

Indo-Japan bio partnerships on rise

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Beaming with confidence at his company's march into the Japanese market, Dr Rashmi Barbhैया CEO, Advinus Therapeutics was quite hopeful that the partnership with Takeda Pharmaceuticals will have a great future. "Takeda and Advinus teams will together advance globally in networked innovation for addressing key pharma R&D productivity and issues for better returns on R&D investments," he had added when this exclusive three-year discovery deal was signed in October 2012. While Takeda will receive worldwide commercial rights to the drug candidates emerging from this alliance, Advinus will receive \$36 million worth guaranteed research funding, \$9 million in milestones leading to candidate selection, and is also eligible to receive future clinical and regulatory milestone payments of up to \$45 million per product, plus royalties on product sales worldwide.

Such a deal surely has made many others in the industry to realize that Japanese manufacturers can offer great opportunities.

In yet another example of the growing proximity between two bioscience industries, Dr Reddy's Laboratories (DRL) had formed a joint venture with Fujifilm in June 2012, to develop, manufacture and promote generic drugs in Japan. The venture has 51 percent stake owned by Fujifilm and 49 percent by Dr Reddy's, and intends to launch its first products in Japan in the next three to four years. Dr Reddy's will develop, manufacture and promote competitive and high quality generic drugs utilizing both Fujifilm's advanced quality control technologies and DRL's expertise in cost competitive production technologies for active pharmaceutical ingredients and formulations.

In fact, the mutual bioscience relationship between the two nations has come a long way since the establishment of the first ever Indo-Japanese joint venture firm, Sanzyme (earlier known as Uni-Sankyo) in 1969. Headquartered in Hyderabad, the company expanded its activities and evolved as the manufacturer of fermentation and biotechnology products in the country.

Driving on generics

The complex regulatory framework in Japan creates a high entry barrier and hence the likely route to gain presence is

through partnerships with local generic companies or acquisitions of local companies. Using the same model, the Indian generic players such as Lupin, Ranbaxy and Cadila Healthcare have made inroads with the Japanese market.

The Japan-based Kyowa Pharmaceutical was acquired by Lupin in 2007, leading to the latter's access to the Japanese market. The company has made an investment of \$63 million in the area of generics in Kyowa. Cadila Healthcare too has presence in the Japanese market since 2007 after it acquired Nippon Universal Pharma. The company is pinning big hopes on the Japanese generics market.

The country, which currently has a one percent share in Cadila's overall revenues, is all set to become a key market in the coming years. It already has around 20 products in the Japanese market including three recent launches.

One of the major example of Japanese pharmaceutical companies entering India, is the acquisition of Ranbaxy Pharmaceuticals by Daiichi Sankyo in 2008 and the establishment of a R&D centre and facility by Eisai Pharmaceuticals. At the beginning of 2010, Eisai, the fourth largest Japanese pharmaceutical company, started operations in India; by setting up an API plant and knowledge center at an investment of \$50 million.

Meanwhile, Ranbaxy is exploring opportunities of marketing its generic products through Daiichi's distribution network post its acquisition by the latter. Astellas, the second largest pharmaceutical company in Japan, too has opened its subsidiary and marketing operations in India four years back.

As against an estimated global 6-7 percent generic drugs market penetration in 2007, the Japanese government has implemented various measures to promote the use of generic drugs to achieve its goal of reaching 30 percent volume share for generic drugs by the end of march 2013. The market thus offers new growth avenue for Indian generic players.

Attracting biosuppliers

Besides pharmaceuticals industry, the biosupplier industry too has not lagged behind in its zeal for collaborative efforts. A well known Japanese supplier, Shimadzu, has set up its direct presence in India in 2006 by establishing Shimadzu Analytical India, as a subsidiary of Shimadzu Asia Pacific, Singapore. The company has tied up with many Indian distributors to supply its broad range of analytical products mainly chromatography and measurement instruments.

The recent example in this vertical is that of a joint venture "DSS Takara Bio India" established between India-based DSS Imagetech and Japanese company Takara Bio, that came into effect in April 2011. With the capital investment of \$1 million and 25 employees, the DSS Takara Bio India has been engaged in the manufacturing and sales of research reagents and kits. Dr Ushakar Nag, director, DSS Takara Bio believes that they are bringing to India world-class Japanese manufacturing technology of high-end molecular biology reagents thereby giving a competitive edge to Indian biological research.

Another Japan-based leading manufacturer of automated nucleic acid extraction systems and supplies, PSS Bio, recently had a technical collaboration with Mumbai-based Biotron Healthcare. The partnership will produce magnetic-based nucleic acid extraction kits, which is expected to reduce the cost of extraction. Mr Hideji Tajima, president, PSS Bio, Japan in an earlier interview with BioSpectrum reiterated that the company is hoping to start the evaluation of fully-automated genetic diagnostics systems in India.

Growing research relationship

Chennai-based Indo-Japanese joint venture, Nichi-In Centre for Regenerative Medicine (NCRM), has in the past 10 years brought together the Indian and Japanese technologies and institutes to accomplish several significant contributions in the field of regenerative medicine/biotechnology. The autologous immune enhancement therapy, which has been in clinical practice in Japan, since 1990s has been brought to India by the NCRM.

Dr Samuel JK Abraham, director, NCRM says, "To my knowledge, the natural killer (NK) cell and cytotoxic T lymphocytes (CTL) based immunotherapy has been provided only by NCRM in India, since 2011 and this was accomplished by the technology fetched from Japan and also the constant interaction of personnel between the two countries. Japan has the advantages of several state-of-the-art technologies in lab chemicals, reagents including cell culture scaffolds and nanomaterials. In India, we have young talents and wide spectrum of clinical diseases which are rare in the West and in Japan and so both the countries will benefit by a collaboration as accomplished by NCRM."

Among the recent examples, the collaboration between Waseda University and GN Corporation, both from Japan and Sankara Nethralaya and NCRM in India, has led to the development of the polymer-based in vitro cell expansion technology for multiplication of corneal limbal stem cells and further animal studies have been already completed and clinical studies are to be conducted soon. The invention was awarded a patent

last year.

Apart from that, encouraging results have been achieved from the joint efforts of Hokkaido University and Waseda University in Japan and Tamil Nadu Veterinary and Animal Sciences University (TANUVAS) and NCRM in India. These research partners have developed a scaffold for spinal cord injury, which can retain the implanted autologous stem cells into the site of the injury. This technology has been tried in animal victims of spinal injury and safety studies has been proven with a publication.

Enhancing bonding efforts

The Japanese government has expressed willingness to invest in all sectors of the Indian economy including the biotechnology, nanotechnology, and life sciences projects. Economically, further consolidating the comprehensive economic partnership agreement (CEPA) signed in August 2011, India and Japan will be cooperating on the life sciences sector in a major way.

It should be noted that the government of Japan, in 2010, has extended a grant of 120 million yen (approximately equivalent to Rs 7.2 crore) under the United Nations Children's Fund (UNICEF) for maintaining a polio free India project to eradicate poliomyelitis from India.

India Japan Science Council, working for the last 14 years, has so far been a very effective vehicle of science and technology cooperation between the two countries. The India-Japan Joint Committee (IJJC) has been the nodal agency to implement the science and technology agreement signed in November 1985. It looks into major policy issues, reviews the progress and proposes measures for enhancing the cooperation.

While from Indian side, it is coordinated by Department of Science and Technology (DST) with members from Council for Scientific and Industrial Research (CSIR), Indian Council for Medical Research (ICMR), Department of Biotechnology (DBT) and other scientific departments of India, the Japanese side is represented by its ministry of foreign affairs with members from education, science, health, industry and other relevant ministries.

With a view to represent the demands of the Indian pharma companies in Japan, the Pharmaceutical Export Promotion Council of India (Pharmexcil), set up by ministry of commerce and industry, constituted an indigenous body called India-Japan Pharma Alliance in Japan last year. This body will be acting as the Pharmexcil's frontal agency to represent the issues and the challenges faced by the Indian pharmaceutical companies in Japan.

The Confederation of Indian Industries (CII) report 2012 titled "India-Japan: A Growing Strategic Relationship" has predicted that the two countries would achieve a trade target of \$25 billion by 2014.

Strong mutual complementarities between two nations are driving the trade and potential sectors of trade and investment including capital goods, auto parts, chemicals and pharmaceuticals among a wide range. It is very important for both the nations to encourage bioscience cooperation and lay down a concrete road map for the future.