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ASIA EDITION

China accepts first application for Humira biosimilar

September 4, 2018 | News

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Bio-Thera Solutions, a global biopharmaceutical company recently announced that the China National Drug Administration (CNDA) has accepted for review the Biologics License Application (BLA) for BAT1406, a proposed biosimilar to Humira (adalimumab), which is used to treat patients with rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, ulcerative colitis, chronic psoriasis, hidradenitis suppurativa, and juvenile idiopathic arthritis. The BLA for BAT1406 is the first BLA for a proposed adalimumab biosimilar accepted for review in China.

“Bio-Thera is proud to file the first BLA for a proposed Humira biosimilar in China,” said Shengfeng Li, Chief Executive Officer of Bio-Thera Solutions. “We expect BAT1406 to be the first Humira biosimilar to be approved for the China market, allowing more patients to have access to an important autoimmune therapy at a more affordable cost.”

The BLA for BAT1406 consists of a comprehensive data package that includes analytical, preclinical and clinical data. Clinical studies included a pharmacokinetic/pharmacodynamic (PK/PD) trial, and a Phase III confirmatory safety and efficacy study in ankylosing spondylitis. Bio-Thera believes these data provide confirmation that the proposed biosimilar matches the reference medicine in terms of safety, efficacy and quality.

Bio-Thera Solutions is developing several additional proposed biosimilars, including a biosimilar version of Avastin, which is currently being evaluated in a global Phase III clinical trial. Bio-Thera Solutions is also pursuing biosimilar versions of

Actemra/RoActemra, Stelara, Cosentyx and Simponi.