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New trends in cancer research and treatments

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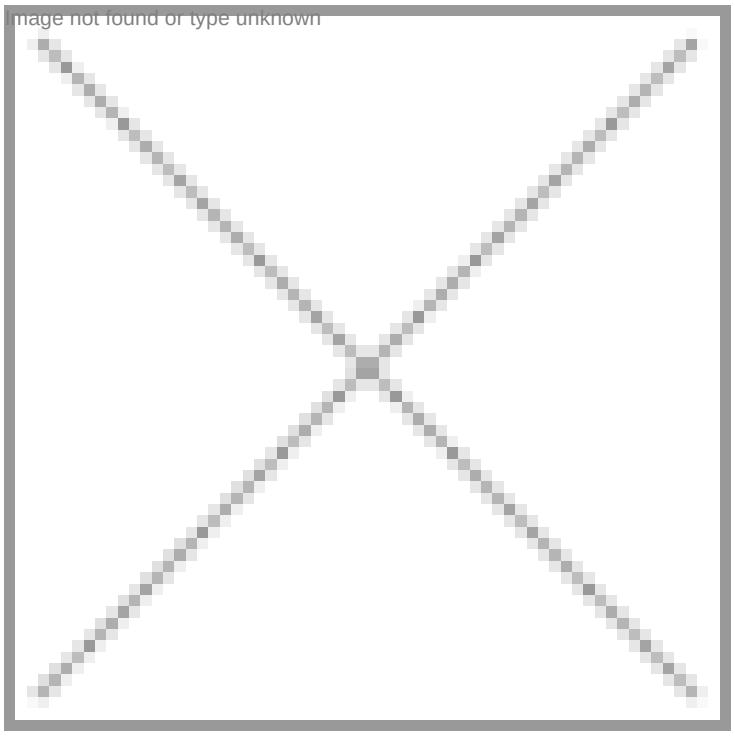


New trends in cancer research and treatments

The gradual metamorphosis on the macro front has led to a three-dimensional change in cancer research and treatments especially in the area immunobiological treatments for cancer.

The area of immunobiology in cancer is rather hot. Several monoclonal antibodies are currently in development against various targets and are undergoing clinical trials at this moment. The idea that tumor cells evade the immune system and that it might be possible to tweak the tumor cells to present themselves as foe to the immune system is a very exciting thought. The preliminary successes of the EGF-vaccine in increasing survival and the HER2 E75 breast cancer vaccine are indicative trends. Nevertheless, more data is still needed to bring these therapies on-board with conventional anti-tumor therapies," said Dr Arun Anand, MD, R&D, Biocon Ltd.

On the other hand, in the field of research, companies across the world are looking at interesting targets that could fuel a shift in the way cancers get treated, including the targeted therapy using monoclonal antibodies. According to Dr Anand, "The identification of cancer stem cells throws in a whole new twist in the battle to cure cancer. Biomarkers and technologies that aim to identify and predict recurrence or a poorer prognosis, including the newly validated CTC chip to detect circulating tumor cells, or mutations in K-ras genes or VEGF expression that predict response to therapy or lack of it are likely to be incorporated in trials early to differentiate therapeutic efficacy."

Apart from launching new products, companies are also looking at innovative drug delivery systems along with some

technological innovations. A lot of emphasis has now come onto companion diagnostics to determine and identify effective responders as well as predictive biomarkers. This will help outline the population that might benefit the most from an active intervention. "While a targeted monoclonal antibody remains a hot target that most companies are pursuing, the large macro-molecular sizes prevent multiple modes of delivery. At best currently, MAbs can be delivered subcutaneously. Oral MAb delivery platforms are being worked upon and so are methods to design MAbs with reduced potential immunogenic responses to therapy," opined Biocon's Dr Anand.

Biocon and Abraxis BioScience recently launched Abraxane the nanotechnology-based anticancer drug in India for the treatment of breast cancer, after failure of combination therapy for metastatic disease or relapse within six months of adjuvant chemotherapy. Abraxane is an important addition to Biocon's oncotherapeutics portfolio. Abraxis claims that the Phase III clinical trial of the product in the US showed Abraxane nearly doubling the response rate, significantly prolonging the time to progression, and improved overall survival in the second-line setting compared to solvent-based Taxol of Bristol-Myers Squibb in the approved indication. The oncotherapeutic product approved for use in breast cancer is currently undergoing advanced phase trials worldwide for other cancers. "Abraxane is the first nanotechnology-based anti-cancer drug that is administered as albumin-bound particles of approximately 130 nanometers and takes advantage of albumin, a natural protein that acts as the body's key transporter of nutrients and other water-insoluble molecules and accumulates in tumor tissues," said an Abraxis Bioscience spokesperson.

Last year, Dabur Pharma, a leading manufacturer of anti-cancer drugs, had also launched nanoxel the novel drug delivery system for the widely used anti-cancer drug Paclitaxel. The nanoscale drug delivery system is claimed to be India's first indigenously developed nanotechnology-based chemotherapy agent. The anticancer drug, based on the principles of nanotechnology, is a cremophor free water-soluble formulation and is indicated as an effective and safe therapy for advanced breast, non-small-cell lung, and ovarian carcinomas.

Dabur Pharma has an in-house capability to develop critical anti-cancer products as well as proprietary technologies that considerably accelerate the ongoing research and development work at its research facility. The company plans to rollout the chemotherapy drug delivery formulation internationally in the near future.

Antigen-Specific Cancer Immunotherapeutics (ASCI) is a new type of immunotherapy developed by GSK aimed at treating cancer. It aims at treating cancer (in this case lung cancer) through the targeting of antigens that are selectively expressed by cancer cells but not (or at low levels) by normal cells. ASCI, which are investigational compounds, selectively target antigens that are expressed by cancer cells but not expressed by normal cells. These are called cancer-specific antigens. ASCI aims at triggering an immune response or enhancing the initial immune response to the patient's tumor. Even though the initial immune response may not be strong enough to remove the cancer, it has been shown to provide a basis for further immunization as treatment.

Intas Biopharmaceuticals Ltd (IBPL) is focusing on developing Novel Drug Delivery System (NDDS) for proteins, a cloning facility, introducing production platforms and developing recombinant products (cytokines, hormones and blood factors). IBPL has constituted a dedicated strategic research team in order to develop technologies, new molecules related to biopharmaceuticals, and evaluate technology platforms.

"IBPL is planning to generate clones for commercial production of protein using state-of-the-art technologies to improve yields, quality as well as adopting novel expression systems (including transgenics) with an objective to build intellectual property over the long run. IBPL, in a planned and phase-wise manner will screen technologies, new molecules and identify the most promising ones, prioritizing them on the basis of their business potential and compatibility," said Dr Rustom Mody, director (Quality & Research), Intas Biopharmaceuticals.

IBPL will also develop NDDS for proteins for nasal and mucosal delivery as an alternative to the generic injectable formulations currently in use. This area has strong potential of generating IP in terms of patents AND publications and could provide a novel platform for delivery of many of the protein therapeutics.

Actis Biologics' recent acquisition is based on Ligand Linker Drug Delivery (LLD) system and is claimed to be of tremendous value in reducing the toxicity of chemotherapeutic agents. Sanjeev Saxena, cofounder and chairman, Actis Biologics, said, "Liver and kidney cancer was something that Anjizoyme did not address and that is when Ligand happened which was developed by Dr Paul Tso at John Hopkins University." Moreover it is found that chemotherapy does not cure liver and kidney cancer. As of now the animal studies for this technology is complete and now the company intends to move to the next level. PN Venugopalan, president, Actis Biologics, added, "Within the next two years we should be able to launch Angiozyme if not globally but at least in South Asian countries and maybe in the matured markets."

On similar lines, Panacea Biotec, which launched seven oncology products last year, is going one step further. The company

feels that it would be able to launch novel drug delivery based anti-cancer drug in the next two-three years. "We plan to develop NDDS of the existing anti-cancer molecule. The new research-based drug development will take two-three years as we need to develop an effective distribution chain and occupy a significant market share in oncology drugs," said Rajesh Jain, joint managing director, Panacea Biotec.

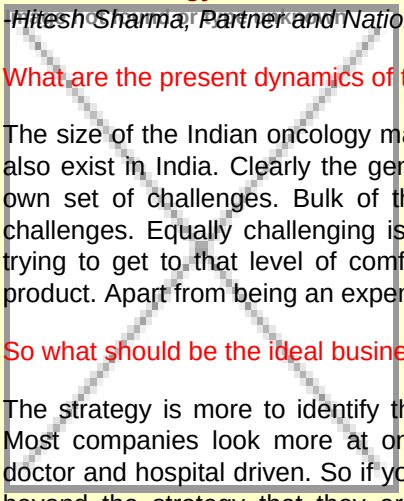
The future

ORG IMS, in its annual forecast, has predicted that globally the growth of the oncology market will level out by 2012 due to various reasons. The foremost reason is seen as the tapering of current blockbusters. Introduction of newer blockbuster medicines will come down allegedly due to predictive biomarkers. Further, the expiry of four major blockbuster oncology drugs in the next five years will give way to a number of players in this same space. This will subsequently heat up the competition and intensify the price pressure.

The market will also see a boom of biotech products in the segment. "Biotech products will dominate the scene along with personalized therapy. Target therapy, biomarkers, gene markers and both therapeutic and prophylactic vaccines would be the key to future anticancer treatment. Targeted therapy would ensure that drugs are safe. Though immunized antibodies are also targeted, they are limited by their own toxicity. Molecular stratification of the patient would lead to the designing of the drug in the future," said Dr Rama Mukherjee, former president, R&D, Dabur Pharma.

"Indian oncology market is worth around Rs 800 crore,"

-Hitesh Sharma, Partner and National Leader Health Science practice at Ernst & Young.



What are the present dynamics of the Indian oncology market?

The size of the Indian oncology market is around Rs 800 crore. The therapies, which exist globally, also exist in India. Clearly the generic drugs are not that dominant in this segment because of its own set of challenges. Bulk of the products is mainly biotech, which again has its own set of challenges. Equally challenging is the investment that goes into the Indian companies which are trying to get to that level of comfort, because in biotech no two facilities can produce the same product. Apart from being an expensive process, it is a high-risk investment segment.

So what should be the ideal business strategy?

The strategy is more to identify the patients and see to it that they get the necessary treatment. Most companies look more at one-to-one doctor inputs and information. This segment is more doctor and hospital driven. So if you ask me, the only strategy that companies should adopt is to go beyond the strategy that they are presently following, i.e., going to tier-2 and tier-3 cities and widening their reach there. That again depends on the kind of facilities required by these kinds of ailments. Because it is a niche segment and you will have the same players continuing to invest and coming out with new products, that itself will be a boost to the market. As far as price is concerned, it is a debatable issue and there isn't any clear solution or answer for any company on the pricing structure. It will remain premium because we all know that the investment an Indian company puts in is quiet huge.

What are the current research trends in cancer?

There is a lot of research happening in the biosimilars space and India is actively participating in that space. This in a way contributes to the drug delivery systems. People are bullish about it because it saves a lot of R&D time and if it is a similar product and if you can show some efficacies in that then you do not need to show a whole host of clinical trails. What I understand is that the products are all in the development phase.

How you see the oncology market emerging in the next three years?

The market in the past three years has been growing at 25 percent and is amongst the top three segments in India. I do not expect it to slow down. You will see the arrival of a lot of biotech companies in this segment and that should only give an alternative to the Indian public. The debate on pharma turning to biotech continues because we have come to a stage where there are no life style diseases which do not have therapies and biotech gives a pharma company the additional space to operate.

Do not be surprised because within a few years you will have some niche solutions rather than a medicine, which takes care of one particular therapy. Suck work will be happening in oncology and similar segments. While blockbusters might be there in the market for a few more years, upcoming niche solutions will cater to a few people, but will be more effective.

Nayantara Som

Nayantara Som with inputs from Jahanara Parveen (Bangalore) and Shalini Gupta (New Delhi)