

Agila and Pfenex enter into JV for developing six biosimilars

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Pfenex and Agila Biotech, a subsidiary of Strides Arcolab have entered into a joint venture to develop, manufacture and commercialize an initial pipeline of six biosimilar products for the global market. Operating as a JV, wherein both parties will equally share in decision making regarding product development and commercialization, Agila Biotech will be a 51 percent equity stakeholder.

The lead product for the joint venture is Interferon beta-1b, a biosimilar to Betaseron, indicated for relapsing-remitting and secondary-progressive forms of multiple sclerosis, commencing human clinical trials by Q4 2013.

This multi-product joint venture combines Pfenex's industry-leading expertise in strain engineering and process development with Agila Biotech's biologics manufacturing and clinical development excellence. Under the terms of the agreement, Pfenex will assume primary responsibility for development of an optimized production strain, process and analytical package for each product, while Agila Biotech will be responsible for pre-clinical and phase I development, as well as cGMP manufacturing. The joint venture will then progress the products through phase III and into commercialization. Manufacture of the collaboration products will be carried out at Agila Biotech's state-of-the-art manufacturing facility being built with Bio-XCell at Nusajaya, Johor, Malaysia - a 160 acre site comprised of customized biotech facilities.

Dr Bertrand Liang, CEO at Pfenex said, "One of the global challenges for the future of healthcare is to develop and produce products within the confines of a constrained cost environment. Biosimilars are and will play an increasingly important role in patient disease management. This venture between Pfenex and Agila Biotech will allow us to leverage our infrastructure for the development of safe, reliable and cost-effective therapies for patients to address unmet medical needs all over the world."

"Successful foray into the biologics space for companies like Agila Biotech will allow us to not only leverage time and cost advantage of developing products in India and Malaysia, but also serve as a gateway to a vast region in South Asia, South-East Asia and the OIC region currently underserved as a result of the lack of high quality, cost effective biologics," said Dr Anand Iyer, CEO at Agila Biotech. Dr Iyer also noted that its facility in Malaysia represents a strategic move to bolster Agila

Biotech's manufacturing presence in the region and tap into unmet global demand for quality biologics at affordable prices.