

## **Development Pipeline Progress Status (Summary) for 1st Quarter of Fiscal Year Ended March 31, 2017**

The development pipeline progress status is described in pages 12-17 of 1st Quarter, Flash Report. The followings summarize the development status updated from the one at the announcement of financial results for the Fiscal Year ended March 31, 2015 released in May 2016:

### **Development status in Japan**

(Approved product)

Kyprolis® (Proteasome inhibitor: Multiple myeloma)

The product was approved for the treatment of multiple myeloma on July 4, 2016. It is expected that the NHI price listing will be made within 60 days after approval, if all goes smoothly.

(Product under clinical development/discontinued)

ONO-6950 (Leukotriene receptor antagonist: Bronchial asthma)

Phase II clinical studies were conducted for the treatment of bronchial asthma in and outside Japan, including the one in comparison with the existing product, Onon® (Leukotriene receptor antagonist). The development of ONO-6950 was discontinued, because an expected efficacy was not confirmed in the studies.

### **Development status outside Japan**

ONO-6950 (Leukotriene receptor antagonist: Bronchial asthma)

The development of ONO-6950 was discontinued outside Japan for the above same reason.

ONO-1266 (S1P receptor agonist: Portal hypertension)

Phase I clinical study has been conducted aiming at potential indication of portal hypertension. The development was discontinued as a drug for portal hypertension because a new drug was introduced, by which originally anticipated marketability was not expected.

### **Development status of Opdivo**

(Japan, South Korea and Taiwan)

In Japan and Taiwan, supplemental applications were filed for head and neck cancer.

(US and Europe)

- An approval for a supplemental Biologics License Application (sBLA) for Opdivo was granted for the treatment of Hodgkin lymphoma (blood cancer) in the US.

- The marketing applications were accepted for the treatment of head and neck cancer by the FDA in the US and EMA in Europe.
- Phase III clinical studies were initiated for treatment of multiple myeloma in the US and Europe.
- Phase III clinical studies were started for the treatment of gastro-esophageal junction cancer and esophageal cancer in the US and Europe. This study is an adjuvant therapy to prevent recurrence of cancer after operation.