May 8, 2026
Eisai Co., Ltd.

Voluntary Recall of Distributed "Halaven®" in the Middle East and Southern Africa

Eisai has decided to conduct a voluntary recall of a released packed bulk batch of the anticancer drug Halaven® (generic name: eribulin mesylate), after confirming it contains levels of the active ingredient below the specified standard. This packed bulk batch has been distributed to regions including the Middle East and Southern Africa.
The issue is isolated to a single bulk batch (which has been assigned various different lot number references during packing). There are no similar concerns with other batches of Halaven that have been previously supplied or are currently in the market.

The recall applies to the lot numbers distributed to the countries listed below. Although the decreased assay may theoretically result in reduced drug exposure, no increase in reports of lack of efficacy or disease progression has been observed in Eisai's global pharmacovigilance database at this time following shipment of the affected lot. In addition, unaffected new lots have already been supplied to these countries. There is no impact on products in other countries where Eisai distributes the product, including Japan.

Countries subject to the voluntary recall (lot numbers):
United Arab Emirates, Oman, Kuwait and Bahrain (148342 for all four countries); Saudi Arabia (148318); South Africa (148482); Namibia and Botswana (148482N).

We sincerely apologize for the significant inconvenience caused to all those using this product in the affected countries. In conducting this voluntary recall, we will strive to provide appropriate information through our local subsidiaries and partner distributors to avoid confusion in medical settings and among patients. Going forward, we will further strengthen our product management system and take all necessary measures to prevent recurrence.

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