

Development Pipeline Progress Status (Summary) in Third Quarter of Fiscal Year Ending March 31, 2017

The followings summarize the changes in development status progressed from the announcement of financial results at the 2nd Quarter of the fiscal year released on November 7, 2016. For details, please refer to pages 12 to 17 of the 3rd Quarter Flash Report.

Development status of ONO products excluding ONO-4538/Opdivo (nivolumab)

(Japan)

Parsabiv[®] Intravenous Injection for Dialysis (ONO-5163/etelcalcetide hydrochloride), a calcium sensing receptor agonist

An application for manufacturing and marketing approval of Parsabiv was approved for the treatment of secondary hyperparathyroidism on hemodialysis on December 19, 2016. The NHI price listing is expected to be this February.

Orencia[®] Subcutaneous Injection (ONO-4164/ BMS-188667), a T-cell activation inhibitor
Global Phase III clinical study of Orencia was started for the treatment of primary Sjögren syndrome.

ONO-4578, a Prostaglandin E2 receptor (EP4) antagonist
Phase I clinical study of ONO-4578 was initiated for solid tumor.

(Outside of Japan)

ONO-4059, a Bruton's tyrosine kinase (Btk) inhibitor
Phase II clinical study of ONO-4059 was started for the treatment of B cell lymphoma in the US by our licensee, Gilead Sciences, Inc.

ONO-7475, an Axl/Mer inhibitor
Phase I clinical study of ONO-7475 was initiated for the treatment of acute leukemia in the US.

ONO-7579, a Tropomyosin receptor kinase (Trk) inhibitor
Phase I clinical study of ONO-7579 was initiated for solid tumor in Europe and the US.

ONO-2952, a Translocator protein (TSPO) antagonist
ONO-2952 had been developed for potential treatment of diseases caused due to stress by suppressing the production of neuroprotein causing stress. However, the development of

ONO-2952 for the treatment of irritable bowel syndrome was discontinued due to the strategic reason considering differentiation among existing products and competing products under development and others comprehensively.

ONO-4232, a Prostaglandin E2 receptor (EP4) agonist

The development of ONO-4232 for the treatment of acute heart failure was discontinued due to the strategic reason considering future development period, development cost and others comprehensively.

Development status of ONO-4538/Opdivo (nivolumab), etc.

ONO-4538/Opdivo (Japan, South Korea and Taiwan)

- An application of Opdivo for a partial change in approved items of the manufacturing and marketing authorization was approved for additional indication of relapsed or refractory classical Hodgkin lymphoma, a blood cancer, in Japan on December 2, 2016.
- An application of Opdivo for a partial change in approved items of the manufacturing and marketing authorization was submitted for the indication of unresectable advanced or recurrent gastric cancer in Japan on December 27, 2016.
- Phase III clinical study was started for the treatment of ovarian cancer in Japan.

ONO-4538/Opdivo (US and Europe)

- In the US, a supplemental Biologics License Application (sBLA) of Opdivo was approved for the treatment of recurrent or metastatic squamous cell carcinoma of the head and neck with disease progression on or after platinum-based therapy.
- In Europe, Opdivo was approved for additional indication of relapsed or refractory classical Hodgkin lymphoma after autologous stem cell transplant and treatment with brentuximab vedotin.
- In the US, Phase I clinical study was initiated for the treatment of sepsis.

ONO-4686/BMS-986207, an Anti-TIGIT antibody (Japan, South Korea and Taiwan)

Phase I/II clinical study was initiated for solid tumors in Japan.