

Development Pipeline Progress Status (Summary)
for cumulative 3rd Quarter of Fiscal Year Ended March 31, 2016

For details of the progress status of development pipeline, refer to pages of 11 to 16 in the Flash Report for cumulative 3rd quarter of the fiscal year. The followings summarize the development status updated from the one released at the 2nd quarter of the fiscal year.

Development status of ONO products excluding ONO-4538/OPDIVO (Nivolumab)

ONO-5163 (Etelcalcetide Hydrochloride)

An application of ONO-5163, a calcium sensing receptor agonist, for a manufacturing and marketing approval for the indication of secondary hyperparathyroidism was submitted in Japan on January 14, 2016.

ONO-2370 (Opicapone)

Phases II clinical study with ONO-2370, a long acting COMT inhibitor, was started in patients with Parkinson's disease.

Development status of ONO-4538/OPDIVO (Nivolumab) in Japan, South Korea and Taiwan

Japan

- An application of OPDIVO for a manufacturing and marketing approval partial amendment was granted on December 17, 2015, for the indication of unresectable, advanced or recurrent non-small cell lung cancer.
- An application of OPDIVO for a manufacturing and marketing approval partial amendment was submitted for the indication of unresectable or metastatic renal cell carcinoma (RCC) on December 11, 2015.
- Phase III clinical study was started in patients with glioblastoma.

Japan, South Korea and Taiwan

- Phase III clinical study was started for the treatment of hepatocellular carcinoma in these countries.

Development status of ONO-4538/OPDIVO (Nivolumab) in the US and Europe

- In the US, a supplemental Biologics License Application (sBLA) of OPDIVO was approved in patients with advanced RCC who have received prior anti-angiogenic therapy.
- In Europe, a supplemental marketing authorization application of OPDIVO was validated in patients with advanced RCC who have received prior therapy.

- In the US and Europe, Phase III studies were started for treatment of urothelial cancer, hepatocellular carcinoma and esophageal cancer.