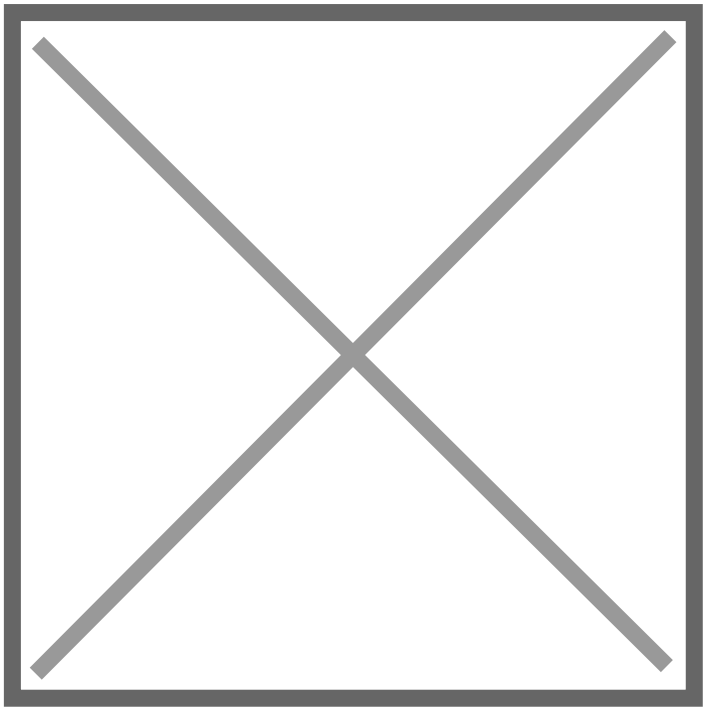
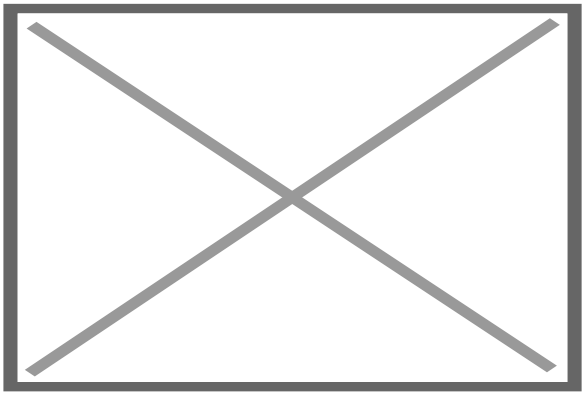
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Drug Discovery Collaborations The Way to go..

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The latest Advinus-Takeda collaboration along with a spate of other recent out-licensing deals in the pharma industry have indicated a trend of multinational pharma companies looking to not just outsource their chemistry services, but rather allow Indian entities to head the part of their drug discovery programs too. *BioSpectrum* looks at where India's potential lies as a drug discovery destination



Over the last few decades, India has reiterated its capabilities in providing dependable and cost-effective chemistry services to big pharma through a multitude of outsourcing deals. A large percentage of these collaborations, however, are no longer limited to short-term outsourcing agreements but rather long-term milestone-based partnerships.

Takeda Pharmaceutical, the Japanese pharma giant, two years after announcing its intention to strengthen its India focus, including those for a variety of functions such as sales and marketing, research and development, chemistry, manufacturing and control (CMC), manufacturing and IT, took the plunge, with a three-year drug discovery collaboration with Advinus Therapeutics in October this year. As a part of the deal, Advinus Therapeutics will receive a guaranteed payment of $36 million as well as a milestone based payment of $9 million, dependent on the targets achieved during investigational new drug (IND) candidates selection.

Ã¢â?¬Å?The Takeda-Advinus deal seems to be a holistic one, which will help other internal programs and provide them good breathing space as well as provide an impetus to drug discovery in India,Ã¢â?¬? said Mr Siddharth Dhodi, manager, life sciences, Yes Bank. Ã¢â?¬Å?This deal will not be based on prior research carried out at Advinus,Ã¢â?¬? Dr Rashmi Barbhaiya, CEO, Advinus Therapeutics,Ã¢â?¬? said by adding, Ã¢â?¬Å?Instead we will involve entirely new projects in therapeutic areas such as inflammation, CNS, and metabolic diseases, on which Advinus has developed expertise through its past projects.Ã¢â?¬?

Highlighting the sentiment, Dr Ajay Kumar Sharma, associate director, pharma and biotech, healthcare practice, Frost & Sullivan, South Asia & Middle East said, Ã¢â?¬Å?Advinus has been focusing on developing its own drug candidates for quite some time and now with the support of Takeda coming in it

would be no surprise if the world sees some blockbuster drugs coming out of their arsenal in the next decade. This move will also increase the confidence for other big pharma's to re-think their strategies.Ã¢â?¬?

Under this collaboration, while Takeda would retain its commercialization rights for any drug candidate emerging out of this partnership, Advinus would be eligible for royalties on its worldwide product sales.

This ofcourse is not the first of such deals. Most Big pharma have struck a deal with Indian contract research organizations (CROs) or pharma companies for drug discovery collaborations in the last decade or less. Pfizer had entered into a R&D collaboration with TCG Lifesciences in 2009. In February this year, TCG Lifesciences delivered a pre-clinical candidate to Pfizer in return for a milestone payment as per the agreement. TCG Lifesciences also has a similar ongoing drug discovery based partnership with Endo Pharmaceuticals, under which it has achieved significant breakthroughs.

Commenting on these developments, Mr Siddharth Dhodi said, Ã¢â?¬Å?The trend of companies moving from a fee-for-service-model to long term partnerships involving research and development of drugs has been growing for some time now. The model which allows for milestone based payments with big pharma owning the assets, is a win-win situation for both.Ã¢â?¬?

Worldwide the trend to outsource research projects to counter the mounting costs seem to have become the norm. As Dr Paul Chapman, general manager, pharmaceutical research division, Takeda said, Ã¢â?¬Å?Collaboration with Advinus is one of our initiatives to enhance our research productivity.Ã¢â?¬? Such collaborations not only mitigate the huge financial risks associated with drug discovery, due to the lower costs for conducting research in India, they also allow to speed up the process considerably.

Another model that is being closely looked at is the one involving out-licensing of Phase I molecules to companies that can conduct further clinical trials for the same. Most experts echo the fact that the Indian pharmaceutical industry still lacks any player that has the resources to take a drug the whole nine yards from discovery to clinical trials. In such a scenario, drug discovery partnerships can help put India on the world map.

Glenmark has been following this strategy to keep its innovation quotient up, and at the same time fund the company's research expenses. Two drugs developed by Glenmark for chronic pain and ulcerative colitis were out-licensed to Sanofi in mid 2011. They are currently in Phase II trials. One of them, a biologic, is a first-in-class therapeutic monoclonal antibody for chronic autoimmune disorders. Sanofi has licensed the rights to all therapeutic indications and is conducting the clinical development program including this trial. Ã¢â?¬Å?This model allows innovative research to be rewarded and presents a niche opportunity to Indian companies, as big pharma is looking for cheaper solutions,Ã¢â?¬? adds Dr Neelima Joshi-Khairatkar, senior vice president, Glenmark Pharmaceuticals.

The road to develop an Indian origin New Chemical Entity (NCE) with a foreign collaborator has however, hitherto been lined by a number of disappointments. None of the molecules developed as a part of licensing deals conducted over the past years, have been successful in clinical trials, yet. Drug discovery programs involving Glenmark, Dr Reddy's Labs, Merck, Eli Lilly and other players have not yielded positive results. Other deals such as Merck-Ranbaxy, Jubilant-Eli Lilly were called off a few years after they were started.

Despite these setbacks, India's capabilities of providing a low-cost alternative for drug discovery continue to be explored. The drug discovery expertise being sought is also evolving. Dr Sharma opined that, Ã¢â?¬Å?The Takeda-Advinus deal is a good start as largely Indian CRO's were considered for their costs for chemistry process involving drug manufacturing. The pre-discovery or the biology processing was mostly absent in outsourcing deals.Ã¢â?¬?

It remains to be seen if the recent positive decisions such as allowing foreign direct investment (FDI) in pharma would send out the right message to big pharma about investing in India's potential, both in terms of cash inflow and creating intellectual property.

Inspite of the challenges, the future is beckoning, as Dr Rashmi expresses, Ã¢â?¬Å?Drug discovery is in its infancy in India and we have a long way to go; especially in the area of early drug discovery. However, we have made a good beginning and there is a promising future.Ã¢â?¬?

Manasi Vaidya