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ASIA EDITION

FDA approves GSK's new self-injectable formulation for systemic lupus erythematosus

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Systemic Lupus Erythematosus (SLE) is the most common form of lupus, a chronic, incurable autoimmune disease producing auto-antibodies that can attack almost any system in the body.

Singapore - GSK announced that the US Food and Drug Administration (FDA) has approved a new subcutaneous formulation of Benlysta (belimumab) for the treatment of adult patients with active, autoantibody-positive SLE who are receiving standard therapy. Systemic Lupus Erythematosus (SLE) is the most common form of lupus, a chronic, incurable autoimmune disease producing autoantibodies that can attack almost any system in the body. The approval marks the first subcutaneous self-injection treatment option for patients with SLE.

After training from their health care provider, patients will be able to administer the medicine as a once weekly injection of 200mg, from either a single-dose prefilled syringe or from a single-dose autoinjector. This is the second formulation of Benlysta to be granted approval for SLE, adding to the existing intravenous (IV) formulation, approved in 2011, which is administered by healthcare professionals to patients as a weight-based dose of 10mg/kg, via a one-hour infusion in a hospital or clinic setting every four weeks.

Vlad Hogenhuis, Senior Vice President, Head of Specialty Care, GSK said, "We are delighted with today's decision. Lupus can impact the lives of patients in many ways with varied and often unpredictable symptoms. Since it launched in its IV form, thousands of patients worldwide have received treatment with Benlysta. The approval of the new injectable formulation will now provide an additional choice for patients, allowing them to self-administer their medicine at home rather than going to

hospitals or clinics for their infusions."

The approval is based on data from the BLISS-SC phase III pivotal study of more than 800 patients with active SLE, which measured reduction in disease activity at Week 52 in patients receiving belimumab plus standard of care, versus those receiving placebo plus standard of care (assessed by SRI, a composite measure of efficacy in lupus).

Benlysta subcutaneous formulation will be available in specialty pharmacies in the US in late August.