Abemaciclib: Adis Evaluation

Clinical Considerations

- **First CDK4/6 inhibitor indicated in combination with adjuvant endocrine therapy in patients with HR+, HER2−, node-positive, high-risk disease**
- **Improvements were seen in invasive disease-free survival and distant recurrence-free survival**
- **Acceptable tolerability; the most common adverse event was diarrhoea**

Plain Language Summary

Background and rationale

- In patients with hormone receptor positive (HR+) cancers, endocrine therapy is often used to reduce the risk of breast cancer recurrence after successful initial treatment; however, in a subset of patients, recurrence rates can remain high

Clinical findings

- In a pivotal phase III trial, the addition of abemaciclib [Verzenio® (USA) or Verzenios® (EU)] to standard endocrine therapy significantly reduced the rate of breast cancer recurrence compared with endocrine therapy alone in patients with HR+, human epidermal growth factor receptor 2 negative (HER2−), node-positive early breast cancer who were at a high risk of recurrence
- Benefit was seen in both patients with characteristics that are associated with higher risk (premenopausal, high Ki-67 scores, previously received neoadjuvant chemotherapy) and comparatively lower risk of recurrence (postmenopausal, low Ki-67 scores)
- Diarrhoea, infections and neutropenia were the most common adverse events in patients receiving abemaciclib plus endocrine therapy
- The overall tolerability of abemaciclib was acceptable

Conclusion

The addition of abemaciclib to endocrine therapy is a valuable therapeutic option for adjuvant therapy in high-risk patients with HR+, HER2−, node-positive early breast cancer