

Malaysian firm Duopharma forays into biosimilars

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Singapore: Malaysia's chemical company Duopharma has tied up with Korea's PanGen Biotech to pioneer a clinical trial of Erythropoietin (EPO) in Malaysia to treat end stage renal failure patients. Under the agreement, Duopharma will obtain commercialization rights for product marketing and distribution in Malaysia, Singapore and Brunei.

This latest development will propel Duopharma to compete for high value added partnership projects in the commercialization of biosimilars while eliminating the need to invest in very expensive clinical trials and long gestation periods to deliver the product to market. Duopharma will undertake the first biological trial Malaysia jointly with PanGen

Biosimilars, dominated by global pharma players, is forecasted to expand at a compounded average growth rate of 12 per cent in Asia to an estimated \$2.5 billion (RM8 billion) in the Southeast Asian region by 2020.

Duopharma has to date invested \$2.2 million (RM7 million) to establish Malaysia's first National Pharmaceutical Control Bureau-certified GMP biological fill & finish facility in Klang and will potentially invest an additional \$2.8 million (RM9 million) for a pre-filled syringe suite should phase III trials prove successful.

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"We will leverage our expertise and partnership with globally renowned biotech players such as PanGen to exploit opportunities upon expiry of patents for blockbuster drugs to create a momentum for our biosimilars expansion," said Encik Amirul Feisal Wan Zahir, managing director, CCM Group.

The technology used in developing the EPO encompasses the usage of serum-free media for the culturing of mammalian cell lines as the animal-free and protein-free media formulations are less complex. Serum-based media, which utilizes animal proteins as feed to cultivate cell growth, is exposed to unwanted contamination in the production of biosimilars and consequently complicating potential Halal status.

Encik Amirul Feisal said the collaboration will indirectly assist in the development of the Malaysian biotech manufacturing industry through the transfer of a significant amount of technical knowhow from the Korean partner, create highly skilled job opportunities and enhance import substitution for this particular drug.

Encik Leonard Ariff Abdul Shatar, chief executive officer, CCM Duopharma, said the company will aggressively leverage the experience gained from this maiden relationship with PanGen as a business model to facilitate the sharing of expertise and knowledge with major industry players to accelerate the division's drive into commercialization and distribution of biosimilars.