

Dr. Reddy's, Merck Serono enter partnership

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Dr. Reddy's, Merck Serono to collaborate on biosimilars



Singapore: Dr. Reddy's Laboratories and Merck Serono, a division of Merck KGaA, Darmstadt, Germany, have entered into a partnership to co-develop a portfolio of biosimilar compounds in oncology, primarily focused on monoclonal antibodies (MAbs). The partnership covers co-development, manufacturing and commercialization of the compounds around the globe, with some specific country exceptions.

Dr. Reddy's has been a pioneer and leader in the biosimilars space through proven product development capabilities and the launch of four biosimilars molecules to date. The partnership with Merck Serono expands on Dr. Reddy's presence in the biosimilar space in select emerging markets and enables participation globally.

Mr G V Prasad, vice-chairman and CEO of Dr Reddy's Laboratories said, "We strongly believe that biosimilars is an important area of future growth and these products give us the opportunity to provide affordable and innovative medicines to patients across the globe. With the recent EMA and FDA guidance on biosimilars, it is clear that any significant player in the field will need strong biologics development, manufacturing and commercialization capabilities. Merck Serono's and Dr. Reddy's joint expertise in these fields makes for a powerful global partnership."

"Our expertise in developing, manufacturing, and commercializing biopharmaceuticals gives us a clear advantage in the biosimilars field, and the partnership with Dr. Reddy's will bring their first-in-market experience in biosimilars, as well as their expertise in generics and Emerging Markets, to the table," added Mr Stefan Oschmann, chief executive officer of Merck Serono. "Sharing know-how, risks and rewards is the right approach to enter the emergent biosimilars market and will be a win-win for both parties. It further strengthens Merck Serono's promise to live science and transform lives, by increasing access to quality medicines for patients, physicians and payers."

The deal structure calls for Merck Serono and Dr. Reddy's to co-develop the molecules included in the agreement. Dr. Reddy's will lead early product development and complete Phase I development. Upon completion of phase I, Merck Serono will take over manufacturing of the compounds and will lead Phase III development. The agreement is based on full R&D cost

sharing.

Merck Serono will undertake commercialization globally, outside the US and with the exception of select emerging markets which will be co-exclusive or where Dr. Reddy's maintains exclusive rights. Dr. Reddy's will receive royalty payments from Merck Serono upon commercialization. In the US, the parties will co-commercialize the products on a profit-sharing basis. Additional terms of the deal were not disclosed.