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Oncologic Drugs Advisory Committee (ODAC) Meeting

April 30, 2026

NDA# 220359

Drug name: camizestrant

Applicant: AstraZeneca UK Limited

Combined FDA and Applicant ODAC Briefing Document

Errata

Errata to AstraZeneca part of combined Briefing Document issued for the Oncologic Drugs Advisory Committee (ODAC) meeting scheduled for 30 April 2026. The erroneous text is identified by a strikethrough, with correction following in bold, unless otherwise specified.

1. Page 18  
2.1.2 Unmet Medical Need in ESR1m/HR+/HER2- ABC

The Applicant's Position:

For patients with ESR1m/HR+/HER2- ABC who progress on 1L AI plus CDK4/6 inhibitor therapy, the optimal next treatment is unclear and there is no ~~established~~ **dominant** SoC.

2. Page 19

Figure 2 Title Change

Figure 2 Diverse Treatment Patterns in HR+/HER2- mBC Patients with ESR1 Mutation Detected ~~During 1L Therapy~~ **Prior to the Initiation of 2L Therapy** (US EHR Flatiron Health Database)

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1. Page 21  
Section 2.1.2

The FDA makes the following edit in response to the Applicant's correction to Figure 2.

The FDA's Position

~~The FDA also disagrees with the characterization of this real-world patient population presented in Figure 2 as having ESR1m detected "during first line therapy."~~ **The FDA agrees with the Applicant's correction that Figure 2 represents patients who have a detectable ESR1m prior to the initiation of second-line therapy.** Serial testing for ESR1m is not performed outside of clinical trials. In clinical practice, testing occurs when a patient is no longer receiving benefit from their first line therapy, as evidenced by clinical or radiographic progression.

2. Page 28  
Section 2.2.3

The FDA's Position

Although FDA did not object to a primary efficacy endpoint of investigator-assessed PFS per RECIST v1.1, FDA ~~cautioned~~ **requested that** the Applicant **provide a rationale for that** the strategy of switching treatment at detection of *ESR1m* prior to radiographic progression ~~would need justification.~~

3. Page 35  
Section 2.3.1.2

The FDA's Position

See Section 3.5 on safety for more information about a ~~fatal~~ case of TdP related to camizestrant and ribociclib on SERENA-1.

4. Page 48  
Section 3

The FDA's Position

The FDA agrees with the size of the presented safety pool for camizestrant.; ~~However,~~ **in SERENA-6**, only a limited number of patients on the camizestrant and CDK4/6 inhibitor arm were treated with camizestrant in combination with either ribociclib (23 patients or 15%) or abemaciclib (15 patients or 10%).