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CROs Are Making Headlines

India's drug discovery service sector is heating up

Setting the tone for new models in drug discovery research, Dilip Shangvi, the managing director of Sun Pharmaceuticals Ltd., said recently that drug research should not always require \$2-2.5 billion worth of investments to develop a drug product.

Sun Pharma, which is presently the largest drug maker in India, is planning on filing its own originally researched products with the U.S. FDA within the next 2-3 years. While addressing a gathering at the Indian School of Business in Hyderabad in south India, Mr. Shangvi said he hopes this plan will validate his conviction that it is possible to bring innovative and differentiated products to market at costs that are affordable to people. Three of these products are currently undergoing clinical studies by Sun Pharma Advanced Research Company, the company's R&D unit.

Cost-effective know-how for R&D processes is the watchword across the spectrum of India's drug making industry and it invariably forms the forte of CROs from the country, as well. While India's R&D services industry is not very big in terms of numbers, industry players have been making headlines in the news lately.

Boosted by IPO

The initial public offering (IPO) launched by Syngene International, a CRO located in Bengaluru, created ripples across the industry. For it was the first time a pure play CRO put its stock up for sale to the public in the country's bourses. Figures from the National Stock Exchange indicated that Syngene's IPO was oversubscribed with bids 32 times the 22 million shares on offer led by strong retail and institutional investor interest as it closed on July 29.

Syngene, a subsidiary of Biocon Ltd., India's leading biotherapeutics firm, offers integrated end-to-end drug discovery and development services for novel molecular entities (NMEs) to clients ranging from start-ups to top MNCs including BMS, Abbott and Baxter. The CRO has capabilities in medicinal chemistry, biology and toxicology, custom synthesis and process research.

Syngene says it is intent on establishing new capabilities and augmenting existing services across the discovery and development continuum, entering areas like neglected diseases and inflammatory pain for research. Currently, its focus areas include oncology, immunology, neurosciences and metabolic disorders.

Another CRO grabbing headlines is GVK Biosciences of Hyderabad. The company signed a deal with Akaal Pharma from Melbourne, Australia for its topical AKP-11 ointment for psoriasis. Akaal is seeking GVK's support to advance Phase II clinical program with the drug. GVK Bio is providing clinical supplies, manufacturing and analytical support, according to the company.

What makes the GVK Bio-Akaal alliance newsworthy is that the deal came even as the CRO is facing regulatory action from the European Medicines Agency (EMA) for alleged "systematic manipulation of clinical trial data" in May last year.

According to EMA, an inspection by the French Medicines Agency (ANSM) at the company's facility in Hyderabad revealed data manipulation of electrocardiograms during the conduct of some studies of generic medicines, which appeared to have taken place over a period of at least five years. Now the EU has imposed a ban on around 700 products in all 28-member nations on the basis of bio-equivalence studies conducted by GVK Bio during the period between 2004 and 2014. GVK Bio, however, feels EMA moved ahead with the ban not paying heed to the CRO's repeated pleas to have "a deeper scientific dialogue."

Discovery deals

Earlier in June, GVK Bio reached an agreement with Medivir AB to undertake all the synthetic chemistry work meant for the Swedish drug firm's discovery portfolio comprising oncology and infectious disease candidates. Medivir said the partnership would consolidate all current outsourced chemistry in a single facility at GVK Bio's discovery research campus, and help cut its R&D costs.

At the same time Curadev, a newcomer CRO from New Delhi, bagged a \$555 million contract from Roche to develop a preclinical immune drug in April. Curadev's small molecule lead could become a mono therapy as well as a combo as the drug can potentially prevent local tumor immune escape and avoid resistance to other immunotherapies. The CRO will receive an upfront payment of \$25 million and up to \$530 million on reaching certain developmental milestones from the Swiss drug maker.

Aurigene Discovery Technologies Ltd., the R&D services division of Dr. Reddy's Labs is another CRO making headlines without any major deals. The CRO said it is planning to develop a few of its NCEs and even bring them to market on its own, and not waiting for out-licensing deals or partnerships with big companies. Besides anti-infectives, the firm runs over a dozen programs in oncology and inflammatory therapies.