

Horizon Scanning Technology Ultra-orphan note

*National
Horizon
Scanning
Centre*

**Trabectedin (Yondelis)
for second and third-
line treatment of soft
tissue sarcoma**

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This technology summary is based on information available at the time of research and a limited literature search. It is not intended to be a definitive statement on the safety, efficacy or effectiveness of the health technology covered and should not be used for commercial purposes.

Trabectedin (Yondelis) for second and third-line treatment of soft tissue sarcoma

Target group

- Advanced soft tissue sarcoma (STS) unresponsive to standard chemotherapy (doxorubicin and ifosfamide).

Technology description

Trabectedin (Yondelis, Ecteinascidin 743, ET-743) is a tetrahydroisoquinolone alkylating anticancer agent which acts as a DNA antagonist, affecting transcription factors to block the cell cycle; it also inhibits the expression of multi-drug resistance. Trabectedin is in pivotal phase II clinical trials as second or third-line therapy for patients with advanced or metastatic soft tissue sarcoma. It is also in phase III clinical trials for ovarian cancer, and phase II development for breast and prostate cancer.

Developer

PharmaMar and Johnson & Johnson (OrthoBiotech Products).

Stage of development and availability in EU/UK

- | | | |
|--|---|--|
| <input type="checkbox"/> Phase III clinical trials or equivalent | <input checked="" type="checkbox"/> Pre-registration in EU (drugs) | <input type="checkbox"/> CE marked, but not yet launched or available in UK |
| <input type="checkbox"/> Licence or CE mark application in UK/EU likely within 12 months | <input type="checkbox"/> Licence or CE mark application in UK/EU likely within 24 months | <input checked="" type="checkbox"/> Launch or use in UK/EU likely within 12 months |
| <input type="checkbox"/> Launch or use in UK/EU likely within 24 months | <input type="checkbox"/> Established product, but this is a new indication in development | <input type="checkbox"/> Other, please specify |

Orphan drug status:

- Orphan drug status in EU Orphan drug status in USA

Clinical need and burden of disease

Soft tissue sarcoma (STS) is a rare condition, with a UK incidence of around 1,300. The developer estimates that there are 500-600 UK patients with advanced metastatic STS. If identified before metastasis occurs, the 5-year survival for STS can be up to 90%. However once metastasised, 5-year survival falls dramatically to around 10-15%.

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