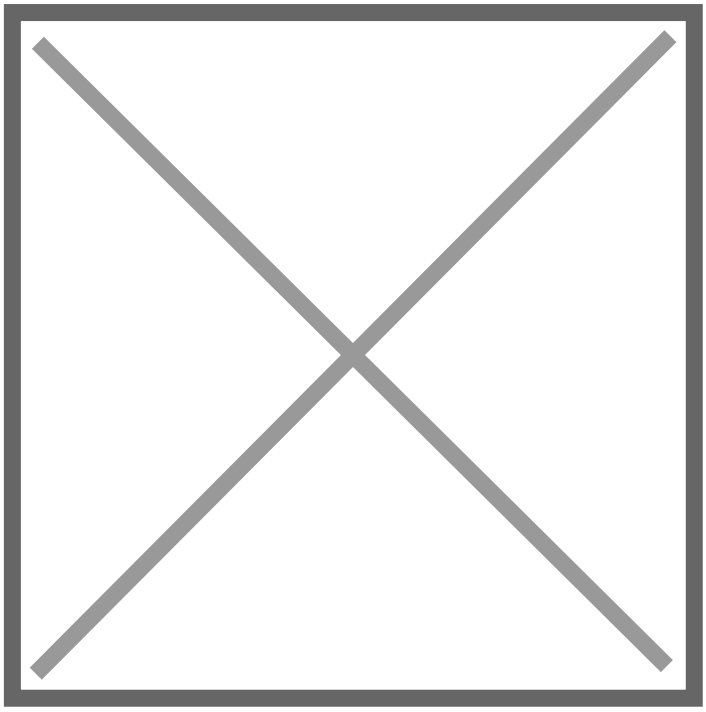
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Nanotech, biotech spur anti-cancer drugs

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Each year more than 10 million people worldwide are diagnosed with cancer, another 24 million people live with cancer being diagnosed in the last five years and every year 6.7 million people worldwide die from cancer. These bleak statistics show an enormous demand for new anti-cancer therapeutics. And pharma companies are rising up to the challenge.

The past few years have seen a spurt of activity in the oncology space globally and in India as well. Though generic drugs have been a ready cash generator till now, immense competition in the generic space has led to price erosion making the field less attractive. The future of the anti-cancer segment lies in new drug discovery. As a result, many pharma companies have realigned their priorities, forged partnerships, and initiated proprietary R&D. Within the country itself, a number of cancer and related drugs were launched during the past one year. There is a rush between the companies to capture a part of the over Rs 1,000-crore oncology market in India. Dabur, Biocon, Cadila, Nicholas, Merck and Lilly have been some of the front-runners in this segment.

In the first week of January 2007, Dabur Pharma launched Nanoxel, a new version of an existing anti-cancer drug Paclitaxel, which is a nanoparticle-based formulation. The good news for patients is that the new drug can be delivered in higher doses while reducing side effects associated with chemotherapy. The generic anti-cancer drug paclitaxel is not usually soluble in water or blood, and so must be administered to patients in a castor oil-based solvent called cremophor that itself can cause dangerous side effects. To circumvent the problem, DRF (Dabur Research Foundation, which spearheads the R&D activity of the company) used nanotechnology to create Nanoxel, a water-soluble version of paclitaxel that can be absorbed into a patient's bloodstream without using toxic cremophor.

According to Dr Anand Burman, chairman, Dabur Pharma, "This is the first commercial application of nanotechnology in the Indian market and the pharma sector outside the US". The only other comparable non-cremophor-based version of Paclitaxel is the more expensive Abraxane, made and marketed in the US.

Paclitaxel belongs to a class of drugs called anti-neoplastics that interfere with the growth of cancerous tumors in certain kinds of breast, lung and ovarian cancers, as well as other forms of cancer. Dabur holds a global patent for this new drug delivery system. The company hopes to get permission to market the drug delivery system in both the US and European Union within 18 to 36 months, and is about to begin international trials.

The market for the blockbuster drug Paclitaxel worldwide is estimated to be just under $1 billion making Dabur upbeat about not only the future of Nanoxel drug but the new drug delivery platform as well. "Within the country, the market size of Paclitaxel, in terms of amount required, is 8-11 kgs. We hope that Nanoxel will replace the conventional Paclitaxel slowly and in about 10 years the regular Paclitaxel will disappear," said Dr Burman.

Dabur has always been a trailblazer in the oncology arena. Way back in 1994, it became one of only two companies worldwide to launch the anti-cancer drug Intaxel (Paclitaxel). It was the first company in the world to isolate the anticancer drug, Paclitaxel, from the leaves of Himalayan Yew Tree using a unique eco-friendly process, which facilitated manufacture of cheaper anti-cancer medicines. In 2001, with the setting up of Dabur Oncology's sterile cytotoxic facility, the company gained entry into the highly specialized area of cancer therapy.

Currently, its new chemical entity DRF-7295, a peptide based anti-cancer drug is in Phase II clinical trials and has shown promising results. In addition to peptide molecules, the company is also working on small organic synthetic molecules, phytochemical molecules and potential cancer therapeutic vaccines.

Besides Dabur, there are several other companies in the country, which are active in the oncology segment. According to oncologists, next to cardiology, cancer is responsible for the maximum mortality. Now with sophisticated research techniques available, most of the companies want to focus on anti-cancer therapies not only for India but the world over. They are keen to capture a share in the international market, which is expected to touch $64 billion by 2010.

In September 2006, Biocon, another company with a long-term focus on cancer therapeutics, launched an anti-cancer drug, Biomab-EGFR, in the country. This marks the company's entry into proprietary immunotherapeutics. The drug is based on a therapeutic antibody and is the first of the eight MAb products being jointly developed by Biocon and its Cuban research partner, CIMAB. The antibody is rigged to target cancer of head and neck in which the sub-continent has 30 percent of the global incidence. Biocon would take up trials soon for other cancers such as lung, colorectal, breast among others. The company has set up a new oncotherapeutics division to handle its upcoming products.

September 2006 also saw the partnership between ClinTec International, a full service global clinical research organization headquartered in the UK and Dr Reddy's Laboratories for the co-development of anti-cancer drug, DRF 1042. This drug belongs to the topoisomerase inhibitors class of compounds and has shown potential in the treatment of various types of cancer in patients. Dr Reddy's has successfully completed Phase I clinical trials for DRF 1042 in India. ClinTec International will lead the clinical development of DRF 1042 including undertaking all regulatory work with the aim of securing USFDA and EMEA approvals as fast as possible. Currently, the phase II clinical trials of the drug are being planned in Europe.

Meanwhile, Cadila Pahrmaceuticals, a Rs 650-crore pharma company, has started the groundwork to launch its anti-cancer therapeutic vaccine, Immuvac, in the US. The move could make it the first Indian drug company to introduce an original Indian pharmaceutical product in the US. Till now, the drugs launched by Indian companies in the US and other countries have been generic versions of pharma products. The firm has got USFDA approval to begin trials there and plans to out-license the vaccine to a US firm. In the US, Cadila is looking at human clinical trials for cancer and tuberculosis. The company has submitted the investigational new drug requirements for Immuvac. The launch may come about only in late 2008 as the trials are expected to go on for at least 12 to 18 months. Immuvac was initially developed as an anti-leprosy vaccine by the National Institute of Immunology, New Delhi, and the technology was transferred to Cadila. The R&D team at Cadila carried out more research and found the vaccine to be efficacious against some types of cancers like non-small cell lung cancer, prostrate cancer, bladder cancer and melanoma as well as Tuberculosis.

Marking the entry of Serum Institute of India in this sector was its tie-up with Chicago-based Akorn Inc last year. This is a 15-year tie-up for the development of anti-cancer and biological products. The manufacture of these products would begin at the new special economic zone of SIIL by end of December 2007. Initially, some generic products would be manufactured and would be available in the markets by end of 2009 and later the facility would also look at the production of specific products with intellectual property, which would happen in about five years. Earlier in October 2004, Akorn and Serum had entered into an exclusive drug development and distribution agreement for oncology and other injectible products.

Another Indian pharmaceutical giant, Nicholas Piramal, has its prospective anti-cancer drug molecule in clinical studies being carried out in Canada and India. The prospective cancer drug molecule is the first in a series of compounds from the company's research centre to enter into clinical trials. It is an inhibitor of a key protein that is required by the cells to divide. Based on the initial laboratory data, P276-00 appears suitable as an agent to treat lung, breast and colon cancers. If all goes well, the company expects the cancer drug to hit the market by 2008.

Subsequently, in late 2006, Nicholas has signed an agreement with Morvus Technology, a UK-based drug discovery company, encompassing a combination therapy for cancer, which utilizes a specific Cyclin Dependent Kinase inhibitor to enhance the effectiveness of known anti-cancer drugs.

While, Merck Specialties, the Indian subsidiary of Merck KGaA, has announced the introduction of Erbitux, a new gold standard targeted therapy for the treatment of Colorectal Cancer (CRC) in India in August 2006. Erbitux, which has already obtained approval for the treatment of CRC in 53 countries works by targeting the Epidermal Growth Factor Receptor (EGFR)

which is found on the surface of cells and is involved in the stimulation of cellular growth, replication and/or differentiation when stimulated by growth factors. EGFR has been shown to be involved in the development and progression of many common types of cancers. Subsequently Merck received approval from the Drug Controller General of India (DCGI) for a second indication-for the treatment of patients with locally advanced squamous cell carcinoma of the head and neck (SCCHN). Now Erbitux is also indicated for use in combination with radiation therapy for the treatment of locally or regionally advanced SCCHN.

Close on the heels of the launch by Merck, Eli Lilly launched Alimta for the treatment of patients with malignant pleural mesothelioma (MPM)-a rare type of cancer that has strong correlation with exposure to asbestos. Alimta has also been approved as second line treatment for non small-cell lung cancer.

Also vying for presence in the Rs 1000-crore oncology market is Zenotech Labs, which will start marketing one generic oncology drug each of Novartis and Amgen/Roche. AstraZeneca Pharma India also expects to be a dominant player in cancer therapeutics in the country by 2008. It has five of the parent's seven oncology brands and is conducting trials before bringing in some more.

Earlier in 2002, Wockhardt introduced a 10,000 iu (international unit) per day version of recombinant erythropoietin, 'Wepox' in the oncology space. The other players in the erythropoietin market include Johnson & Johnson, Zydus Cadila, Nicholas Piramal, Hindustan Antibiotics, Emcure and LG of South Korea.

According to Dr SK Advani, a well-known oncologist, "Next to cardiology, cancer is responsible for the most mortality. India has a high incidence of one million cancer cases a year. There is a need for more targeted treatment. All of us are trying to introduce relatively patient friendly drugs and change this area from an area of fear to that of hope."

Rolly Dureha