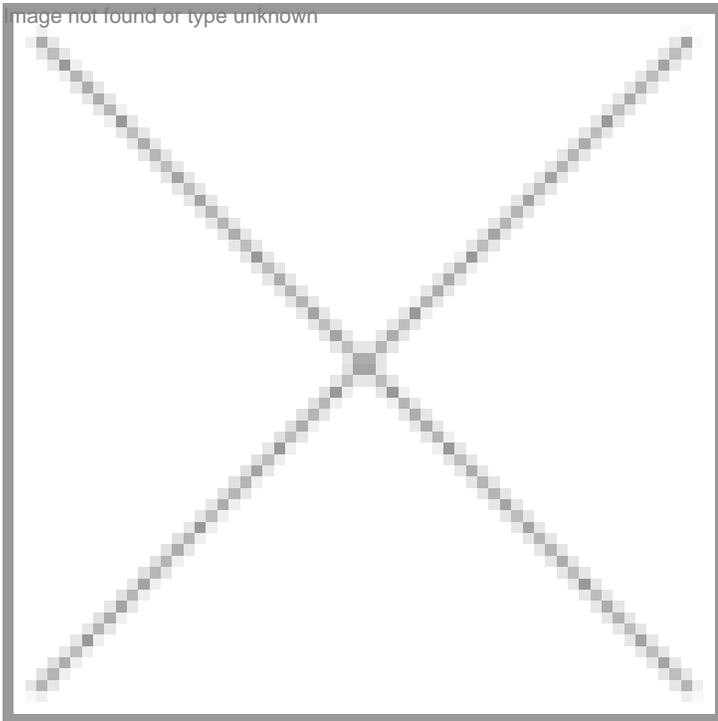


PacliALL leverages the nanoparticle advantage

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**BioSpectrum Product of the Year
Award 2011
PacliALL**

The indigenously developed PacliALL from Panacea Biotec is a formulation of albumin-bound Paclitaxel particles. The product is more affordable and safer than the conventional formulations of Paclitaxel as a chemotherapeutic agent for the treatment of breast cancer

PacliALLproductpic1

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According to the World Health Organization (WHO), female breast cancer is one of the major challenges and one out of every eight woman is likely to suffer from this dreaded disease by 2020, across the globe. Therefore, in a developing country such as India, where more than 80,000 patients have been diagnosed with breast cancer every year, PacliALL is seen as a major relief to patients since the treatment costs are highly unaffordable.

Launched by Panacea Biotec on Feb 12, 2011, the indigenously developed PacliALL uses one of the world's most advanced particle size optimization technology to reduce serious adverse effects, including severe anaphylaxis and sensory neuropathy associated with conventional Paclitaxel formulations. The new product also offers several patient convenience aspects like shorter infusion time and elimination of need of premedication. The product is available at a price that is approximately 50 percent less than its competition in domestic and global markets. The product is priced at 9,000 per vial as compared to 18,000 per vial in the international market.

The unique selling point of PacliALL is that it is three times more efficacious than conventional, solvent based, Paclitaxel, in terms of response rate. It is free from the undesirable side effects of chremophore like anaphylaxis and skin reaction and higher grade neutropenia among others.

Also, the patients need not to be treated with pre-medication, containing steroids. Drug related neuropathy is reversible unlike the conventional, solvent based, Paclitaxel. With this product, a higher dosage of approximately 1.5 times can be given to patients, without the risk of increasing side effects. The intra tumor concentration of drug is very high when compared with the conventional one because of targeted delivery.

According to the company, the product has been well accepted and is being used across the length and breadth of the country. Within three months, the volume of sales (units) is almost equivalent to that of the brand leader. With the market size of the drug in India estimated to be about 180 crore, the company is expecting to grab around 10 percent market share within a year.

Panacea Biotec sees great potential for the product in the rest of world. The company is in the process of setting up a new manufacturing facility at Baddi, Himachal Pradesh, in order to cater to the world market.

About the future plans, Dr Sarabjit Singh, vice president, R&D, Panacea Biotec, says, "We intend to provide this product for global healthcare needs, complying to the best quality standards and make it an affordable therapy."

Birth of the product

The research on the project started almost six years ago with the objective of bringing the latest, state-of-the-art safe and effective medication to the country. These areas included the nanoparticles, microparticles and liposomes. At that time, the company was already into novel drug delivery system with an R&D center located at Lalru, Punjab, with focus on oral drug delivery.

Narrating the idea behind the product, Dr Rajesh Jain, joint managing director, Panacea Biotec, says, "We decided to move away from conventional technology and develop something that was upcoming at that time. We hired a core team of scientists to look into this area of advanced drug delivery system and found that nano-particle technology could help treat breast cancer patients with fewer side effects and efficaciously."

In 2005, the company hired some space on the premises of SNTD Women's College, Mumbai, and started research on nanoparticles. They also started work on the R&D Center, which is now known as global research and development (GRAND), Navi Mumbai. The work at the center, inaugurated on February, 11, 2008, was conceptualized over four core areas of advanced drug delivery through specially programmable oral drug delivery system.

Taking it to the market

A team of about 15 scientists from India and abroad worked dedicatedly to make this product a market reality. The technology involved emulsion-solvent evaporation and is based on the principle of high pressure homogenization. Paclitaxel and albumin are in intimate mixture and of a controlled particle size of less than 150 nm. The final product is stabilized by lyophilization. Without giving the exact amount of investment to develop this product, Dr Jain points out that the process of investments is still on.

'We are far ahead of competition'

Dr Rajesh Jain

Dr Rajesh Jain,
joint managing director,
Panacea Biotec

Is there any room for improvement in the cost of PacliALL?

Dr Rajesh Jain: Further possibilities for improvement in the product cost may not be feasible at this stage. At present manufacturing and supply of the product is from a pilot plant at the GRAND R&D Center, Mumbai, which is not enough for us to venture in global markets. Therefore, we are investing ~~in 55 crore in setting up~~ a commercial anti-cancer formulation facility at Baddi, Himachal Pradesh. The same is expected to be licensed and inaugurated by Feb 2012. In the next three years, the product will be globalized and we expect it to do well across the developing markets, such as Africa, CIS Republics and Latin America. Once we obtain returns on our investment, we can subsequently look at reducing the price. Although this is the investment phase for us, we never wanted to keep patients waiting for the product. While it is important to use advanced technology, it must come with a price tag that is affordable to people.

How do you view the competition?

Dr Rajesh Jain: At present the market is quite large, equivalent to \$500 million. We believe that competition is healthy as it helps us to focus on the value we deliver to the customer in the absence of which one is not successful. The right spirit in a competitive environment will help in bringing down the price, offer a better product to the ultimate beneficiary, the patient.

Our business is about saving lives. When you look at the global generic players, they are focusing

on reduction in price of already existing conventional Paclitaxel product. Our product development strategy includes three important aspects: affordability, efficacy and safety. Currently, the focus of the competition is on price. So, we feel that we are much ahead and they have a long way to go.

What are your views on cancer research and drug discovery in India?

Dr Rajesh Jain:We have a long way to go in cancer or drug discovery research. Indian academic research is not focused on outcomes that aim at products for different diseases, either in India or overseas.

What is the need of the hour?

Dr Rajesh Jain:I think with time, the academia, government and the industry have matured and now it is time to synergize our efforts to create new innovative but affordable drugs from India for the developing world.

We need translational capabilities with a proper support system, such as national laboratories that can supply cell lines, reference standards, enabling animal model for efficacy studies and new targets among others.

The product is reconstituted immediately before infusion. Complete manufacturing of the product is carried out in a state-of-the-art isolator facility, ensuring safety of the formulator and the product.

“It took us approximately six years from idea to commercialization. Major stages of development included strategizing path of development, machinery to prepare nanoparticles, preparing the product on lab scale, establishing proof-of-concept, scaling up to GMP guidelines and finally validating the upscaled process,” says Dr Sarabjit Singh.

“The objective of Panacea Biotec is to take ideas to the market in a proactive manner and establishing brand India globally in sync with its adage “Think Medicine Think India”. We will remain committed to its mission providing the latest and most affordable preventive and therapeutic care to people across the globe. The launch of PacliALL reflects the hardwork of Panacea Biotec’s scientists who worked tenaciously for the development of this drug,” adds Dr Rajesh Jain.

Rahul Koul in New Delhi