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Pharma R&D opportunities in India

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Opportunity to established pharma and biotech companies to discover and develop new molecules

Pharma R&D in developed countries is experiencing serious problems in terms of huge bottlenecks, lengthening timelines, and flat productivity in spite of exponential increase in budget over the last one decade. The emerging positive trends in India offer a potential solution to some of the these problems. There are seven key broad areas to leverage the advantages that India offers to the established pharma and biotech industries. These include contract research, R&D alliances, clinical trials, R&D for neglected diseases, in-licensing of preclinical as well as early clinical drug candidates, IT applications and data management and herbal heritage.

India has already established its strength in developing, manufacturing and marketing generic products for global market. This success is attributed primarily to its strength in the process chemistry, formulation development and manufacturing areas. Transition to innovative R&D is the natural next step for India. To that end, there are a number of contract research organizations that offer quality and cost-effective services in medicinal chemistry, formulation development, and toxicology areas. In order to do justice to idle intellectual properties and to address the issue of bottlenecks, pharma companies from developed countries are already forging R&D alliances with Indian companies. Such alliances are expected to yield preclinical candidates or clinical candidates with proof of concept in humans. Failure is the norm in pharma R&D business. One of the key contributing factors for the huge projected cost ($800 million) for bringing a new molecule to market include the cost of failures. Within the pharma R& D value chain, failures occur at various stages and cumulative success rate of a given drug discovery program is about 1.5 percent. The probability of success increases to about 50-75 percent once a

molecule enters Phase III clinical trials. By conducting R&D on new molecules up to Phase II clinical trails in a country where the cost of innovation and development can be one fourth, it is conceivable to reduce the cost of failure and eventually overall cost of bring new medicines to patients. This is one of the unique opportunities that India offers at this time.

There are not enough patients and qualified clinical investigators in North America and Western Europe to support clinical evaluation of all drug candidates in development. Such shortage obviously results in costly delays in obtaining proof of concept in humans as well as completing required regulatory clinical trials.

Low cost of innovation and development will allow bringing new molecules for the neglected diseases to market at a much reduced cost. Since the medicines for neglected diseases must be affordable to patients in the poor countries, it is essential to develop these drugs in the most cost-effective manner. India is an obvious option to address the need for the neglected diseases.

Indian pharma R&D has already proven its capabilities in discovering and developing druggable molecules. A number of development candidates are out-licensed by Indian companies to the medium size as well as large pharma companies in the developed countries. This trend is expected to continue.

India is recognized as one of the leaders in the IT industry. This strength in India is already being leveraged in the bioinformatics area to support a variety of drug discovery efforts. In addition, a number large pharma companies are leveraging India's IT strength to support clinical trials and data management. This can be easily extended for safety monitoring and post-marketing surveillance.

Traditional medicines are well-established in India. However, the molecular mechanism of action and identity of active ingredient(s) may not be known for most of these traditional medicines. There are opportunities to apply modern science to elucidate molecular mechanism of action and to identify active ingredients of these medicines. The process of reverse pharmacology can be applied to discover druggable new molecules from these traditional medicines.

In summary, India offers a unique opportunity to established pharma and biotech companies to discover and develop new molecules â€“ offering key advantages in the areas of quality, speed and cost-effectiveness.

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