

Overview of Development Pipeline Progress Status for the Third Quarter of the Fiscal Year Ending March 31, 2019

The followings summarize the progress status in development pipeline from the announcement of the previous quarter of the financial results released on November 1, 2018. For details, please refer to pages 14 to 23 of the Consolidated Financial Results for the Third Quarter (Apr 1 - Dec 31, 2018).

Main Status of Development Pipelines (Oncology)

1. Development Status in Japan

<Approved>

1) ONO-7702 (encorafenib) and ONO-7703 (binimetinib)

A manufacturing and marketing approval for combination therapy with a BRAF inhibitor, ONO-7702 and a MEK inhibitor, ONO-7703 was obtained in Japan for the treatment of BRAF-mutant unresectable melanoma.

2) ONO-5371 (metyrosine)

A manufacturing and marketing approval for a tyrosine hydroxylase inhibitor, ONO-5371 was obtained in Japan for the improvement of status of catecholamine excess secretion in patients with pheochromocytoma.

<Filed>

1) ONO-7643 (anamorelin)

A manufacturing and marketing approval application for a ghrelin receptor agonist, ONO-7643 was filed in Japan for the improvement of body weight loss and anorexia in patients with cancer cachexia.

<Clinical Trial Stage>

1) ONO-7701 (Combination therapy with Opdivo Intravenous Infusion)

Phase III of combination therapy with IDO1 inhibitor, ONO-7701 and Opdivo was initiated for the treatment of bladder cancer.

2) Opdivo Intravenous Infusion

Phase II of Opdivo Intravenous Infusion for the treatment of multiple myeloma was discontinued due to the strategic reason.

2. Development Status in South Korea and Taiwan

<Approved>

1) Opdivo Intravenous Infusion (Combination therapy with Yervoy)

A supplemental approval for combination therapy with Opdivo and Yervoy was obtained in Taiwan for the treatment of previously untreated intermediate and high risk advanced renal cell carcinoma.

<Clinical Trial Stage>

1) ONO-7701 (Combination therapy with Opdivo Intravenous Infusion)

Phase III of combination therapy with IDO1 inhibitor, ONO-7701 and Opdivo was initiated for the treatment of bladder cancer.

3. Development Status in Europe and the United States

<Clinical Trial Stage>

1) Opdivo Intravenous Infusion (Combination therapy with ONO-7701)

Phase III of combination therapy with Opdivo and IDO1 inhibitor, ONO-7701 was initiated for the treatment of bladder cancer.

Main Status of Development Pipelines (Non-Oncology)

1. Development Status in Japan

<Filed>

1) ONO-1162 (ivabradine)

A manufacturing and marketing approval application for HCN channel inhibitor (ONO-1162) was filed in Japan for the treatment of chronic heart failure with a sinus rhythm resting heart rate of 75 beats per minute or higher.

<Clinical Trial Stage>

1) ONO-4059 (tirabrutinib)

Phase II of Btk inhibitor, ONO-4059 was initiated for the treatment of pemphigus.

2) Orencia for I.V. Infusion

Phase III of Orencia IV for the treatment of lupus nephritis was discontinued due to the strategic reason.

3) Opdivo Intravenous Infusion

Phase I/II of Opdivo Intravenous Infusion for the treatment of sepsis was discontinued due to the strategic reason.

2. Development Status in Overseas

<Clinical Trial Stage>

1) ONO-7684

Phase I of FXIa inhibitor (ONO-7684) was initiated for healthy adult subjects.

2) Opdivo Intravenous Infusion

Phase I of Opdivo Intravenous Infusion for the treatment of hepatitis C and sepsis was discontinued due to the strategic reason.