



# Summary of Investigation Results

## Cladribine

April 19, 2018

### **Non-proprietary name**

Cladribine

### **Brand name (marketing authorization holder)**

Leustatin Injection 8 mg (Janssen Pharmaceutical K.K.)

### **Indications**

Hairy cell leukemia

Recurrent, relapsing, or refractory indolent B-cell non-Hodgkin's lymphoma including follicular lymphoma, and mantle cell lymphoma

### **Summary of revision**

“Progressive multifocal leukoencephalopathy” should be added to the Clinically Significant Adverse Reactions section.

### **Investigation results and background of the revision**

Cases of progressive multifocal leukoencephalopathy have been reported in patients treated with cladribine including cases reported overseas during the previous 3 fiscal years. Based on the results of their investigation of the currently available evidence and in consultation with expert advisors, MHLW/PMDA concluded that revision of the package insert was necessary.

### **Number of adverse reactions and patient mortalities reported in Japan during the previous 3 fiscal years**

No cases associated with progressive multifocal leukoencephalopathy have been reported during the previous 3 fiscal years.