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ASIA EDITION

CHMP backs Sanofi's Dupixen in asthma

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Dupixent is a human monoclonal antibody that inhibits the signaling of interleukin-4 (IL-4) and interleukin-13 (IL-13), two key proteins that play a central role in type 2 inflammation that underlies specific types of asthma as well as several other allergic diseases.

Regeneron Pharmaceuticals and Sanofi recently announced that the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion for Dupixent® (dupilumab) in asthma.

The CHMP recommended Dupixent be approved for use in adults and adolescents 12 years and older as add-on maintenance treatment for severe asthma with type 2 inflammation characterized by raised blood eosinophils and/or raised fractional exhaled nitric oxide (FeNO), who are inadequately controlled with high dose inhaled corticosteroid plus another medicinal product for maintenance treatment.

The positive CHMP opinion is based on clinical data from 2,888 adults and adolescents who participated in three pivotal trials from the global LIBERTY ASTHMA program, including the Phase 3 QUEST and VENTURE trials.

QUEST compared Dupixent vs. placebo in asthma patients inadequately controlled on a medium or high dose inhaled corticosteroid and a second controller medication. VENTURE compared Dupixent vs. placebo in oral corticosteroid dependent asthma patients.

The European Commission is expected to make a final decision on the application for Dupixent in the coming months.