3435: Sarcoma: Soft Tissue: Sarcoma: Soft Tissue and Bone

A non-interventional, multicenter, prospective phase IV study of trabectedin in patients with advanced soft tissue sarcoma (STS): The first interim analysis of Y-IMAGE study

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Background: Trabectedin (Yondelis®) is the first marine-derived drug approved in Europe for the treatment of advanced STS. The Y-IMAGE study evaluates trabectedin in real-life clinical practice across Europe, aiming to compare radiological response assessments obtained by RECIST or Choi.

Material and Methods: Data from adult STS patients treated with trabectedin with the approved schedule (1.5mg/m^2; 24-h i.v. infusion every 3 weeks) have been collected in a non-interventional phase IV study. The primary endpoint is progression-free survival (PFS) as defined by investigators. Secondary endpoints include objective response rate, disease control rate, overall survival and safety. Here we present the analysis of the primary endpoint.

Results: From 11/2011–6/2014 217 patients (123 female) from 41 European centers were enrolled. Median number of administered trabectedin cycles at enrolment was 2 with 16% of patients receiving 6 or more cycles. Median age of patients was 58 years (range: 21–79) and 70.5% had ECOG performance status 0/1. Among 27 sarcoma histotypes as defined by investigators main subtypes were leiomyosarcoma (41.9%), liposarcoma (23.5%) and synovial sarcoma (10.6%). Patients had received a median of 1 prior line of chemotherapy (range: 0–6), mostly with anthracyclines ± ifosfamide (83.9%), whereas 22 (10.1%) patients were chemotherapy-naïve at study entry. Median number of trabectedin cycles received per patient was 6 (range: 1–44) with 121 (56%) patients receiving ≥6 cycles and up to a maximum of 44 cycles. Median treatment duration was 5.5 months (range: 0.7 –44.2). 18 patients remain on treatment at the time of this analysis. Most patients were treated on an outpatient basis (outpatient: 63.2%; inpatient: 28.7%; both: 8.1%). With 166 PFS events recorded, median PFS was 5.5 months (95%CI: 4.8 –7.1 months) as assessed by RECIST (n=178), Choi (n=6) or clinically (n=59). At 3 and 6 months, 69.4% and 46.9% of patients were progression-free and 16.1% received trabectedin for 1 year or more. Intra-patient comparison of RECIST vs. retrospective Choi evaluation in 44 patients revealed a differential PFS response with median 15.3 months (95%CI: 6.9–21.2) by Choi vs. 8.1 (95%CI: 5.3–10.7) by RECIST. Most common grade 3/4 adverse events were neutropenia and transaminase increase, reported in 17.9% and 7.9% of patients, respectively. Febrile neutropenia was reported in 2.7% of patients. Fatigue (3.7% of patients), nausea (1.4%) and vomiting (1.4%) were the most common trabectedin-related grade 3 adverse events. A fatal case of pulmonary embolism was registered.

Conclusions: Trabectedin confers long term efficacy when used in real practice in different subtypes of sarcoma with a manageable safety profile. Choi criteria are not commonly used in clinical practice; however, they may reveal a differential pattern of response assessment to trabectedin.

No conflict of interest.

- trabectedin
- Sarcoma
- Yondelis