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Anti-cancer moves of biotech companies

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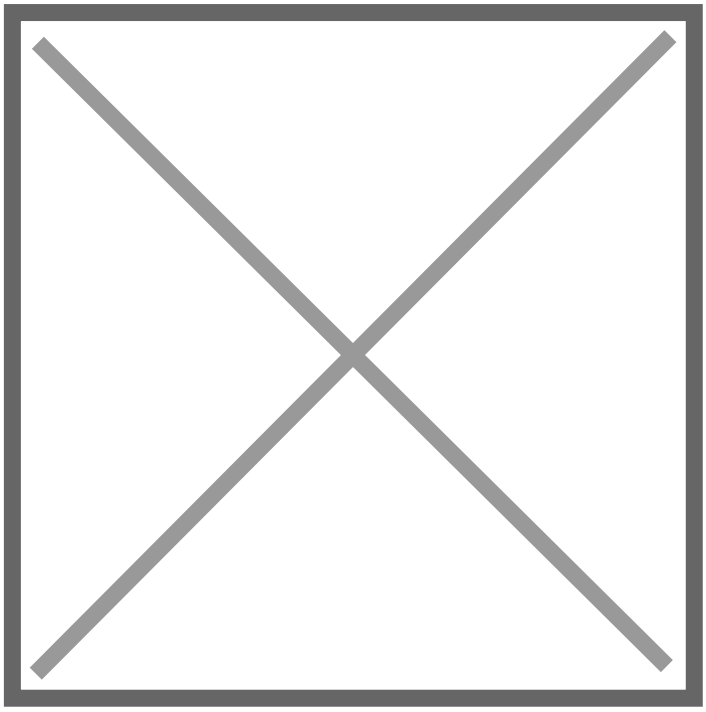

Anti-cancer moves of biotech companies

Biotech companies are bullish about the prospects in the oncology segment and are making announcements more frequently now. A list of some of the major developments is presented here.

Actis Biologics

Mumbai-headquartered Actis Biologics (ABPL), founded in December 2005, is an emerging biopharmaceutical company developing new therapies for life-threatening diseases. It has a strong focus in the areas of cancer and cardiovascular disease. The company is building a strong pipeline of clinical stage products (some of which are already in human trials) through in-licensing and internal research. ABPL has in-licensed technology platforms in the areas of ribozymes, gene therapy, vaccines and recombinant protein technologies. All of them have shown promise in either human (Phase I and Phase II molecules) or in animal models (preclinical molecules).

The company submitted a project titled "Delivery of MSP36 with Lenti Viral Vector" to the DBT in December 2005. This was approved for funding in 2006 and the loan was sanctioned in April 2007 and funds dispersed in May 2007. ABPL's major product is Anjizoyme, which will target mainly lung and breast cancer. "This will target a $16 million market opportunity, the first application being lung and breast cancer. Angiozyme was found to be very effective in Phase II trials and we have now applied to DCGI for Phase III trials," said PN Venugopalan, president, Actis Biologics. The company was also in news recently for the acquisition of its technology platform for effective treatment of hepatic cancer, from CellPoint Diagnostics, USA. This technology, which was given the orphan drug status by the FDA also, helps in drastically reducing toxicity.

Biocon

Biocon in 2006 launched its lead molecule in oncology--BioMAb EGFR, the monoclonal antibody for head and neck cancer treatment. The pivotal trial for BioMAb-EGFR along with standard of care chemo-radiotherapy in advanced Squamous cell of the head and neck (SCCHN) indicated a significant survival benefit as compared to chemo-radiotherapy alone. Clinical trials are on going in glioma and NSCLC. A novel monoclonal antibody targeting CD20 for NHL, B-CLL is in preclinical development.

Kiran Mazumdar Shaw, chairperson and managing director, Biocon shared, "It was interesting to bring the first true proprietary immunotherapeutics to the Indian market. BioMAb-EGFR is competitively priced, making cancer treatment more affordable. It has the potential to be a billion dollar product and we expect it to be worth Rs 100 crore in the next three years."

The company has made an investment of approximately Rs 150 crore in developing BioMAb EGFR, including the clinical development programs and the manufacturing facility. The investment in the clinical development program is still in progress for other cancers and each clinical trial is costing around Rs 15-20 crore. Biocon's other products for use in the oncology segment includes EPO and G-CSF.

MNCs

GlaxoSmithKline

With in-licensing being a major part of its strategy, which also accounts for a major part of its growth, the Indian market saw the launch of Tykerb in the first quarter of 2008. With around eight in-licensing deals already signed and with sales of Rs 80 crore in biologicals in the previous fiscal, GSK has a good number of anti-cancer products in the pipeline. One of its major offerings in the pipeline for the Indian market is its anti-cancer vaccine for cervical cancer. The product is to be launched in India by 2009, despite industry experts claiming that the product can face hurdles of pricing issues. Launched in the US and the EU in 2007, the product did face some hiccups with the FDA. The authority was seeking clarification on the clinical data details related to this vaccine thus delaying the launch. However, the feather in the cap for GSK proved to be when in June 2008, Cervarix was confirmed as the UK Department of Health's vaccine of choice for its national human papilloma virus (HPV) immunization program.

Novartis India

Novartis India's approach to the Indian oncology market is slightly different from its global business model. It has taken into account two factors. First, the Indian market has a small segment of patients who are covered by total medical care and second, while direct-to-patient promotion is allowed in the US, in India the promotion of healthcare products is only through physicians. The Indian business model focuses on generating the prescriptions by sending representatives. "Global pricing in developing markets restricts the access of innovative therapies to the reimbursed masses," said Ranjit Shahani, vice chairman and MD, Novartis India. Hence, on these lines the company supplied its oncology drug, Glivec, free to around 9,700 patients. Same is the case with Asunara which is available globally as Exjade. Exjade is available at a cost of Rs 60,000 per month's therapy, while Novartis has slashed the rate down to Rs 4,000 per month!

Dabur

The oncology major, Dabur Pharma has almost 40 anticancer drugs in its portfolio. This consists of both cytotoxic agents as well as hormonal drugs that cover various types of cancer. Dabur came out with a formulation, Nanoxel (a nanoparticle-based formulation) which is free from chremophore and the toxicity (hypersensitivity reactions). "Nanoxel is India's first nanotech-based drug delivery system that was released in January 2007. In a conventional Paclitaxel-based formulation, one has to give a premedication, whereas this is not required in Nanoxel. There is no nuetropenia in Nanoxel and its efficacy is higher than conventional Paclitaxel," said Dr Shivakant Mishra, vice president, clinical research and medical services, Dabur.

Nanoxel was first approved for metatstatic breast cancer and later, based on a few studies, was found suitable for other indications such as ovarian cancer and small-cell lung cancer. "We are working on a NDDS formulation that is in clinical trials. We would like the anti-cancer drugs available to the patient in a very cost-effective manner. We are making both APIs and formulations and we have the interest and ability to see that drugs are available to a maximum number of patients," Dr Shivakant added.

Intas Biopharmaceuticals

Currently Intas Biopharmaceuticals has an oncology portfolio of 26 products comprising of 22 oncology drugs and four biotechnology products. "The introduction of GEFFY, for treatment of lung cancer, especially non-small cell lung cancer (NSCLC), has strengthened our domestic market share in the lung-cancer market. Expanding current portfolio of lung cancer drugs, which comprises CYTAX, GEMIBINE, CARBOPA, and TAXOCARE, the company is poised to grab a major market

share in India," said Simon Daniel, chief executive (marketing), Intas Biopharmaceuticals Ltd. As part of its expansion strategy, Intas Biopharmaceuticals Ltd will be launching four oncology products in the coming months. "Two drugs in solid tumor segment, namely Pemetrexed (brand name: PEMMET) and Oxaliplatin (brand name: OXITOZ) and two drugs in hematological malignancies segment, namely Lenalidomide (brand name: LENOME) and Amphotericin B (brand name: AMFY), are coming up," added Daniel.

With target revenues of Rs 100 crore, currently the company has a couple of biotech products in the pipeline, which will be launched in the near future. With these targets, the company believes that growth is fuelled by deeper penetration into the less regulated markets of Asia, Africa, Latin America and the Middle East.

Panacea Biotec

The third largest biotech company in India, Panacea Biotec, forayed into the oncology segment last year. It launched seven ant-cancer products--for treatment of breast cancer, brain tumor, ovarian cancer, pancreatic cancer, prostrate cancer and colorectal cancer-in India. The drugs were manufactured by a Mumbai-based company and sold under the brand name of Panacea Biotec. A new strategic business unit SBU, Oncotrust, with a strength of 50 sales specialists was set up to market the drugs with an aim to register sales volumes of Rs 15-20 crore in the oncology chemotherapy segment over the next three years. The company, which generated total sales of Rs 830.44 crore in 2007-08, hopes to achieve Rs 12 crore in revenues from this segment by the financial end. "Market for oncology products is highly competitive, yet we have been able to garner sales of around Rs 50 lakh every month," said Rajesh Jain, joint managing director, Panacea Biotec.

RPG Life Sciences

RPG Life Sciences, the life sciences division of the Kolkata-based RPG Group, is revamping its business strategies to enter the biotech industry. "We will be launching one product every year. We will gradually move from being an API player to a formulation player. The investments will be on three fronts-capacity expansion, capacity creation and facility upgradation for regulated markets," said Arvind Vasudeva, managing director, RPG Life Sciences.

According to him, RPG Life Sciences' biotech division will predominantly focus on prime segments such as oncology, immunosuppressant and other high value biotech products. "We have expanded our R&D team so as to bring one-two new molecules in the market every year. We have also doubled our oncology capacity and are working on enhancing our immunosuppressant capacity. This will help us to commercialize our pipeline products," said Vasudeva. He also added that the company would spend about Rs 30-35 crore over the next three years on these initiatives.

Shantha Biotech

Hyderabad-based Shantha had launched the Cytocrest initiative, in an effort to prolong the life of cancer patients through cost-effective therapies. Under this initiative, it's introducing several new generation oncocare products which are either developed in-house or through alliances with major pharmaceutical companies. Shantha's whole gamut of therapies in cancer care has therefore been planned under the flagship of Cytocrest, which includes chemotherapeutics, biological therapy and supportive therapy. These are for marketing in India only.

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