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Affordable cancer treatment Competition hots up

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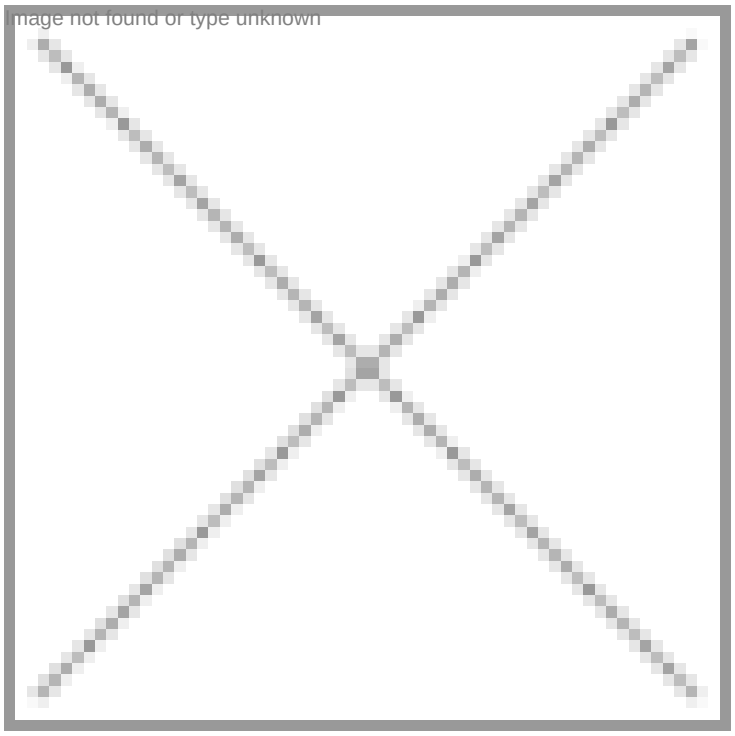

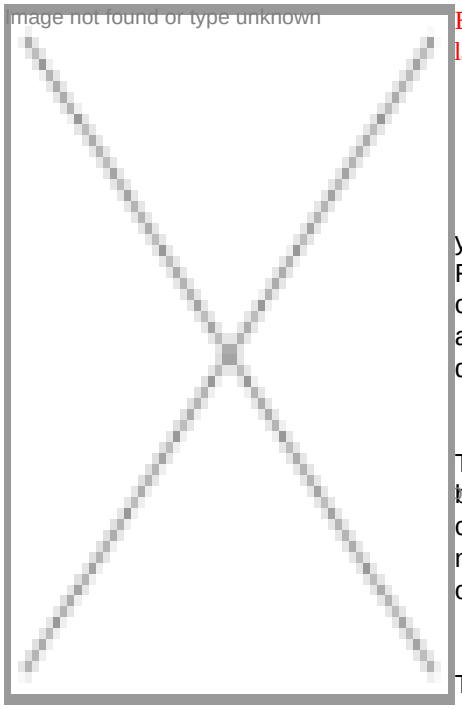

Big and small biopharma companies are trying to capitalize on the India oncology market via lars.

India accounts for 7.5 percent of the total new cases of cancer globally, with only China and the US ahead in reporting the emergence of new cases. With approximately one million cases and approximately eight percent fatalities each year, cancer is becoming a leading cause of death in India. According to the Cancer Foundation of India, cancer impacts up to 2.5 million people in India annually. Lung cancer among males, cervical cancer and breast cancer among females, and head and neck cancer in general are the most common cancers in India. The primary drivers are an aging population, changes in lifestyle, pollution and genetic causes

The current size of the anti-cancer market in India, according to Frost & Sullivan, is between 1,650 and 1,750 crore (2011). The market is expected to grow at a compound annual growth rate (CAGR) of 21 percent from 2008 to 2014, touching nearly 3,309 crore. In fact, drugs that are used to treat cancers have emerged as one of the fastest growing segments in the pharma sector, often outperforming the

The future growth is being driven by the introduction of new treatments, increasing number of patients on chemotherapy and improved access to modern cancer

therapies. Also, the shortfall in diagnostic infrastructure in India to combat cancer is huge. The top 10 drugs to treat cancers account for 70 percent of the market and the annual sales in 2009 for this class of drugs was estimated to be over 2,60,000 crore ($50 billion) and is expected to hit the 3,90,000 crore ($75 billion) mark by 2013.

Commenting on the market potential, Dr Manu Jaggi, director, R&D, Dabur Research Foundation (DRF), says, â€œThe global cancer market will be primarily driven by the increase in sales of biologic drugs. The targeted drugs now appearing on the market should be just the first wave of new anti-cancer therapies. The repertoire will expand rapidly over the next five years as more targets are identified. Cancer vaccines have also seen a great deal of R&D investment with over 30 different cancers. Breast cancer will become most common cancer among Indian women by 2020.â€?

Sharing his thoughts, Dr Shiladitya Sengupta, assistant professor of health science and technology, Harvard Medical School, US, says, â€œThe projections point to the fact that soon cancer is going to emerge as one of the biggest killer disease and close to 12.5 percent of the Indian population will die of cancer in the next 20 years.â€?

Competition hots up

Oncology remains the single largest therapeutic area for both large pharmas and start-up companies. According to Mr Ajaykumar Sharma, practice head, pharma and biotech practice, Frost & Sullivan, South Asia and Middle East, â€œGlaxoSmithKline (GSK) and Merck Sharp & Dohme (MSD) are leading the market crossing the billion dollar mark in sales. Each is witnessing a growth of 50 percent year-on-year in the cancer vaccine space.â€?

According to reports, the sales of MSD pharmaceutical's Gardasil, used to tackle cervical cancer, is said to have increased72 percent in 2010 as compared to 2009. At the same time, GlaxoSmithKline's Cervarix gained 60 percent market. Both are available in India, since they got approval from the Drug Controller General for sale in India for use by women aged between nine and 45 years.

Pointing towards the fact that the oncology market is dominated by MNCs, Mr Ajaykumar says, â€œThe profits from salesfor MNCs such as Roche, account for approximately 22 percent and Dr Reddy's Laboratories has approximately 13-to-14 percent of the share. Other top Indian companies in the segment include Intas Biopharma and Natco.â€?

Besides big pharma players such as Bayer, Fresenius Kabi, Novartis, Pfizer, Roche and Sanofi-aventis, companies thathave an active role in offering cancer treatment are Natco Pharma, Sun Pharmaceuticals, Dr Reddy's, Lupin, Cipla, Zydus Cadila, Biocon and Intas Biopharma. These are promoting products for the treatment of different cancers, including breast cancer, lung cancer, ovarian cancer, prostate cancer, head and neck cancer, cervical cancer, renal cell carcinoma and pancreatic cancer.

At the same time, looking at the huge market potential and opportunities, many Indian companies such as Intas Biopharma, Biocon, Dr Reddy's Laboratories, Transgene Biotek, Inbiopro Solutions, IMGENEX, Panacea Biotec, Mitra Biotech, Bharat Biotech and Shantha Biotechnics, have also been working on developing new therapeutics, kits and drugs for many years. While some of them have already launched products, others are still at various stages of R&D.

Biocon, the leading biotech company in India, launched BIOMAb EGFR, a humanized monoclonal antibody that falls under a class of cancer treatment option known as targeted therapy. The price of the product is said to be much lower than similar drugs available in the country.

Dabur Pharma launched nanotech-based chemotherapy in India. This nanoscale drug delivery system for the widely used anti-cancer agent paclitaxel was the first-of-its-kind in the country. Nanoxel is a cremophor free water soluble formulation and is indicated as a safe therapy for advanced breast, non-small-cell lung and ovarian cancers. Dabur Research Foundation successfully developed a peptide-based anticancer drug for treating colorectal and periampullary cancers.

Besides these, DRF developed a large oncology pipeline, including cytotoxics, anti-metastatics, biologically targeted drugs and phytochemicals for treating various cancers. Panacea Biotec, a leading vaccine player, in 2011, launched an anti-breast cancer product, albumin-bound Paclitaxel particles formulation drug, PacliALL. The product is available at a price, which is approximately 50 percent lower than competitive products in the domestic and global markets. The company is investing 55 crore on a commercial anti-cancer formulation facility at Baddi, Himachal Pradesh, expected to be licensed and operational this month.

Chandigarh-based Venus Remedies, apart from its product 'Gemcitabine' currently in market and used in the treatment for cancer, also developed a novel formulation for targeted delivery.

According to Dr (Mrs) Manu Chaudhary, joint managing director, Venus Remedies, â€œVenus has developed a novel formulation for the targeted delivery for increasing the specificity and the efficacy of anti-cancer drug, which would reduce the

side effects of the therapy to a great extent. At present, the formulation is in pre-clinical stage.â€?

Working towards affordable treatment
With the increase in the incidence of people being affected by cancer, the focus is rapidly shifting towards developing novel drug delivery systems and combination therapies. The monoclonal antibodies (mAbs) are considered to be worthy candidates for developing a safe therapy, due to their specificity, as compared to chemo and radiation therapy.

mAbs therapy in India is very expensive and out-of-reach of most cancer patients. â€œWhile targeted drugs are here to stay for at least another decade, stem cells hold tremendous potential for treating cancer. DRF has taken several steps to face the challenges ahead,â€? adds Dr Jaggi.

Syngene International, a subsidiary of biotechnology major Biocon, entered into a discovery and development collaboration with US-based Endo Pharmaceuticals in order to develop novel biological therapeutic molecules against cancer. The company has also collaborated with a US-based start-up company, IATRICa, for creating a â€œtherapeutic vaccineâ€? that will help the body activate the immune system to fight cancer on its own, with technology developed at the Johns Hopkins University.

IMGENEX India, which is based at Bhubneshwar, is developing a herceptin biosimilar, which will be available to Indian patients at an affordable cost. IMGENEX estimates that around 3,500 patients are responsive to herceptin, out of the 70,000 new breast cancer patients that are diagnosed every year in India. It is also developing novel therapeutic monoclonal antibodies for the treatment of prostate cancer in collaboration with Dr G P Talwar Research Foundation, New Delhi. The development of these antibodies is at a very early stage. The company is building a state-of-the art GMP facility in Bhubaneswar, Orissa, for production of biosimilar monoclonal antibodies and the same will be operational in mid-2013 with an initial investment worth approximately 20 crore.

Dr Sujoy Singh, MD, IMGENEX India, says, â€œBreast cancer treatment using Herceptin mAb costs about 16 lakh per year. Most of the cancer patients in India cannot afford this treatment. Our goal is to make the monoclonal antibody therapy affordable to the masses. We expect to release our first product in the year 2014-15.â€?

Gurgaon-based ARA Healthcare is working on cancer molecules, ARA I, ARA II and ARA III, which are viewed as valuable addition to the current line of therapy with high commercial potentials. The company is carrying out pre-clinical and phase I clinical development of ARA I, a novel anti-metastatic protein with a potential therapeutic effect in several cancer types. The company is also working on ARA II, a novel recombinant pro-apoptotic protein that helps in selective targeting of cancer cells with potential of wider application in variety of cancer types, including cancers of gastro-intestine, lung, ovaries, pancreas and gliomas among others.

Furthermore, the company is also conducting trials of ARA III, a thrombopoietic growth factor. â€œIn the last two-and-a-half years, the pharmacological activities of these molecules have been studied. The process for commercial scale production and purification and formulation have been developed," says Dr Rama Mukherjee, MD, ARA Healthcare.

Chennai-based Shasun Pharmaceuticals recently entered into a joint drug development agreement with Nanoparticle Biochem Incorporated (NBI), a spin-off company of the University of Missouri, and created a new joint venture, Shasun-NBI LLC. This will involve research on new therapy for treating late-stage prostate cancer for more than five years. The efficacy studies in mice with prostate tumors have demonstrated an unprecedented 85 percent reduction in tumour volume after administering a single dose of radioactive gold nanoparticle.

According to Mr Abhaya Kumar, managing director, Shasun, â€œTo capitalize on the changing trends, Shasun will make a 7.8 crore ($1.5 million) initial investment to bring promising new nanotechnology for cancer treatment. We are now gearing-up to formulate nanomedicine kits at our FDA approved facilities as we still await the FDA approval for clinical trials in India and in the US. Hospitals in India and at the University of Missouri could be among the first to initially test the drug in pilot level clinical trials offering benefit for cancer patients.â€?

LeadInvent, which is based at New Delhi in collaboration with the International Center for Genetic Engineering and Biotechnology (ICGEB), is working on the development of combination therapy for treatment of cancers with enhanced efficacy, particularly for resistant and non-responsive cancers. Another New Delhi-based start-up Invictus Oncology, aims to develop affordable and effective cancer drugs with a team of scientists already working in the area.

Bangalore-based Mitra Biotech aims to personalize treatment option for cancer based on detailed molecular characterization and identification of key drivers of cancer progression and metastasis. The company is actively working towards the development of technology for cancer diagnostics.

Venus Remedies developed a novel detection product for the early detection of cancer. This formulation has successfully undergone phase I and phase II clinical trials and now permission is awaited from the Drug Controller General of India (DCGI) for conducting phase III clinical trials.

Recently Sanofi-aventis, and the Oxford University, UK, entered into an agreement to conduct multi-phase oncology clinical and translational research with INDOX, India's leading academic oncology network. Through this partnership and experience of India's top oncologists and scientists, clinical research would be conducted in accordance with the highest internationally recognized ethical standards.

The researchers and doctors from the Indian Institute of Technology (IIT), Mumbai; LV Prasad Eye Institute, ApolloHospitals, Hyderabad; and Tata Memorial Hospital, Mumbai; have researched and developed a nano version of an existing cancer drug, carboplatin. The new drug will reach the cancerous cells at a faster pace, reduce toxicity levels of chemotherapy and further increase chances of survival of the patient.

Future forward

Since the drugs developed in the West are very expensive and even generic versions have higher costs, the big question is that how many Indians can afford to go for the treatment. Hence the best way before India, seems to be proper planning and encouragement of the firms involved in oncology drug development.

Mr Ajaykumar Sharma of Frost & Sullivan says, â€œAlthough oncology is the next game changer for the industry, the market is mainly import driven with MNCs dominating the market. We hardly see any R&D in cancer coming out of the Indian companies. This is because cancer research requires a huge investment and Indian companies do not have the cash flow. Indian companies are active more on the biosimilar front in oncology, which requires an investment of around 104 crore ($20 million) for research.â€?

â€œCurrently we are a young country but after 20 years, the situation is going to change and we will have a much older population. Therefore, planning for the next 15 years is a must before it becomes an epidemic due to various lifestyle factors. This is the good time to start investing heavily in research and build up our capabilities for future. We need to create mechanism for industry to come out with innovation,â€? Dr Shiladitya Sengupta of Harvard Medical School points out.

The burden on healthcare systems can certainly be lowered if diagnosis is done at the right time. Both preventive and post-treatment diagnosis can help to reduce the number of deaths as well as the recurrence of the diseases. While the recent proposal to reduce prices of oncology drugs by the government is expected to help the patients, it might affect Indian companies as there would be very less margins.

However, looking at the market potential, Indian companies need to continue to put efforts in the segment.

â€œI believe that in the coming years we will see tremendous advances in molecular diagnostics and therapeutics using off-patent chemical and biological drugs, especially therapeutic mAbs for treatment of cancers in India,â€? concludes Dr Sujoy Singh of Imgenex.

Rahul Koul in New Delhi
(with inputs from Nayantara Som in Mumbai)