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*This English version is intended to be a reference material to provide convenience for users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.*

# Revision of Precautions

## Trabectedin

April 21, 2016

### Non-proprietary name

Trabectedin

### Safety measure

Precautions should be revised in the package insert.

In the Careful administration section, the following texts should be added (underlined parts are revised):

Patients with previous anthracycline exposure or those with cardiac dysfunction

In the Important Precautions section, the following text should be added (underlined parts are revised):

Cardiac dysfunction may occur. Heart function test, such as echocardiography (including measurement of left ventricular ejection fraction [LVEF]) should be performed periodically before and during treatment with this drug. Clinical cardiac signs or symptoms should be carefully monitored.

In the Clinically significant adverse reaction subsection of the Adverse reaction section, the following text should be added (underlined parts are revised):

Cardiac dysfunction: Cardiac dysfunction, such as congestive cardiac failure and decreased left ventricular ejection fraction, may occur. Patients should be carefully monitored. If any abnormalities are observed, appropriate measures such as dose reduction, drug suspension, or discontinuation should be adopted.