

24 January 2024

Professor Andrew Wilson Chair, Pharmaceutical Benefits Advisory Committee (PBAC) MDP 952, GPO Box 9848 Canberra, ACT 2601

Email: pbac@health.gov.au

Dear Professor Wilson,

Re: Saphnelo® (anifrolumab) resubmission for severe systemic lupus erythematosus (SLE)

On behalf of the Australasian Society of Clinical Immunology and Allergy (ASCIA) we write in support of a resubmission from AstraZeneca to request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) for Pharmaceutical Benefits Scheme (PBS) listing of Saphnelo[®] (anifrolumab) for the treatment of severe systemic lupus erythematosus (SLE) with a high level of disease activity despite standard therapy.

ASCIA supports this resubmission for the following reasons:

- Clinical immunology/allergy specialists manage a significant proportion of patients with SLE, which
 is usually lifelong and impacts quality of life and health outcomes. Current treatments for patients
 with severe SLE have limitations, including effectiveness in controlling disease and side effects.
- There are considerable costs to patients and the healthcare system due to delayed or inadequate treatment of severe SLE, associated with medical consultations for poorly controlled disease.
- A Section 100 (Highly Specialised Drugs Program) Authority Required (Written) PBS listing of Saphnelo® (anifrolumab) should improve access to effective therapeutic options for patients with severe SLE, with a high level of disease activity despite standard therapy.

We hope that this letter provides sufficient information for the proposed PBS listing of Saphnelo® (anifrolumab) for treatment of SLE with a high level of disease activity despite standard therapy.

Yours sincerely,

A/Professor Theresa Cole Jill Smith ASCIA President ASCIA CEO

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