Annual Flash Report (unaudited)
Fiscal Year ended March 31, 2016

ONO PHARMACEUTICAL CO., LTD.

May 11, 2016

Ono Pharmaceutical Co., Ltd. ("The Company") has announced its consolidated financial results ended March 31, 2016.
The consolidated financial statements have been prepared in accordance with International Financial Reporting Standards (“IFRSs”).

This Annual Flash Report for the year ended March 31, 2016 (unaudited) is summary information extracted from the financial statements announced, and the financial statements and the figures contained herein are prepared for reference only for the convenience of readers outside Japan with certain modifications and reclassifications made from the original financial statements presented in Japanese language.

The translations of Japanese yen amounts into U.S. dollar amounts are included solely for the convenience of readers outside Japan using the rate of 112 to $1, the approximate rate of exchange at March 31, 2016.

Amounts of less than one million yen and one thousand U.S. dollars have been rounded to the nearest million yen and one thousand U.S. dollars in the presentation of the accompanying consolidated financial statements.

Financial Highlights

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

	Millions of yen		Thousands of US$
	Year ended March 31, 2015	**Year ended March 31, 2016**	**Year ended March 31, 2016**
Revenue	¥ **135,775**	¥ **160,284**	$ **1,431,108**
Profit (Owners of the parent company)	**12,976**	**24,979**	**223,028**
Total equity	**475,213**	**476,255**	**4,252,279**
Total assets	**524,588**	**540,450**	**4,825,445**
	Yen		US$
Basic earnings per share	¥ **24.48**	¥ **47.13**	$ **0.42**
Diluted earnings per share	¥ **-**	¥ **47.13**	$ **0.42**

(Note) The company conducted a stock split of common stocks at a ratio of 1:5 with an effective date of April 1, 2016. As for “Basic earnings per share” and “Diluted earnings per share”, it is calculated assuming that the stock split was conducted at the beginning of the previous fiscal year.

MANAGEMENT POLICY

(1) Corporate philosophy and policy

The Ono Pharmaceutical Group is "Dedicated to Man's Fight against Disease and Pain." Under this corporate philosophy, we are committed to fulfilling unmet medical needs and aim to create innovative drugs that deliver true benefit to patients.

We are highly aware of corporate responsibilities required as a pharmaceutical company dealing in medicinal drugs upon which human lives depend, working to further strengthen compliance to ensure that all of our actions are to not only fully comply with all legal regulations but also be based on higher ethical standards.

(2) Challenges for management

To realize sustainable growth as an innovative drug producing company, we have set our unique approach of drug discovery, which is the fundamental of our business and current tasks.

Drug discovery

Our drug discovery approach of innovative drugs has been very unique “compound-oriented” approach focusing on “lipids” and “enzyme inhibitors” but not on certain diseases as our strategic targets, through accumulating libraries of compounds acting on those targets and enabling discovery of innovative drug candidates. Our current drug discovery has been based on further improved “compound-oriented” approach of drug discovery, for example, by introducing cutting-edge technologies to find more druggable candidates faster and more efficiently. And our “open-innovation” of flexible alliances with research institutes and academia with state-of-art knowledge and technology allow more productivity and increase probability of success in drug discovery. To accelerate this effort, we are going to build up a new type of research network of industry-academia collaboration called “orientem innovation” inside and outside Japan under which we furnish our unique and novel compounds to academic institutions with cutting-edge knowledge and technologies so that we can explore pharmaceutical use of the compounds more rapidly than before.

Current challenges

Pharmaceutical industry faces severe environmental changes worldwide where productivity is decreasing and investment is increasing in R&D year by year while healthcare system reforms accelerate suppression of healthcare expenditures. Under such circumstances, our challenges are as follows:

(i) Enrichment of Development Pipeline

For sustainable growth, it is essential to launch new drugs into the market in a constant manner based on high quality of development pipeline. For this, we are in pursuit of continuous launch of new drugs, by accelerating in-house drug discovery of unique and innovative drug candidates with cutting-edge technologies as well as by focusing on in-licensing of drug candidates with strategic potential or high unmet medical needs. Further, we are also committed to earlier confirmation of efficacy and safety of compounds in clinical development to speed up the development of new drugs.

(ii) Acceleration of Overseas Operations

We are pushing forward global delivery of our innovative drugs to patients worldwide. We are aiming at launching our innovative drugs through proactively conducting clinical development overseas as well as out-licensing to foreign business partners. We have initiated building a base to sell by ourselves our specialty products such as anticancer drugs overseas and such attempts have already started in Asia. In South Korea and Taiwan, we have already established subsidiaries and built a base to sell by ourselves. In the future, we are going to strengthen our overseas infrastructures for such overseas business developments as mentioned above.

(iii) Enhancement of Company Infrastructure

We are in pursuit of speeding up of business and the fostering of human resources to enhance our competitiveness on a global basis. We are also seeking enhancement of diversity, including support system to enable women to utilize their ability at work, in order to align with environmental variations. Further, we are promoting Corporate Social Responsibility (CSR) activities to fulfill CSR to all stakeholders with a focus on “Corporate Governance”, “Innovative Pharmaceutical Products”, “Human Resources and Human Rights”, “The Environment”, “Fair Operating Practices", and “Society”. We are going to move ahead with these CSR activities and enhance company infrastructure.

(3) Basic policy concerning dividends

Distribution of profits to all our shareholders is one of our key management policies, and we place great importance on the maintenance of stable dividends based on business performance for each fiscal year.

The year-end dividend for Fiscal 2015 (April 1, 2015 – March 31, 2016) is projected to be JPY 90 per share, achieving the company's annual dividend for Fiscal 2015 of JPY 180 per share including the interim dividend of JPY 90 per share (before the stock split). The annual dividend for the next fiscal term is projected to be JPY 40 per share (after the stock split).

We actively utilize retained earnings for the future business development including research and development of new innovative drugs in Japan and abroad, alliance with bio-venture companies, and in-license of new drug candidate compounds for development risk reduction.

(Note) The company conducted a stock split of common stocks at a ratio of 1:5 with an effective date of April 1, 2016.

Gyo Sagara
President, Representative Director and CEO

Consolidated Financial Forecast for the Six Months Ending September 30, 2016 and for the Year Ending March 31, 2017

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

	Six months ending September 30, 2016		Year ending March 31, 2017	
	Millions of yen	Thousands of US$	Millions of yen	Thousands of US$
Revenue	¥ 116,500	$ 1,040,179	¥ 259,000	$ 2,312,500
Operating profit	27,500	245,536	72,500	647,321
Profit before tax	29,000	258,929	75,000	669,643
Profit	21,500	191,964	55,800	498,214
(Owners of the parent company)				
	Yen	US$	Yen	US$
Basic earnings per share	¥ 40.56	$ 0.36	¥ 105.28	$ 0.94

(*)The foregoing are forward-looking statements based on a number of assumptions and beliefs in light of the information currently available to management and are subject to risks and uncertainties. Actual financial results may differ materially depending on a number of economic factors, including conditions and currency exchange rate fluctuations.

(*) The company conducted a stock split of common stocks at a ratio of 1:5 with an effective date of April 1, 2016. As for “Basic earnings per share”, it is calculated based on the number of shares after the stock split.

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Consolidated Statement of Financial Position

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

ASSETS	Millions of yen		Thousands of US$
	As of March 31, 2015	**As of March 31, 2016**	**As of March 31, 2016**
Current assets			
Cash and cash equivalents	¥ 104,222	¥ **110,485**	$ **986,471**
Trade and other receivables	41,960	**62,043**	**553,953**
Marketable securities	22,746	**21,583**	**192,709**
Other financial assets	820	**800**	**7,143**
Inventories	25,805	**23,232**	**207,430**
Other current assets	2,311	**5,430**	**48,479**
Total current assets	197,865	**223,573**	**1,996,185**
Non-current assets			
Property, plant, and equipment	70,754	**80,094**	**715,121**
Intangible assets	33,913	**38,324**	**342,181**
Investment securities	212,162	**182,396**	**1,628,534**
Investments in associates	1,023	**982**	**8,770**
Other financial assets	6,314	**6,753**	**60,298**
Deferred tax assets	45	**5,179**	**46,238**
Other non-current assets	2,512	**3,149**	**28,117**
Total non-current assets	326,723	**316,877**	**2,829,260**
Total assets	¥ 524,588	¥ **540,450**	$ **4,825,445**

LIABILITIES AND EQUITY	Millions of yen		Thousands of US$
	As of March 31, 2015	**As of March 31, 2016**	**As of March 31, 2016**
Current liabilities			
Trade and other payables	¥ 13,745	¥ **31,250**	$ **279,021**
Borrowings	287	**328**	**2,930**
Other financial liabilities	2,585	**3,068**	**27,392**
Income taxes payable	6,587	**6,585**	**58,798**
Provisions	684	**1,355**	**12,102**
Other current liabilities	11,109	**9,607**	**85,776**
Total current liabilities	34,997	**52,194**	**466,019**
Non-current liabilities			
Borrowings	317	**515**	**4,602**
Other financial liabilities	21	**19**	**171**
Retirement benefit liabilities	5,426	**4,093**	**36,547**
Provisions	89	**30**	**268**
Deferred tax liabilities	1,156	**885**	**7,901**
Long-term advances received	6,724	**5,814**	**51,913**
Other non-current liabilities	645	**643**	**5,746**
Total non-current liabilities	14,378	**12,000**	**107,147**
Total liabilities	49,375	**64,195**	**573,166**
Equity			
Share capital	17,358	**17,358**	**154,985**
Capital reserves	17,080	**17,103**	**152,708**
Treasury shares	(59,308)	**(59,358)**	**(529,986)**
Other components of equity	45,756	**43,307**	**386,669**
Retained earnings	449,690	**452,983**	**4,044,489**
Equity attributable to owners of the parent company	470,575	**471,393**	**4,208,865**
Non-controlling interests	4,638	**4,862**	**43,414**
Total equity	475,213	**476,255**	**4,252,279**
Total liabilities and equity	¥ 524,588	¥ **540,450**	$ **4,825,445**

Consolidated Statement of Income

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

	Millions of yen		Thousands of US$
	Year ended March 31, 2015	**Year ended March 31, 2016**	**Year ended March 31, 2016**
Revenue	¥ 135,775	¥ **160,284**	$ **1,431,108**
Cost of sales	(35,136)	**(41,524)**	**(370,752)**
Gross profit	100,639	**118,760**	**1,060,356**
Selling, general, and administrative expenses	(42,222)	**(43,979)**	**(392,671)**
Research and development costs	(41,346)	**(43,369)**	**(387,222)**
Other income	368	**708**	**6,320**
Other expenses	(2,645)	**(1,612)**	**(14,396)**
Operating profit	14,794	**30,507**	**272,387**
Finance income	3,565	**3,088**	**27,568**
Finance costs	(67)	**(291)**	**(2,600)**
Share of profit (loss) from investments in associates	13	**(32)**	**(286)**
Profit before tax	18,305	**33,272**	**297,069**
Income tax expense	(5,089)	**(8,080)**	**(72,140)**
Profit for the year	13,216	**25,192**	**224,928**
Profit for the year attributable to:			
Owners of the parent company	12,976	**24,979**	**223,028**
Non-controlling interests	240	**213**	**1,901**
Profit for the year	13,216	**25,192**	**224,928**
Earnings per share:	Yen		US$
Basic earnings per share	24.48	**47.13**	**0.42**
Diluted earnings per share	**-**	**47.13**	**0.42**

(Note) The company conducted a stock split of common stocks at a ratio of 1:5 with an effective date of April 1, 2016. As for “Basic earnings per share” and “Diluted earnings per share”, it is calculated assuming that the stock split was conducted at the beginning of the previous fiscal year.

Consolidated Statement of Comprehensive Income

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

	Millions of yen		Thousands of US$
	Year ended March 31, 2015	**Year ended March 31, 2016**	**Year ended March 31, 2016**
Profit for the year	¥ 13,216	**¥ 25,192**	**$ 224,928**
Other comprehensive income:			
Items that will not be reclassified to profit or loss:			
Net gain (loss) on financial assets measured at fair value through other comprehensive income	29,529	**(1,411)**	**(12,599)**
Remeasurement of defined benefit plans	(640)	**(3,261)**	**(29,119)**
Share of net gain (loss) on financial assets measured at fair value through other comprehensive income of investments in associates	4	**(7)**	**(59)**
	28,894	**(4,679)**	**(41,776)**
Items that may be reclassified subsequently to profit or loss:			
Exchange differences on translation of foreign operations	505	**(360)**	**(3,216)**
Net fair value gain (loss) on cash flow hedges	(6)	**-**	**-**
	499	**(360)**	**(3,216)**
Total other comprehensive income (loss)	29,393	**(5,039)**	**(44,992)**
Total comprehensive income for the year	42,609	**20,153**	**179,936**
Comprehensive income for the year attributable to:			
Owners of the parent company	42,364	**19,926**	**177,906**
Non-controlling interests	245	**227**	**2,030**
Total comprehensive income for the year	42,609	**20,153**	**179,936**

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Consolidated Statement of Changes in Equity

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

	Millions of yen							
	Equity attributable to owners of the parent company							
	Share capital	Capital reserves	Treasury shares	Other components of equity	Retained earnings	Equity attributable to owners of the parent company	Non-controlling interests	Total equity
Balance at April 1, 2014	17,358	17,080	(59,274)	15,626	456,537	447,327	4,397	451,724
Profit for the year					12,976	12,976	240	13,216
Other comprehensive income				29,389		29,389	4	29,393
Total comprehensive income for the year	–	–	–	29,389	12,976	42,364	245	42,609
Purchase of treasury shares			(34)			(34)		(34)
Cash dividends					(19,082)	(19,082)	(4)	(19,086)
Transfer from other components of equity to retained earnings				742	(742)	–		–
Total transactions with the owners	–	–	(34)	742	(19,823)	(19,116)	(4)	(19,119)
Balance at March 31, 2015	**17,358**	**17,080**	**(59,308)**	**45,756**	**449,690**	**470,575**	**4,638**	**475,213**
Profit for the year					**24,979**	**24,979**	**213**	**25,192**
Other comprehensive income				**(5,054)**		**(5,054)**	**14**	**(5,039)**
Total comprehensive income for the year	**–**	**–**	**–**	**(5,054)**	**24,979**	**19,926**	**227**	**20,153**
Purchase of treasury shares			**(50)**			**(50)**		**(50)**
Cash dividends					**(19,081)**	**(19,081)**	**(3)**	**(19,084)**
Share-based payments		**23**				**23**		**23**
Transfer from other components of equity to retained earnings				**2,605**	**(2,605)**	**–**		**–**
Total transactions with the owners	**–**	**23**	**(50)**	**2,605**	**(21,686)**	**(19,108)**	**(3)**	**(19,111)**
Balance at March 31, 2016	**17,358**	**17,103**	**(59,358)**	**43,307**	**452,983**	**471,393**	**4,862**	**476,255**

	Thousands of US $							
	Equity attributable to owners of the parent company							
	Share capital	Capital reserves	Treasury shares	Other components of equity	Retained earnings	Equity attributable to owners of the parent company	Non-controlling interests	Total equity
Balance at March 31, 2015	**154,985**	**152,499**	**(529,537)**	**408,536**	**4,015,085**	**4,201,567**	**41,409**	**4,242,976**
Profit for the year					**223,028**	**223,028**	**1,901**	**224,928**
Other comprehensive income				**(45,121)**		**(45,121)**	**129**	**(44,992)**
Total comprehensive income for the year	–	–	–	**(45,121)**	**223,028**	**177,906**	**2,030**	**179,936**
Purchase of treasury shares			**(448)**			**(448)**		**(448)**
Cash dividends					**(170,369)**	**(170,369)**	**(25)**	**(170,394)**
Share-based payments		**209**				**209**		**209**
Transfer from other components of equity to retained earnings				**23,255**	**(23,255)**	–		–
Total transactions with the owners	–	**209**	**(448)**	**23,255**	**(193,623)**	**(170,608)**	**(25)**	**(170,633)**
Balance at March 31, 2016	**154,985**	**152,708**	**(529,986)**	**386,669**	**4,044,489**	**4,208,865**	**43,414**	**4,252,279**

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Consolidated Statement of Cash Flows

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

	Millions of yen		Thousands of US$
	Year ended March 31, 2015	**Year ended March 31, 2016**	**Year ended March 31, 2016**
Cash flows from operating activities			
Profit before tax	¥ 18,305	¥ **33,272**	$ **297,069**
Depreciation and amortization	6,100	**6,534**	**58,342**
Impairment losses	560	**1,188**	**10,609**
Interest and dividend income	(2,528)	**(2,782)**	**(24,835)**
Interest expense	13	**13**	**112**
(Increase) Decrease in inventories	(1,541)	**2,562**	**22,875**
(Increase) Decrease in trade and other receivables	282	**(20,099)**	**(179,453)**
Increase (Decrease) in trade and other payables	3,999	**9,312**	**83,145**
Increase (Decrease) in retirement benefit liabilities	526	**(6,031)**	**(53,845)**
(Increase) Decrease in retirement benefit assets	915	**-**	**-**
Increase (Decrease) in long-term advances received	6,724	**(909)**	**(8,119)**
Other	327	**(3,110)**	**(27,767)**
Subtotal	33,685	**19,951**	**178,132**
Interest received	450	**314**	**2,808**
Dividends received	2,138	**2,522**	**22,520**
Interest paid	(13)	**(13)**	**(112)**
Income taxes paid	(4,680)	**(9,932)**	**(88,683)**
Net cash provided by (used in) operating activities	31,579	**12,842**	**114,664**
Cash flows from investing activities			
Purchases of property, plant, and equipment	(17,540)	**(7,021)**	**(62,687)**
Proceeds from sales of property, plant and equipment	1	**936**	**8,360**
Purchases of intangible assets	(13,578)	**(7,061)**	**(63,043)**
Purchases of investments	(3,677)	**(863)**	**(7,707)**
Proceeds from sales and redemption of investments	22,396	**27,693**	**247,257**
Other	(358)	**(647)**	**(5,778)**
Net cash provided by (used in) investing activities	(12,756)	**13,037**	**116,403**
Cash flows from financing activities			
Dividends paid to owners of the parent company	(19,060)	**(19,059)**	**(170,169)**
Dividends paid to non-controlling interests	(4)	**(3)**	**(25)**
Repayments of long-term borrowings	(487)	**(366)**	**(3,266)**
Net increase (decrease) in short-term borrowings	(19)	**11**	**102**
Purchases of treasury shares	(33)	**(49)**	**(438)**
Net cash provided by (used in) financing activities	(19,603)	**(19,465)**	**(173,797)**
Net increase (decrease) in cash and cash equivalents	(780)	**6,414**	**57,270**
Cash and cash equivalents at the beginning of the year	104,898	**104,222**	**930,557**
Effects of exchange rate changes on cash and cash equivalents	104	**(152)**	**(1,356)**
Cash and cash equivalents at the end of the year	¥ 104,222	¥ **110,485**	$ **986,471**

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Sales of Major Products

Supplemental Data

For information purpose only

		Hundreds of Millions of yen					
		Year ended March 31, 2016			Year ending March 31, 2017		
		Results	Increase/Decrease		Forecast	Increase/Decrease	
Opdivo	Agent for treatment of unresectable melanoma and unresectable, advanced or recurrent non-small cell lung cancer	**¥ 212**	**¥** +186	+741.0 %	**¥ 1,260**	**¥** +1,048	+495.7 %
Glactiv	Agent for type II diabetes	**314**	+6	+2.1 %	**295**	Δ 19	Δ 6.1 %
Opalmon	Circulatory system agent	**227**	Δ 21	Δ 8.6 %	**175**	Δ 52	Δ 22.9 %
Recalbon	Agent for osteoporosis	**113**	+10	+9.9 %	**115**	+2	+1.8 %
Forxiga	Agent for type II diabetes	**43**	+27	+177.3 %	**100**	+57	+134.0 %
Orencia SC	Agent for rheumatoid arthritis	**80**	+39	+93.7 %	**100**	+20	+24.8 %
Emend/Proemend	Agent for Chemotherapy-induced nausea and vomiting	**95**	+9	+10.2 %	**100**	+5	+5.6 %
Rivastach	Agent for Alzheimer's disease	**78**	+11	+15.6 %	**90**	+12	+14.9 %
Onon	Agent for bronchial asthma and allergic rhinitis	**90**	Δ 13	Δ 12.6 %	**65**	Δ 25	Δ 27.4 %
Onoact	Agent for tachyarrhythmia during and post operation	**57**	+10	+22.4 %	**65**	+8	+13.9 %
Staybla	Agent for overactive bladder (pollakiuria and urinary incontinence)	**52**	Δ 1	Δ 1.9 %	**50**	Δ 2	Δ 3.2 %
Onon dry syrup	Agent for pediatric bronchial asthma and allergic rhinitis	**56**	Δ 2	Δ 3.2 %	**45**	Δ 11	Δ 19.7 %
Foipan	Agent for chronic pancreatitis and postoperative reflux esophagitis	**52**	Δ 9	Δ 15.1 %	**40**	Δ 12	Δ 22.4 %
Kinedak	Agent for diabetic peripheral neuropathy	**41**	Δ 7	Δ 14.6 %	**30**	Δ 11	Δ 26.6 %
Elaspol	Agent for acute lung injury associated with SIRS	**17**	Δ 9	Δ 34.7 %	**10**	Δ 7	Δ 42.8 %

Note: Sales of products are shown in a gross sales basis.

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Revenue of Goods and Products by Geographic Area and Royalty and Other Revenue

Supplemental Data

For information purpose only

(Hundreds of Millions of yen)

	Year ended March 31, 2015	Year ended March 31, 2016
Revenue of Goods and Products		
Japan	1,230	1,421
Asia	15	20
Europe	4	3
Others	-	2
Subtotal	1,249	1,446
Royalty and Other Revenue	109	157
Total	1,358	1,603

Note: Revenue of goods and products is presented on the basis of the place of destination for sales.

Consolidated Statement of Income
excluding the Impact of Retirement Benefits Plan Revision

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

Supplemental Data

For information purpose only

The Retirement Benefits Plan Revision was agreed between labor and management in April 2015. For the 1st quarter ended June 30, 2015, the company computed actuarial calculations based on the revised retirement benefits plan and past service costs of retirement benefits obligations. As a result, operating profit increased by 63 hundreds of millions of yen, for the reason of decrease of personnel expenses due to the effect of past service costs by the retirement benefits plan revision.
The consolidated statement of income for the year ended March 31, 2016 excluding this impact is as follows.

	Hundreds of Millions of yen				Millions of US$
	Year ended March 31, 2015	Year ended March 31, 2016		Year ended March 31, 2016	Year ended March 31, 2016
	Actual	Actual	Change (%)	Excluding the Impact of Retirement Benefits Plan Revision	Change (%)	Excluding the Impact of Retirement Benefits Plan Revision
Revenue	¥ 1,358	¥ 1,603	18.1 %	¥ 1,603	18.1 %	$ 1,431
Cost of sales	(351)	(415)	18.2 %	(420)	19.4 %	(375)
Gross profit	1,006	1,188	18.0 %	1,183	17.6 %	1,057
Selling, general, and administrative expenses	(422)	(440)	4.2 %	(476)	12.8 %	(425)
Research and development costs	(413)	(434)	4.9 %	(456)	10.3 %	(407)
Operating profit	148	305	106.2 %	242	63.7 %	216
Profit before tax	183	333	81.8 %	270	47.4 %	241
Income tax expense	(51)	(81)	58.8 %	(62)	20.9 %	(55)
Profit for the period	132	252	90.6 %	208	57.6 %	186
Profit for the period attributable to:						
Owners of the parent company	130	250	92.5 %	206	58.8 %	184

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Supplemental Information

Status of Development Pipeline

as of May 9, 2016

I. Main Pipelines Other than ONO-4538

ⅰ. Developments Status in Japan

Approved

- **Proemend® for i.v. infusion (ONO-7847 / MK-0517)*1**
  - **Additional indication for pediatric use**
  - Chemotherapy-induced nausea and vomiting in pediatric patients [NK_1 receptor antagonist]
  - Injection
  - ***In-license (Merck & Co., Inc.)***

- **Orencia® SC (ONO-4164 / BMS-188667)*2**
  - **Additional formulation**
  - Orencia® SC 125 mg Auto-injector 1 mL
  - Injection
  - ***In-license (Bristol-Myers Squibb Company)***

Filed

- **ONO-7057 / Carfilzomib**
  - **New chemical entities**
  - Multiple Myeloma [Proteasome inhibitor]
  - Injection
  - ***In-license (Onyx Pharmaceuticals, Inc.)***
- **ONO-5163 / AMG-416 / Etelcalcetide Hydrochloride**
  - **New chemical entities**
  - Secondary hyperparathyroidism [Calcium sensing receptor agonist]
  - Injection
  - ***In-license (Amgen Inc.)***

Ongoing clinical studies

- **Orencia® IV (ONO-4164 / BMS-188667)**
  - **Additional indication**
  - Juvenile Rheumatoid Arthritis [T-cell activation inhibitor] / Phase III
  - Injection
  - ***In-license (Bristol-Myers Squibb Company)***
- **Orencia® IV (ONO-4164 / BMS-188667)**
  - **Additional indication**
  - Lupus nephritis[T-cell activation inhibitor] / Phase III
  - Injection
  - ***In-license (Bristol-Myers Squibb Company)***
- **Orencia® SC (ONO-4164 / BMS-188667)**
  - **Additional indication**
  - Rheumatoid Arthritis [T-cell activation inhibitor] / Phase III
  - Injection
  - ***In-license (Bristol-Myers Squibb Company)***
- **ONO-7057 / Carfilzomib**
  - **Additional Dosing Regimen and additional indication**
  - Multiple Myeloma [Proteasome inhibitor] / Phase III
  - Injection
  - ***In-license (Onyx Pharmaceuticals, Inc.)***
- **ONO-1162 / Ivabradine**
  - **New chemical entities**
  - Chronic heart failure [If channel inhibitor] / Phase III
  - Tablet
  - ***In-license (Les Laboratoires Servier)***
- **Onoact® Intravenous Infusion 50 mg / 150 mg (ONO-1101)**
  - **Additional indication for pediatric use**
  - Tachyarrhythmia in low cardiac function [Short acting beta 1 blocker] / Phase II/III
  - Injection
  - ***In-house***

Ongoing clinical studies

- **Onoact® Intravenous Infusion 50 mg / 150 mg (ONO-1101)**
  - **Additional indication**
  - Ventricular arrhythmia [Short acting beta 1 blocker] / Phase II/III
  - Injection
  - ***In-house***
- **ONO-7643 / RC-1291**
  - **New chemical entities**
  - Cancer anorexia/cachexia [Ghrelin mimetic] / Phase II
  - Tablet
  - ***In-license (Helsinn Healthcare, S.A.)***
- **ONO-6950**
  - **New chemical entities**
  - Bronchial asthma [LT receptor antagonist] / Phase II
  - Tablet
  - ***In-house***
- **ONO-2370 / Opicapone**
  - **New chemical entities**
  - Parkinson's disease [Long acting COMT inhibitor] / Phase II
  - Tablet
  - ***In-license (Bial)***
- **ONO-5371 / Metyrosine**
  - **New chemical entities**
  - Pheochromocytoma [Tyrosine hydroxylase inhibitor] / Phase I/II
  - Capsule
  - ***In-license (Valeant Pharmaceuticals North America LLC.)***
- **ONO-7268 MX1**
  - **New chemical entities**
  - Hepatocellular carcinoma [Therapeutic cancer peptide vaccines] / Phase I
  - Injection
  - ***In-license (OncoTherapy Science, Inc.)***
- **ONO-7268 MX2**
  - **New chemical entities**
  - Hepatocellular carcinoma [Therapeutic cancer peptide vaccines] / Phase I
  - Injection
  - ***In-license (OncoTherapy Science, Inc.)***
- **ONO-2160/CD**
  - **New chemical entities**
  - Parkinson's disease [levodopa pro-drug] / Phase I
  - Tablet
  - ***In-house***
- **ONO-4059**
  - **New chemical entities**
  - B cell lymphoma [Bruton's tyrosine kinase (Btk) inhibitor] / Phase I
  - Capsule
  - ***In-house***
- **ONO-8577*3**
  - **New chemical entities**
  - Overactive bladder [bladder smooth muscle relaxant] / Phase I
  - Tablet
  - ***In-house***

Changes from Third Quarter Flash Report for the Fiscal Year ending March 2016 announced on February 2, 2016
*1: Approval for a partial change in approved items of the manufacturing and marketing authorization of Proemend® for intravenous infusion was obtained in Japan for the treatment of chemotherapy-induced nausea and vomiting for pediatric patients.
*2: Orencia® SC was obtained in Japan for the manufacturing and marketing approval of subcutaneous injection 125 mg Auto-injector 1 mL.
*3: Phase I of ONO-8577 (bladder smooth muscle relaxant) was initiated for overactive bladder.

Note: "In-house" compounds include a compound generated from collaborative research.
In the case of clinical development of the anticancer compound in the same indication, the most advanced clinical phase is described.

ⅱ. Developments Status outside Japan

Ongoing clinical studies

- **ONO-6950**
  - **New chemical entities**
  - Bronchial asthma [LT receptor antagonist] / Phase II
  - Tablet
  - USA
  - ***In-house***
- **ONO-2952**
  - **New chemical entities**
  - Irritable bowel syndrome [TSPO antagonist] / Phase II
  - Tablet
  - USA
  - ***In-house***
- **ONO-9054*4**
  - **New chemical entities**
  - Glaucoma, ocular hypertension [PG receptor (FP / EP3) agonist] / Phase II
  - Eye drop
  - USA
  - ***Out-license (Santen Pharmaceutical Co., Ltd.)***
- **ONO-4059**
  - **New chemical entities**
  - B cell lymphoma [Bruton's tyrosine kinase (Btk) inhibitor] / Phase I
  - Capsule
  - USA & Europe
  - ***Out-license (Gilead Sciences, Inc.)***
- **ONO-8055**
  - **New chemical entities**
  - Underactive bladder [PG receptor (EP2 / EP3) agonist] / Phase I
  - Tablet
  - Europe
  - ***In-house***
- **ONO-1266**
  - **New chemical entities**
  - Portal hypertension [S1P receptor antagonist] / Phase I
  - Capsule
  - USA
  - ***In-house***
- **ONO-4232**
  - **New chemical entities**
  - Acute heart failure [PG receptor (EP4) agonist] / Phase I
  - Injection
  - USA
  - ***In-house***
- **ONO-4474**
  - **New chemical entities**
  - Osteoarthritis [Tropomyosin receptor kinase (Trk) inhibitor] / Phase I
  - Capsule
  - Europe
  - ***In-house***

Changes from Third Quarter Flash Report for the Fiscal Year ending March 2016 announced on February 2, 2016
*4: A licensing agreement was entered with Santen Pharmaceutical Co., Ltd. to grant Santen exclusive right to manufacture, develop and commercialize globally ONO-9054, an FP and EP3 dual receptor agonist.

Note: "In-house" compounds include a compound generated from collaborative research.
In the case of clinical development of the anticancer compound in the same indication, the most advanced clinical phase is described.

II. Main Pipelines ONO-4538 etc

ⅰ. Developments Status in Japan, South Korea, and Taiwan

Approved

Product Name / Development Code	Development Indications	Area	In-house / In-license
Opdivo® Intravenous Infusion (ONO-4538) /BMS-936558	Non-small cell lung cancer*1	South Korea	In-house (Co-development with Bristol-Myers Squibb Company)
	Melanoma*2	Taiwan	In-house (Co-development with Bristol-Myers Squibb Company)
	Non-small cell lung cancer (Squamous)*2	Taiwan	In-house (Co-development with Bristol-Myers Squibb Company)

Changes from Third Quarter Flash Report for the Fiscal Year ending March 2016 announced on February 2, 2016
*1: Approval for the partial change in approved items of the manufacturing and marketing approval for Opdivo® Intravenous Infusion was obtained in South Korea for the additional indication of locally advanced or metastatic non-small cell lung cancer refractory to existing chemotherapy.
*2: The manufacturing and marketing approval for Opdivo® Intravenous Infusion was obtained in Taiwan for the treatment of unresectable or metastatic melanoma and metastatic squamous non-small cell lung cancer.

Note: "In-house" compounds include a compound generated from collaborative research.
In the case of clinical development of the anticancer compound in the same indication, the most advanced clinical phase is described.

Filed

Product Name / Development Code	Development Indications	Area	In-house / In-license
Opdivo® Intravenous Infusion (ONO-4538) /BMS-936558	Non-small cell lung cancer (Non- Squamous)	Taiwan*3	In-house (Co-development with Bristol-Myers Squibb Company)
	Renal cell carcinoma	Japan Taiwan*3	In-house (Co-development with Bristol-Myers Squibb Company)
	Hodgkin's lymphoma*4	Japan	In-house (Co-development with Bristol-Myers Squibb Company)

Changes from Third Quarter Flash Report for the Fiscal Year ending March 2016 announced on February 2, 2016
*3: A supplemental application for approval for the additional indication of Opdivo® Intravenous Infusion was filed in Taiwan for the treatment of unresectable or metastatic renal cell carcinoma and previously treated non-squamous non-small cell lung cancer.
*4: A supplemental application for approval for the additional indication of Opdivo® Intravenous Infusion was filed in Japan for the treatment of relapsed or refractory Hodgkin's lymphoma.

Note: "In-house" compounds include a compound generated from collaborative research.
In the case of clinical development of the anticancer compound in the same indication, the most advanced clinical phase is described.

Ongoing clinical studies

Product Name / Development Code	Development Indications	Clinical Stage	Area	In-house / In-license
Opdivo®Intravenous Infusion (ONO-4538) /BMS-936558	Head and neck cancer	Phase III	Japan South Korea Taiwan	In-house (Co-development with Bristol-Myers Squibb Company)
	Gastric cancer	Phase III	Japan South Korea Taiwan	In-house (Co-development with Bristol-Myers Squibb Company)

Ongoing clinical studies

Product Name / Development Code	Development Indications	Clinical Stage	Area	In-house / In-license
Opdivo®Intravenous Infusion (ONO-4538) /BMS-936558	Esophageal cancer	Phase III	Japan South Korea Taiwan	In-house (Co-development with Bristol-Myers Squibb Company)
	Small cell lung cancer	Phase III	Japan South Korea Taiwan	In-house (Co-development with Bristol-Myers Squibb Company)
	Hepatocellular carcinoma	Phase III	Japan South Korea Taiwan	In-house (Co-development with Bristol-Myers Squibb Company)
	Glioblastoma	Phase III	Japan	In-house (Co-development with Bristol-Myers Squibb Company)
	Urothelial cancer*5	Phase III	Japan South Korea Taiwan	In-house (Co-development with Bristol-Myers Squibb Company)
	Ovarian cancer	Phase II	Japan	In-house (Co-development with Bristol-Myers Squibb Company)
	Solid tumor*6 (Cervical cancer, Endometrial cancer, Soft tissue sarcoma)	Phase II	Japan	In-house (Co-development with Bristol-Myers Squibb Company)
	Malignant pleural mesothelioma*7	Phase II	Japan	In-house (Co-development with Bristol-Myers Squibb Company)
	Virus-positive/negative solid tumor	Phase I/II	Japan South Korea Taiwan	In-house (Co-development with Bristol-Myers Squibb Company)
	Biliary tract cancer	Phase I	Japan	In-house (Co-development with Bristol-Myers Squibb Company)
Urelumab (ONO-4481) /BMS-663513	Solid tumor	Phase I	Japan	In-house (Co-development with Bristol-Myers Squibb Company)

Changes from Third Quarter Flash Report for the Fiscal Year ending March 2016 announced on February 2, 2016
*5: Phase III of Opdivo® Intravenous Infusion was initiated for the treatment of Urothelial cancer.
*6: Phase II of Opdivo® Intravenous Infusion was initiated for the treatment of Solid tumor (Cervical cancer, Endometrial cancer, and Soft tissue sarcoma).
*7: Phase II of Opdivo® Intravenous Infusion was initiated for the treatment of Malignant pleural mesothelioma.

Note: "In-house" compounds include a compound generated from collaborative research.
In the case of clinical development of the anticancer compound in the same indication, the most advanced clinical phase is described.

ⅱ. Developments Status in Europe and the United States

Approved

Product Name / Development Code	Development Indications	Area	In-house / In-license
Opdivo® Intravenous Infusion (ONO-4538) / BMS-936558	Renal cell carcinoma *8	Europe	In-house (Co-development with Bristol-Myers Squibb Company)
	Non-small cell lung cancer (Non-squamous) *9	Europe	In-house (Co-development with Bristol-Myers Squibb Company)

Changes from Third Quarter Flash Report for the Fiscal Year ending March 2016 announced on February 2, 2016
*8: Approval for the partial change in approved items of the manufacturing and marketing approval for Opdivo® Intravenous Infusion was obtained in Europe for the additional indication of previously treated advanced renal cell carcinoma.
*9: Approval for the partial change in approved items of the manufacturing and marketing approval for Opdivo® Intravenous Infusion was obtained in Europe for the additional indication of locally advanced or metastatic non-squamous non-small cell lung cancer after prior chemotherapy.

Note: "In-house" compounds include a compound generated from collaborative research.
In the case of clinical development of the anticancer compound in the same indication, the most advanced clinical phase is described.

Filed

Product Name / Development Code	Development Indications	Area	In-house / In-license
Opdivo® Intravenous Infusion (ONO-4538) /BMS-936558	Hodgkin's lymphoma*10	USA Europe	In-house (Co-development with Bristol-Myers Squibb Company)

Changes from Third Quarter Flash Report for the Fiscal Year ending March 2016 announced on February 2, 2016
*10: A supplemental application for approval for the additional indication of Opdivo® Intravenous Infusion was filed in USA and Europe for the treatment of previously treated classical Hodgkin lymphoma.

Note: "In-house" compounds include a compound generated from collaborative research.
In the case of clinical development of the anticancer compound in the same indication, the most advanced clinical phase is described.

Ongoing clinical studies

Product Name / Development Code	Development Indications	Clinical Stage	Area	In-house / In-license
Opdivo®Intravenous Infusion (ONO-4538) / BMS-936558	Head and neck cancer	Phase III	USA Europe	In-house (Co-development with Bristol-Myers Squibb Company)
	Glioblastoma	Phase III	USA Europe	In-house (Co-development with Bristol-Myers Squibb Company)
	Small cell lung cancer	Phase III	USA Europe	In-house (Co-development with Bristol-Myers Squibb Company)
	Urothelial cancer	Phase III	USA Europe	In-house (Co-development with Bristol-Myers Squibb Company)
	Hepatocellular carcinoma	Phase III	USA Europe	In-house (Co-development with Bristol-Myers Squibb Company)
	Esophageal cancer	Phase III	USA Europe	In-house (Co-development with Bristol-Myers Squibb Company)

Ongoing clinical studies

Product Name / Development Code	Development Indications	Clinical Stage	Area	In-house / In-license
Opdivo® Intravenous Infusion (ONO-4538) / BMS-936558	Diffuse large B cell lymphoma	Phase II	USA Europe	In-house (Co-development with Bristol-Myers Squibb Company)
	Follicular lymphoma	Phase II	USA Europe	In-house (Co-development with Bristol-Myers Squibb Company)
	Colon cancer	Phase I/II	USA Europe	In-house (Co-development with Bristol-Myers Squibb Company)
	Solid tumors (triple negative breast cancer, gastric cancer, pancreatic cancer, small cell lung cancer, urothelial cancer, ovarian cancer)	Phase I/II	USA Europe	In-house (Co-development with Bristol-Myers Squibb Company)
	Virus-positive/negative solid tumor	Phase I/II	USA Europe	In-house (Co-development with Bristol-Myers Squibb Company)
	Hematologic cancer (T-cell lymphoma, multiple myeloma, chronic leukemia, etc.)	Phase I	USA Europe	In-house (Co-development with Bristol-Myers Squibb Company)
	Chronic myeloid leukemia	Phase I	USA Europe	In-house (Co-development with Bristol-Myers Squibb Company)
	Hepatitis C	Phase I	USA Europe	In-house (Co-development with Bristol-Myers Squibb Company)

Note: "In-house" compounds include a compound generated from collaborative research.
In the case of clinical development of the anticancer compound in the same indication, the most advanced clinical phase is described.

Supplemental Information

New Drugs in Development

as of May 9, 2016

In our ongoing effort to create products that will promote the health of more people worldwide, Ono has many new drug formulations under development, including the following main drugs:

Rivastach® Patch(ONO-2540 / ENA713D)

Japan: J-NDA approved / Alzheimer's disease (additional dosing regimen) (co-development with Novartis Pharma AG)

Proemend® Intravenous Infusion (ONO-7847 / MK-0517)

Japan: J-NDA approved in March 2016 / chemotherapy-induced nausea and vomiting in pediatric patients (additional indication)
USA & Other Countries: Phase III / chemotherapy-induced nausea and vomiting in pediatric patients (additional indication) (Merck & Co., Inc.)

ONO-7057 / Carfilzomib (injection)

ONO-7057 is a proteasome inhibitor being developed for multiple myeloma, which is a cancer of plasma cells (one of blood cells). ONO-7057 is highly expected to be a new treatment option for multiple myeloma of which prognosis is considered poor.

Japan: J-NDA filed / multiple myeloma, Phase III / multiple myeloma (Additional Dosing Regimen)
Overseas: Approved in the United States / multiple myeloma (launched in August 2012), Filed in Europe / multiple myeloma (Onyx Pharmaceuticals, Inc.).

ONO-4164IV / BMS-188667IV (injection)

ONO-4164IV is an intravenous preparation of Orencia® and is marketed in Japan where it is indicated for use in patients of rheumatoid arthritis for whom other therapies have failed and overseas where it is indicated for use in patients with juvenile idiopathic arthritis.

Japan: Phase III / juvenile idiopathic arthritis (additional indication) (co-development with Bristol-Myers Squibb Company), Phase III / lupus nephritis (additional indication) (co-development with Bristol-Myers Squibb Company, being conducted as global clinical trial)
Overseas: Phase III / lupus nephritis (additional indication) (Bristol-Myers Squibb Company, being conducted as global clinical trial)

ONO-4164SC / BMS-188667SC (injection)

ONO-4164SC is a subcutaneous formulation of Orencia® and is marketed in Japan where it is indicated for use in patients of rheumatoid arthritis for whom other therapies have failed.

Japan: J-NDA approved in February 2016 / Orencia® SC 125 mg Auto-injector 1 mL, Phase III / rheumatoid arthritis (additional indication) (co-development with Bristol-Myers Squibb Company, being conducted as global clinical trial)
Overseas: Phase III / rheumatoid arthritis (additional indication) (Bristol-Myers Squibb Company, being conducted as global clinical trial)

ONO-5163 / AMG-416 (injection)

ONO-5163 is a calcium sensing receptor agonist currently being developed for the treatment of secondary hyperparathyroidism.

Japan: J-NDA filed / secondary hyperparathyroidism
Overseas (USA & Europe): Filed / secondary hyperparathyroidism (Amgen Inc.)

ONO-1162 (tablet)

ONO-1162 is an If channel blocker and is approved for the indication of chronic heart failure in addition to stable angina in Europe. It is under development in Japan for the indication of chronic heart failure.

Japan: Phase III / chronic heart failure
Overseas: Marketed / stable angina, chronic heart failure (Les Laboratoires Servier)

Onoact® Intravenous Infusion 50mg/150 mg (ONO-1101) (injection)

Japan: Phase II/III / tachyarrhythmia in low cardiac function in pediatric patients (additional indication), Phase II/III / ventricular arrhythmia (additional indication)

ONO-7643 / RC-1291 (tablet)

ONO-7643 is a small-molecule ghrelin mimetic being developed for cancer anorexia / cachexia. ONO-7643 has similar pharmacological actions to ghrelin, a circulating peptide hormone with multiple physiological actions, including appetite stimulation and muscle-building, and is therefore expected to be a breakthrough drug that improves quality of life (QOL) for patients impaired by a systemic wasting condition characterized by anorexia, lipolysis and muscle loss associated with the progression of cancer.

Japan: Phase II / cancer anorexia / cachexia
USA: Phase III / cancer anorexia / cachexia (Helsinn Healthcare, S.A.)
Europe: Filed / cancer anorexia / cachexia (Helsinn Healthcare, S.A.)

ONO-6950 (tablet)

ONO-6950 is a leukotriene receptor antagonist, and is under clinical development for bronchial asthma. It is expected to improve symptoms associated with the disease by inhibiting airway inflammation.

Japan: Phase II / bronchial asthma
USA: Phase II / bronchial asthma

ONO-2370/Opicapone (tablet)

ONO-2370 is a long acting COMT inhibitor being developed for the treatment of Parkinson's disease. ONO-2370 is filed in Europe by Bial and the compound has shown a long-lasting effect on COMT inhibition from once daily dosing in clinical studies so far and is expected to improve a dosing convenience.

Japan: Phase II / Parkinson's disease
Europe: Filed / Parkinson's disease (Bial)

ONO-5371/ Metyrosine (capsule)

ONO-5371 is a tyrosine hydroxylase inhibitor against catecholamine biosynthesis, and is under clinical development for pheochromocytoma. ONO-5371 was approved and launched in the United States in 1979. In Japan, the Review Committee on Unapproved and Off-Label Drugs with High Medical Needs, set up by the Ministry of Health, Labour and Welfare (MHLW) regarded metyrosine as a drug with high medical needs and MHLW publicly sought pharmaceutical companies to develop metyrosine.

Japan: Phase I/II / pheochromocytoma
USA: Marketed / pheochromocytoma (Valeant Pharmaceuticals North America LLC)

ONO-7268MX1 / ONO-7268MX2 (injection)

ONO-7268MX1 and ONO-7268MX2 are peptide vaccines and are expected to have effects on cancers such as hepatocellular carcinoma.

Japan: Phase I / hepatocellular carcinoma

ONO-2160/CD (tablet)

ONO-2160 is a combination product with levodopa pro-drug and carbidopa which is currently developed for Parkinson's disease.

Japan: Phase I / Parkinson's disease

ONO-4059 (capsule)

ONO-4059 is a Btk inhibitor being developed for the treatment of B cell lymphoma.

Japan: Phase I / B cell lymphoma
USA & Europe: Phase I / B cell lymphoma (Gilead Sciences, Inc.)

ONO-8577 (tablet)

ONO-8577 is a bladder smooth muscle relaxant being developed for the treatment of overactive bladder.

Japan: Phase I / overactive bladder

ONO-2952 (tablet)

ONO-2952 is an antagonist of translocator protein (TSPO) that is involved in neurosteroid production mainly in central nervous system, and is under clinical development for irritable bowel syndrome. It is expected to improve various symptoms of the disease by blocking the mechanism eliciting abnormality of brain-gut interactions under stress.

USA: Phase II / Irritable bowel syndrome

ONO-9054 (eye drop)

ONO-9054 is a prostaglandin receptor (FP/EP3) agonist being developed for glaucoma and ocular hypertension.

USA: Phase II / glaucoma and ocular hypertension (Santen Pharmaceutical Co., Ltd.)

ONO-8055 (tablet)

ONO-8055 is a prostaglandin receptor (EP2/EP3) agonist being developed for the treatment of underactive bladder.

Europe: Phase I / underactive bladder

ONO-1266 (capsule)

ONO-1266 is a sphingosine-1-phosphate receptor (S1P) antagonist being developed for the treatment of portal hypertension.

USA: Phase I /portal hypertension

ONO-4232 (injection)

ONO-4232 is a prostaglandin receptor (EP4) agonist being developed for the treatment of acute heart failure.

USA: Phase I /acute heart failure

ONO-4474 (capsule)

ONO-4474 is a tropomyosin receptor kinase (Trk) inhibitor being developed for the treatment of osteoarthritis.

Europe: Phase I /osteoarthritis

ONO-4538 / BMS-936558 (injection)

ONO-4538, a human anti-human PD-1 monoclonal antibody, is expected to be a potential treatment for cancer etc. PD-1 is one of the receptors expressed on activated lymphocytes, and is involved in the negative regulatory system to suppress the activated lymphocytes. It has been reported that tumor cells utilize this system to escape from the host immune responses. It is anticipated that blockade of the negative regulatory signal mediated by PD-1 will promote the host's immune response, in which tumor cells and viruses are recognized as foreign and eliminated.
In Japan, South Korea, and Taiwan, Ono is co-developing with Bristol-Myers Squibb Company. In the other areas, Bristol-Myers Squibb Company is developing.

Japan:
Launched in September 2014 / melanoma,
J-NDA approved in December 2015 / non-small cell lung cancer,
J-NDA filed / renal cell cancer,
J-NDA filed / hodgkin's lymphoma,
Phase III / head and neck cancer (global clinical trial),
Phase III / gastric cancer (global clinical trial),
Phase III / esophageal cancer (global clinical trial),
Phase III / small cell lung cancer (global clinical trial),
Phase III / urothelial cancer (global clinical trial),
Phase III / hepatocellular carcinoma (global clinical trial),
Phase III / glioblastoma (global clinical trial),
Phase II / ovarian cancer,
Phase II / solid tumor (cervical cancer, endometrial cancer, soft tissue sarcoma),
Phase II / malignant pleural mesothelioma,
Phase I/II / virus-positive/negative solid tumor (global clinical trial),
Phase I / biliary tract cancer,
Phase I / Solid tumor (combination with Urelumab)

Overseas:
USA / Launched in December 2014 / melanoma,
South Korea / Approved in March 2015 / melanoma,
USA / Approved in March 2015 / squamous non-small cell lung cancer,
Europe / Approved in June 2015 / melanoma,
Europe / Approved in July 2015 / squamous non-small cell lung cancer,
USA / Approved in September 2015 / melanoma (combination with Yervoy),
USA / Approved in October 2015 / non-squamous non-small cell lung cancer,
USA / Approved in November 2015 / renal cell cancer,
Europe / Approved in April 2016 / non-squamous non-small cell lung cancer,
South Korea / Approved in April 2016 / non-small cell lung cancer,
Europe / Approved in April 2016 / renal cell cancer,
Taiwan / Approved in May 2016 / melanoma,
Taiwan / Approved in May 2016 / squamous non-small cell lung cancer,
Europe / Filed / melanoma (combination with Yervoy),
Taiwan / Filed / non-squamous non-small cell lung cancer,
USA, Europe / Filed / hodgkin's lymphoma,
Taiwan / Filed / renal cell cancer,
South Korea, Taiwan / Phase III / gastric cancer,
USA, Europe, South Korea, Taiwan / Phase III / esophageal cancer,
USA, Europe, South Korea, Taiwan / Phase III / head and neck cancer,
USA, Europe / Phase III / glioblastoma,
USA, Europe, South Korea, Taiwan / Phase III / small cell lung cancer,
USA, Europe, South Korea, Taiwan / Phase III / urothelial cancer,
USA, Europe, South Korea, Taiwan / Phase III / hepatocellular carcinoma,
USA, Europe / Phase II / diffuse large B cell lymphoma,
USA, Europe / Phase II / follicular lymphoma,
USA, Europe / Phase I/II / colon cancer,
USA, Europe / Phase I/II / solid tumors (triple negative breast cancer, gastric cancer, pancreatic cancer, small cell lung cancer, urothelial cancer, ovarian cancer),
USA, Europe, South Korea, Taiwan / Phase I/II / virus-positive/negative solid tumor,
USA, Europe / Phase I / hematological cancer (T-cell lymphoma, multiple myeloma, chronic leukemia, etc),
USA, Europe / Phase I / chronic myelocytic leukemia,
USA, Europe / Phase I / hepatitis C