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Malaysia approves AstraZeneca's drug for systemic lupus erythematosus treatment

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Approval was based on positive results from the Saphnelo clinical development programme



British-Swedish multinational pharmaceutical and biotechnology company AstraZeneca's Saphnelo (anifrolumab) has now become available as add-on treatment for adult patients in Malaysia with moderate to severe, active autoantibody-positive systemic lupus erythematosus (SLE) following insufficient response to standard therapy, after obtaining regulatory approval earlier this year.

SLE is a chronic and complex autoimmune condition that can affect any organ, and patients often experience inadequate disease control, long-term organ damage, and poor health-related quality of life.

The approval was based on positive results from the Saphnelo clinical development programme, including the TULIP Phase III trials. Across clinical trials, more patients treated with Saphnelo experienced a reduction in overall disease activity across most targeted organ systems and achieved sustained reduction in oral steroid (OCS) use compared to placebo.

Vinod Narayanan, Country President, AstraZeneca Malaysia said, "The approval and availability of Saphnelo in Malaysia represents an important milestone in our ongoing efforts to broaden patients' access to innovative, life-changing medicines and ultimately, improve health outcomes."

"Eligible people living with SLE can now benefit from the treatment of this chronic, complex and often disabling disease," explained Narayanan.

Saphnelo targets the type I interferon pathway, which is known to play a central role in SLE pathophysiology.