Drugs

PEER-REVIEWED FEATURE

Elacestrant: Adis Evaluation

Key Points

- An orally available SERD being developed by Stemline Therapeutics, a subsidiary of Menarini Group, for the treatment of ER-positive, HER2-negative breast cancer
- Received its first approval on 27 January 2023 in the USA
- Approved for use in postmenopausal women or adult men with ER-positive, HER2-negative, *ESR1*-mutated (as determined by a US FDA-approved test) advanced or metastatic breast cancer with disease progression following ≥ 1 line of endocrine therapy

Summary

Elacestrant (ORSERDU™) is an orally available selective estrogen receptor degrader (SERD) being developed by Stemline Therapeutics, a subsidiary of Menarini Group, for the treatment of estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer

In January 2023, elacestrant received its first approval for the treatment of postmenopausal women or adult men with ER-positive, HER2-negative, *estrogen receptor 1* (*ESR1*)-mutated (as determined by a US FDA-approved test) advanced or metastatic breast cancer with disease progression following ≥ 1 line of endocrine therapy in the USA

A regulatory assessment of elacestrant for the treatment of ER-positive, HER2-negative advanced or metastatic breast cancer is currently underway in the EU. Development of elacestrant for the treatment of vasomotor symptoms has been discontinued.

Hoy, S. M. Drugs. 2023. https://doi.org/10.1007/s40265-023-01861-0