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ASIA EDITION

FDA OKs prefilled syringe formulations for Roche's Xolair

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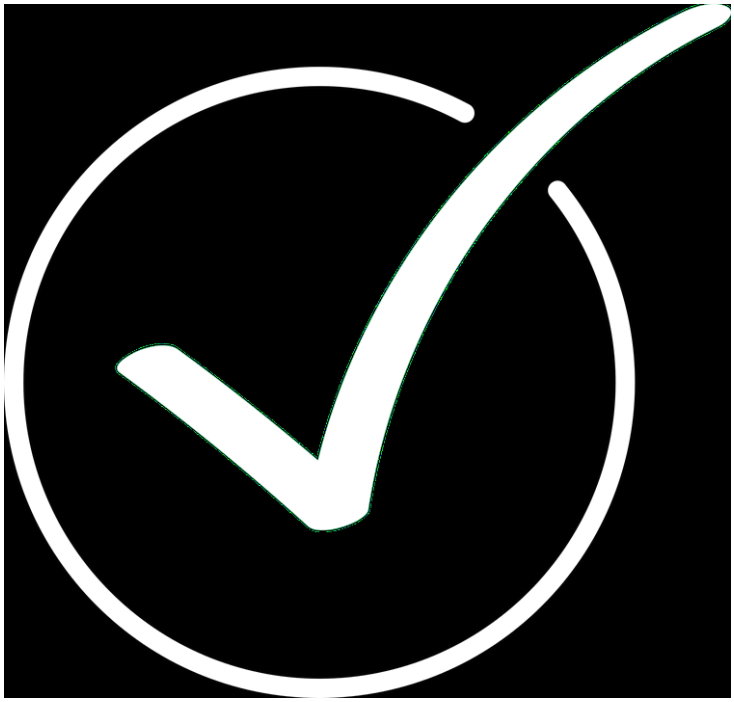
Xolair, the only biologic approved for both allergic asthma and chronic idiopathic urticaria indications, is now also approved in a prefilled syringe (PFS) formulation



Singapore - Genentech, a member of the Roche Group, announced that the U.S. Food and Drug Administration (FDA) has approved 75 mg/0.5 mL and 150 mg/1 mL single-dose prefilled syringes (PFS) for Xolair (omalizumab) as an additional formulation for both allergic asthma and chronic idiopathic urticaria (CIU) indications. The new Xolair PFS formulation is expected to be available by the end of this year for the first time in the U.S. Xolair is currently available in a 150 mg single-dose vial with lyophilized, sterile powder for reconstitution.

“Xolair has long been an important treatment option for people with allergic asthma and CIU,” said Sandra Horning, M.D., chief medical officer and head of Global Product Development. “The prefilled syringe formulation reflects our continued commitment to provide healthcare professionals with choices to best support each patient's unique needs."

The Xolair PFS eliminates the need for healthcare providers to procure Sterile Water for Injection (SWFI) and reconstitute Xolair before administering the medicine.

Xolair is approved for the treatment of moderate to severe persistent allergic asthma in people six years of age or older whose asthma symptoms are not controlled by inhaled corticosteroids, and for CIU in people 12 years of age and older who continue to have hives that are not controlled by H1 antihistamines. Over 330,000 people in the U.S. have been treated with Xolair since its initial approval for people 12 years and older with allergic asthma in 2003.