



Summary of investigation results

Trabectedin

April 21, 2016

Non-proprietary name

Trabectedin

Brand name (Marketing authorization holder)

Yondelis I.V. Infusion 0.25 mg, 1 mg (Taiho Pharmaceutical Co., Ltd.)

Indications

Soft tissue sarcoma

Summary of revision

1. "Patients with previous anthracycline exposure or those with cardiac dysfunction" should be newly added in the Careful administration section.
2. Precautions regarding cardiac dysfunction should be newly added in the Important Precautions section.
3. "Cardiac dysfunction" should be newly added in the Clinically significant adverse reaction.

Background of the revision and investigation results

- a. In the foreign Phase III clinical trial of patients treated for soft tissue sarcoma who have received prior anthracyclines, incidence rate of cardiac dysfunction (including congestive cardiac failure and decreased left ventricular ejection fraction, etc.) was higher in the trabectedin group than in the control group. In addition, some cases of cardiac dysfunction for which a causal relationship to the drug could not be ruled out were observed in the trial.
- b. This drug is often administered to patients who have received prior anthracyclines, which have cardiotoxicity, or those with cardiac dysfunction. Therefore, upon administration to these patients, more careful administration is required.

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- c. Based on the results from the foreign Phase III clinical trial, actions have been taken in the company core datasheet (CCDS)* and label in the United States to alert caution for cardiac dysfunction.

Following an investigation result based on the opinions of expert advisors and the available evidence, the MHLW/PMDA concluded that revision of the package insert was necessary.

The number of reported adverse reactions and fatal cases in the last 3 fiscal years in Japan

No case associated with cardiac dysfunction has been reported.

Note:

*CCDS is prepared by the marketing authorization holder and covers material relating to safety, indications, dosing, pharmacology, and other information concerning the product.