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GSK receives Japanese nod for Benylsta

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Benlysta treats adult patients with systemic lupus erythematosus (SLE) who are inadequate responders to existing therapies

Global pharma giant GlaxoSmithKline PLC announced that it has received the Japanese nod for Benlysta for sale in Japan. Benlysta treats adult patients with systemic lupus erythematosus (SLE) who are inadequate responders to existing therapies. There are an estimated 60,000 registered lupus patients in Japan.

Benlysta is for use as an add-on therapy in autoantibody positive SLE patients. SLE is a chronic, incurable, autoimmune disease associated with a range of symptoms that can fluctuate over time, affecting almost any system in the body.

Benlysta is a human monoclonal antibody that works by selectively targeting B-lymphocyte stimulator (BLyS), an important factor in SLE. It binds to BLyS directly, which reduces B-cells and helps decrease the immuno-inflammation observed in SLE patients.

The medicine will be available for patients in two formulations, as an injection, for intravenous (IV) use and an injection, for subcutaneous (SC) use. The IV formulation is administered by healthcare professionals to patients as a weight-based dose of 10mg/kg, via a one-hour infusion in a hospital or clinical setting every four weeks (following an initial loading phase given at Weeks 0, 2 and 4). The subcutaneous formulation can be administered as a once weekly injection of 200mg, from either a single-dose prefilled syringe or from a single-dose autoinjector.

Vlad Hogenhuis, Senior Vice President, Head of Specialty Care, GSK said, “Patients living with SLE have limited treatment choices available and may have to endure the associated side effects these can cause. SLE symptoms are broad, variable and unpredictable in their intensity, which means an individualised treatment approach is needed. Benlysta, in its IV form, has been used to treat thousands of patients worldwide and with today’s approval of two formulations, we are delighted that we can now provide an important new treatment option to physicians and SLE patients in Japan.”

The approval is based on data from two recent pivotal Phase III studies (Northeast Asia IV study and BLISS-SC study) and also efficacy and safety data from two earlier global BLISS-IV Phase III studies (BLISS-52, BLISS-76). The studies measured

reduction in disease activity at Week 52 in patients with active SLE 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 IV 10 mg/kg is also licensed for use in the US, EU and more than 70 countries worldwide. Benlysta subcutaneous formulation was approved for use in the US in July 2017 and further regulatory submissions are under review or planned in other countries during the course of 2017.