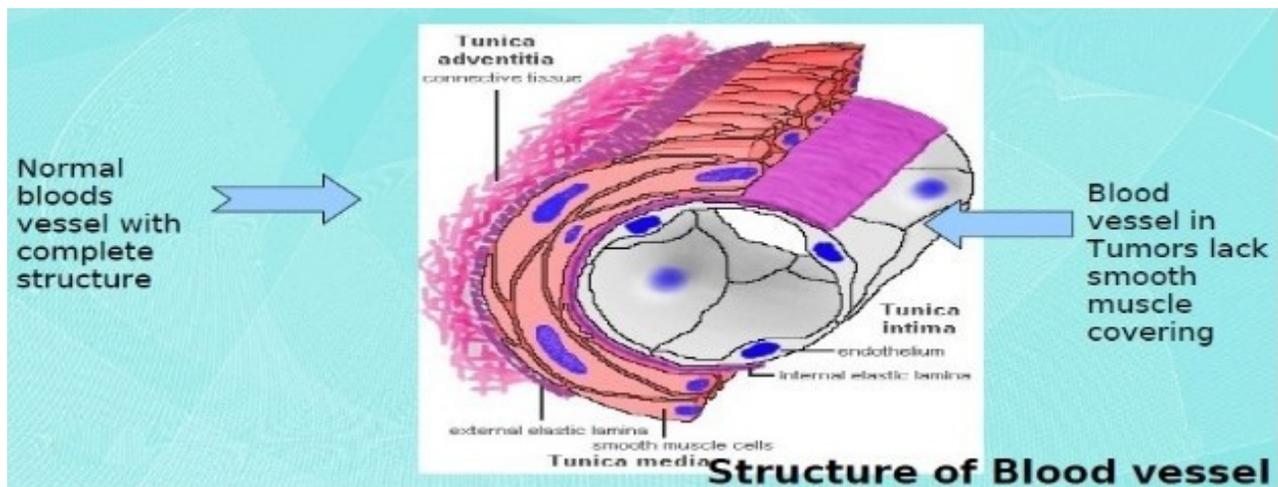
About 1.3 lakh fresh cases of breast cancer are reported in India every year; a decade ago the number stood at 54,000. Doctors attribute this increase to both rise in awareness among people and rise in cases of cancer.

### **Technology In – Licensing**

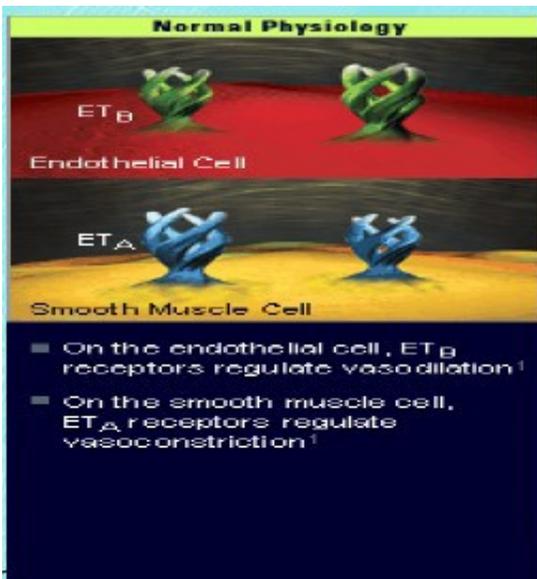
In the year 2007, VRL In-licensed a concept technology for early diagnosis of solid tumors, “Diagnostic use of Endothelin ETB receptor Agonists (IRL 1620) and ETA receptor antagonist in Tumor Imaging” from US. Team of scientists at VRL started working on the technology and thereafter technology started maturing from concept to formulation to toxicological studies to preclinical then finally to clinical. The test product (Endothelin receptor agonist) was given the code VRP-1620.

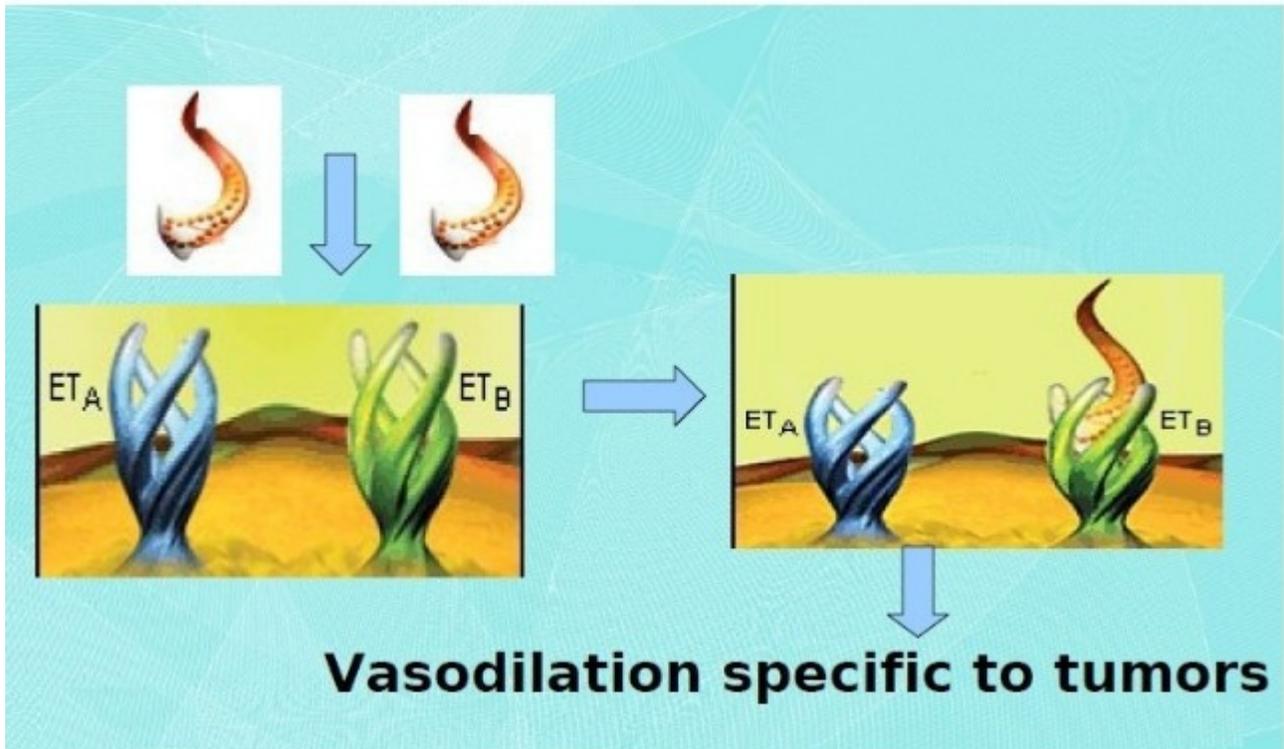
### Mechanism of action

Tumors are characterized by unorganized growth with rapid multiplication of blood vessel. These vessels lack outer smooth muscle covering.



The fast dividing & growing endothelial cells have large number of endothelin B receptors (ETB Receptors)





VRP 1620 is highly specific agonist for Endothelin B receptors ( $ET_B$  Receptors) causes transient selective tumor specific vasodilation which confirms a very small size tumor and clearly differentiate between malignant and benign tumor.



## **Development Pathways – Road to Commercialization**

A team of scientists from Venus Medicines Research Center (VMRC), R & D extension of VRL were working for past couple of years on the technology of using Endothelin ETB receptor agonist, (VRP 1620, a novel peptide), which is highly selective ETB receptor agonist and is involved in selective vasodilation in solid tumors.

### **Phase I Clinical Study**

Phase I study was conducted at one of the prestigious Medical institute to find the maximum tolerable dose.

### **Phase II Clinical Study**

Phase II clinical study was conducted at multiple institutions throughout India. This clinical study documented the pharmacokinetic profile and appropriate dose range for the drug. It also detailed the efficacy for its use as a diagnostic agent for breast cancer.

Tolerability of VRP 1620 was also assessed by the investigators and subjects at the end of study treatment period, which showed that the product is well tolerated.

### **Phase III Clinical Study**

After successful completion of Phase I & II, VRL received approval from Drugs Controller General, India (DCGI) to conduct Phase-III Clinical Trials. After thorough screening by IND committee for the investigational New Chemical Entity, VRP1620, DCGI found Clinical Phase-I and Phase II data satisfactory and thus granted permission to conduct Phase-III Clinical Trials. This advancement towards Phase III has made VRL pioneers among the companies working and providing innovative solution for cancer detection.

At present, Phase III study is under process under strict GCP guideline, with target of recruiting total of 220 subjects spread across 8 different zones in India.



## Product Launch

VRL will launch this product under brand name Tumatrek after receiving market authorization (MA).

### Doctor's Voice

“This technology can offer new ray of hope for early detection of breast cancer”, said **Dr Shyam Aggarwal**, Medical Oncologist, Sir Ganagaram Hospital, Delhi.

“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 VRP-1620 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.

### Benefits

1. Detection of tumors at Early Stage
2. Specific and Easy Detection of tumor proliferation
3. Tumor Detection possible by Conventional modes like sono mammography and Doppler
4. Can differentiate between malignant and benign tumors
5. Safe in human due to Low dose & Shorter half life

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