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ASIA EDITION

Bio-Thera launches first Humira biosimilar in China

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QLETLI® is Bio-Thera's first biosimilar to receive regulatory approval and is the second biosimilar approved in China by the NMPA

Bio-Thera Solutions, Ltd., a fully-integrated pharmaceutical company, has announced that QLETLI®, a biosimilar to Humira® (adalimumab), is now available in China. QLETLI® , the first adalimumab biosimilar approved by the China National Medical Products Administration (NMPA), is authorized for the treatment of three autoimmune diseases: rheumatoid arthritis, ankylosing spondylitis, and plaque psoriasis. QLETLI® is Bio-Thera's first biosimilar to receive regulatory approval and is the second biosimilar approved in China by the NMPA.

QLETLI® was approved based on the totality of evidence from a comprehensive data package supporting biosimilarity to adalimumab which includes analytical, nonclinical, pharmacokinetics, pharmacodynamics and clinical data. The Phase III clinical study met its primary endpoint showing no clinically meaningful differences in safety, immunogenicity and efficacy compared to adalimumab.

Bio-Thera Solutions is developing several additional proposed biosimilars, including biosimilars to Avastin® and to Actemra® /RoActemra®, which are both currently being evaluated in global Phase III clinical trials. Bio-Thera is also pursuing biosimilars to Simponi® and to Stelara®.