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ASIA EDITION

Bio-Thera Solutions & Tabuk Pharma to commercialise Stelara (Ustekinumab) biosimilar in Saudi Arabia

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BAT2206 is a proposed biosimilar to Jansen's Stelara



China-based Bio-Thera Solutions Inc., a commercial-stage biopharmaceutical company developing a pipeline of innovative therapies and a pipeline of biosimilars, has partnered with Tabuk Pharmaceutical Manufacturing Company (a fully-owned subsidiary of Astra Industrial Group), a leading pharmaceutical company in the Middle East and North Africa (MENA) region, for BAT2206, its ustekinumab biosimilar, under which Tabuk will have exclusive rights to manufacture, distribute and market the drug in Saudi Arabia.

BAT2206 is a proposed biosimilar to Jansen's Stelara. Bio-Thera has filed for regulatory approval of BAT2206 with the China National Medical Products Administration (NMPA), the European Medicines Agency (EMA) and the United States Food and Drug Administration (FDA).

This partnership will leverage Tabuk's strong local presence, sales and marketing capabilities in Saudi Arabia. Under this agreement Tabuk Pharmaceuticals will hold the marketing authorisation and will be responsible to manufacture, register, import, and promote BAT2206 in Saudi Arabia. Bio-Thera will be responsible for full development, and commercial supply of BAT2206 out of its manufacturing facilities in Guangzhou, China.

BAT2206 is a proposed biosimilar to Jansen's Stelara® which is a human monoclonal antibody that inhibits the bioactivity of human IL-12 and IL-23 by preventing shared p40 from binding to the IL-12R?1 receptor protein expressed on the surface of immune cells. IL-12 and IL-23 are involved in inflammatory and immune responses, such as natural killer cell activation and CD4+ T-cell differentiation and activation. IL-12 and IL-23 have been implicated as important contributors to the chronic inflammation that is a hallmark of Crohn's disease and ulcerative colitis, among many other autoimmune diseases.