



## Summary of investigation results

### enzalutamide

October 21, 2014

#### **Non-proprietary Name**

enzalutamide

#### **Brand Name (Marketing Authorization Holder)**

Xtandi Capsules 40 mg (Astellas Pharma Inc.)

#### **Indications**

Castration-resistant prostate cancer

#### **Summary of revision**

‘Thrombocytopenia’ should be added in Clinically significant adverse reactions section.

#### **Background of the revision and investigation results**

Cases of thrombocytopenia have been reported in patients treated with enzalutamide in Japan. Following an investigation result based on opinions of expert advisors and available evidence, the MHLW/PMDA concluded that revision of the package insert was necessary.

#### **The number of reported adverse reaction and fatal cases in the last 3 fiscal years in Japan**

A total of 12 cases associated with thrombocytopenia has been reported (including 7 cases in which causality could not be ruled out). Of the 12 cases, no fatalities have been reported.