

First-Second Quarter (April 1 – September 30, 2013) Flash Report (unaudited)
Six months ended September 30, 2013

ONO PHARMACEUTICAL CO., LTD.

November 5, 2013

Ono Pharmaceutical Co., Ltd. has announced its consolidated financial results for six months ended September 30, 2013.

This First - Second Quarter Flash Report 2014 (unaudited) is summary information extracted from financial statements announced, and the financial statements contained herein are prepared for the reference only for the convenience of readers outside Japan with certain modifications and reclassifications made from the original financial statements presented in Japanese language.

Financial Highlights

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

| | (Note) All yen amounts are rounded off to the nearest million yen. | | | Thousands of US\$ |
|-----------------------------|--|---|---|---|
| | Millions of yen | | | |
| | 1st-2nd Quarter 6 months ended Sep 30 2013 | 1st-2nd Quarter 6 months ended Sep 30 2012 | Annual 12 months ended Mar 31 2013 | 1st-2nd Quarter 6 months ended Sep 30 2013 |
| Net sales | ¥ 71,703 | ¥ 71,112 | ¥ 145,393 | \$ 731,663 |
| Net income | 10,158 | 11,072 | 24,120 | 103,653 |
| Total Net assets | 428,623 | 401,207 | 423,291 | 4,373,704 |
| Total assets | 460,806 | 430,038 | 455,573 | 4,702,102 |
| | | Yen | | US\$ |
| Net income per common share | ¥ 95.82 | ¥ 104.44 | ¥ 227.51 | \$ 0.98 |

Consolidated Financial Forecast for the Year Ending March 31,2014

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

| | Year ending March 31,2014 | |
|------------------------------------|--------------------------------------|--------------------------|
| | Millions of yen | Thousands of US\$ |
| Net sales | ¥ 148,300 | \$ 1,513,265 |
| Operating income | 27,900 | 284,694 |
| Ordinary income | 29,000 | 295,918 |
| Net income | 20,400 | 208,163 |
| | Yen | US\$ |
| Net income per common share | 192.42 | 1.96 |

(*)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.

First-Second Quarter (April 1 – September 30, 2013) Flash Report (unaudited)
Six months ended September 30, 2013

Consolidated Balance Sheets

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

(Note) All amounts are rounded off to the nearest million yen.

| ASSETS | Millions of yen | | | Thousands of US\$ |
|---|---|---|----------------------------|---|
| | 1st-2nd Quarter September 30 2013 | 1st-2nd Quarter September 30 2012 | Annual March 31 2013 | 1st-2nd Quarter September 30 2013 |
| Current assets | | | | |
| Cash and bank deposits | ¥ 26,776 | ¥ 16,474 | ¥ 24,262 | \$ 273,224 |
| Notes and accounts receivable | 36,914 | 35,200 | 37,823 | 376,673 |
| Marketable securities | 107,457 | 112,957 | 105,877 | 1,096,500 |
| Inventories | 25,131 | 21,273 | 23,409 | 256,439 |
| Others | 20,884 | 19,213 | 23,377 | 213,103 |
| Allowance for doubtful receivables | (5) | (6) | (6) | (51) |
| Total current assets | 217,157 | 205,111 | 214,742 | 2,215,888 |
| Property, plant and equipment | | | | |
| Land | 23,484 | 22,544 | 23,479 | 239,633 |
| Buildings and structures | 21,485 | 22,328 | 21,780 | 219,235 |
| Machinery, equipment and others | 2,670 | 2,492 | 2,933 | 27,245 |
| Construction in progress | 2,346 | 658 | 1,438 | 23,938 |
| Net property, plant and equipment | 49,985 | 48,022 | 49,630 | 510,051 |
| Investments and other assets | | | | |
| Investment securities | 182,338 | 160,338 | 180,200 | 1,860,592 |
| Intangible assets | 1,877 | 1,142 | 1,384 | 19,153 |
| Others | 9,449 | 15,425 | 9,617 | 96,418 |
| Total investments and other assets | 193,664 | 176,905 | 191,201 | 1,976,163 |
| Total assets | 460,806 | 430,038 | ¥ 455,573 | \$ 4,702,102 |

(Note) All amounts are rounded off to the nearest million yen.

| LIABILITIES AND EQUITY | Millions of yen | | | Thousands of US\$ |
|---|---|---|----------------------------|---|
| | 1st-2nd Quarter September 30 2013 | 1st-2nd Quarter September 30 2012 | Annual March 31 2013 | 1st-2nd Quarter September 30 2013 |
| Current liabilities | | | | |
| Current portion of long-term debt | ¥ 102 | ¥ 102 | ¥ 104 | \$ 1,041 |
| Notes and accounts payable | 3,925 | 4,142 | 4,244 | 40,051 |
| Income tax payable | 4,185 | 6,202 | 5,606 | 42,704 |
| Others | 15,570 | 14,095 | 15,833 | 158,878 |
| Total current liabilities | 23,782 | 24,541 | 25,787 | 242,674 |
| Long-term liabilities | | | | |
| Long-term debt, less current portion | 84 | 185 | 176 | 857 |
| Liabilities for retirement benefits | 1,199 | 1,342 | 1,076 | 12,235 |
| Asset retirement obligations | 55 | 54 | 54 | 561 |
| Others | 7,063 | 2,709 | 5,189 | 72,071 |
| Total long-term liabilities | 8,401 | 4,290 | 6,495 | 85,724 |
| Equity | | | | |
| Common stock | 17,358 | 17,358 | 17,358 | 177,122 |
| Capital surplus | 17,080 | 17,080 | 17,080 | 174,286 |
| Retained earnings | 431,441 | 427,318 | 430,824 | 4,402,459 |
| Treasury stock-at cost | (59,224) | (59,210) | (59,214) | (604,326) |
| Total equity | 406,655 | 402,546 | 406,048 | 4,149,541 |
| Other comprehensive income | | | | |
| Unrealized gain on securities (*) | 26,945 | 4,485 | 22,451 | 274,949 |
| Land revaluation surplus | (8,578) | (8,578) | (8,577) | (87,531) |
| Deferred gains on hedges | 14 | — | — | 143 |
| Foreign currency translation adjustments | 214 | (408) | 67 | 2,184 |
| Total other comprehensive income | 18,595 | (4,501) | 13,941 | 189,745 |
| Minority interests | 3,373 | 3,162 | 3,302 | 34,418 |
| Total net assets | 428,623 | 401,207 | 423,291 | 4,373,704 |
| Total liabilities and total net assets | 460,806 | 430,038 | ¥ 455,573 | \$ 4,702,102 |

(*) Unrealized gain on securities classified as available for sale, net of tax

First-Second Quarter (April 1 – September 30, 2013) Flash Report (unaudited)

Six months ended September 30, 2013

Consolidated Statements of Income

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

(Note) All amounts are rounded off to the nearest million yen.

| | Millions of yen | | | Thousands of US\$ |
|---|---|---|---|---|
| | 1st-2nd Quarter 6 months ended Sep 30 2013 | 1st-2nd Quarter 6 months ended Sep 30 2012 | Annual 12 months ended Mar 31 2013 | 1st-2nd Quarter 6 months ended Sep 30 2013 |
| Net sales | ¥ 71,703 | ¥ 71,112 | ¥ 145,393 | \$ 731,663 |
| Cost of sales | 16,416 | 16,283 | 33,983 | 167,510 |
| Gross profit | 55,287 | 54,829 | 111,410 | 564,153 |
| Selling, general and administrative expenses | 42,130 | 37,323 | 79,489 | 429,898 |
| Operating income | 13,157 | 17,506 | 31,921 | 134,255 |
| Other income (expenses) | | | | |
| Interest and dividend income | 1,492 | 1,448 | 2,575 | 15,224 |
| Interest expenses | (3) | (0) | (2) | (31) |
| Other, net | (152) | (1,480) | 165 | (1,550) |
| | 1,337 | (32) | 2,738 | 13,643 |
| Income before income taxes and minority interests | 14,494 | 17,474 | 34,659 | 147,898 |
| Income taxes | 4,255 | 6,307 | 10,318 | 43,418 |
| Income before minority interests | 10,239 | 11,167 | 24,341 | 104,480 |
| Minority interests | (81) | (95) | (221) | (827) |
| Net income | 10,158 | 11,072 | ¥ 24,120 | \$ 103,653 |
| | | | | |
| | | | | |
| Per share of common stock | | | | |
| Basic net income | ¥ 95.82 | ¥ 104.44 | ¥ 227.51 | \$ 0.98 |
| Cash dividends applicable to the period | ¥ 90.00 | ¥ 90.00 | ¥ 180.00 | \$ 0.92 |

First-Second Quarter (April 1 – September 30, 2013) Flash Report (unaudited)

Six months ended September 30, 2013

Consolidated Statements of Comprehensive Income

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

(Note) All amounts are rounded off to the nearest million yen.

| | Millions of yen | | | Thousands of US\$ |
|---|---|---|---|---|
| | 1st-2nd Quarter 6 months ended Sep 30 2013 | 1st-2nd Quarter 6 months ended Sep 30 2012 | Annual 12 months ended Mar 31 2013 | 1st-2nd Quarter 6 months ended Sep 30 2013 |
| Net income before minority interests | ¥ 10,239 | ¥ 11,167 | ¥ 24,341 | \$ 104,480 |
| Other comprehensive income | | | | |
| Unrealized gain (loss) on available-for-sale securities | 4,492 | (1,243) | 16,722 | 45,837 |
| Deferred gain (loss) on hedges | 14 | — | — | 143 |
| Foreign currency translation adjustments | 146 | (131) | 344 | 1,490 |
| Share of other comprehensive income in associates | (4) | 2 | 17 | (41) |
| Total other comprehensive income | 4,648 | (1,372) | 17,083 | 47,429 |
| Comprehensive income | 14,887 | 9,795 | 41,424 | 151,909 |
| Total comprehensive income attributable to | | | | |
| Owners of the parent | 14,812 | 9,701 | 41,190 | 151,144 |
| Minority interests | 75 | 94 | 234 | 765 |

First-Second Quarter (April 1 – September 30, 2013) Flash Report (unaudited)

Six months ended September 30, 2013

Consolidated Statements of Cash Flows

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

(Note) All amounts are rounded off to the nearest million yen.

| | Millions of yen | | | Thousands of US\$ |
|--|---|---|---|---|
| | 1st-2nd Quarter 6 months ended Sep 30 2013 | 1st-2nd Quarter 6 months ended Sep 30 2012 | Annual 12 months ended Mar 31 2013 | 1st-2nd Quarter 6 months ended Sep 30 2013 |
| Operating activities: | | | | |
| Income before income taxes and minority interests | ¥ 14,494 | ¥ 17,474 | ¥ 34,658 | \$ 147,898 |
| Adjustments for: | | | | |
| Depreciation and amortization | 1,323 | 1,333 | 2,845 | 13,500 |
| Increase (decrease) in allowance for doubtful receivables | (0) | 0 | 0 | (0) |
| Increase (decrease) in provision for retirement benefits, net | 118 | (296) | (569) | 1,204 |
| Interest and dividend income | (1,492) | (1,448) | (2,575) | (15,224) |
| Gain on sales of investment securities | - | (128) | (771) | - |
| Loss on valuation of investment securities | 104 | 1,606 | 66 | 1,061 |
| Interest expenses | 3 | 1 | 2 | 31 |
| Decrease in notes and accounts receivable | 909 | 2,651 | 31 | 9,276 |
| Increase in inventories | (1,721) | (2,636) | (4,772) | (17,561) |
| Decrease in trade notes and accounts payable | (170) | (1,677) | (1,660) | (1,735) |
| Others | 3,384 | 346 | 757 | 34,530 |
| Interest and dividend income received | 1,575 | 1,546 | 2,749 | 16,071 |
| Interest paid | (3) | (1) | (2) | (31) |
| Income taxes paid | (5,640) | (8,997) | (15,097) | (57,551) |
| Net cash (used in) provided by operating activities | 12,884 | 9,774 | 15,662 | 131,469 |
| Investing activities: | | | | |
| Payments for purchases of marketable securities | (4,998) | (10,116) | (23,012) | (51,000) |
| Proceeds from sales and redemption of marketable securities | 25,800 | 25,478 | 50,591 | 263,265 |
| Payments for purchases of property, plant and equipment | (2,117) | (1,978) | (4,578) | (21,602) |
| Payments for purchases of investment securities | (9,964) | (8,668) | (20,004) | (101,673) |
| Proceeds from sales of investment securities | 1,503 | 218 | 4,414 | 15,337 |
| Other payments | (803) | (121) | (241) | (8,194) |
| Net cash generated from provided by investment activities | 9,421 | 4,813 | 7,170 | 96,133 |
| Financing activities: | | | | |
| Repayment of current portion of long-term loans payable | (51) | (26) | (77) | (520) |
| Proceeds from long-term loans payable | - | 300 | 300 | - |
| Payments for obtaining treasury stock | (9) | (5) | (9) | (92) |
| Cash dividends | (9,539) | (9,526) | (19,056) | (97,337) |
| Cash dividends to minority shareholders | (3) | (4) | (4) | (31) |
| Others | (3) | - | (1) | (30) |
| Net cash used in financing activities | (9,605) | (9,261) | (18,847) | (98,010) |
| Foreign currency translation adjustments | | | | |
| on cash and cash equivalents | 37 | (89) | 65 | 378 |
| Net decrease in cash and cash equivalents | 12,737 | 5,237 | 4,050 | 129,970 |
| Cash and cash equivalents, beginning | 89,117 | 85,067 | 85,067 | 909,357 |
| Cash and cash equivalents, ending | ¥ 101,854 | ¥ 90,304 | ¥ 89,117 | \$ 1,039,327 |

Notes to Consolidated Financial Statements

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

Note 1 This First-Second Quarter Flash Report 2014 (unaudited) is a summary information extracted from the financial statements announced by the Company on November 5, 2013.

The financial statements announced have been prepared and stated in accordance with accounting principles generally accepted in Japan.

The financial statements and figures contained in this First-Second Quarter Flash Report 2014 (unaudited) are prepared for the reference only for the convenience of readers outside Japan with certain modifications and reclassifications made from the original financial statements presented in Japanese language.

Note 2 All amounts expressed herein in millions of Japanese yen are rounded off to the nearest million yen, which are to follow the basis of presentation in the above original announcement.

Note 3 U.S. Dollar amounts herein are given solely for the convenience of readers outside Japan and are stated, as a matter of arithmetical computation only, at the rate of Japanese yen 98 = US\$ 1, the approximate exchange rate prevailing on September 30, 2013.

First-Second Quarter (April 1 – September 30, 2013) Flash Report (unaudited)

Six months ended September 30, 2013

Sales of Major Products

Supplemental Data

For information purpose only

(Note) All amounts are rounded off to the nearest hundred million yen.

| | | 1st-2nd Quarter 6 months ended Sep 30, 2013 | | | Year ending March 31,2014 |
|-----------------------|---|--|-------------------|----------|---------------------------------|
| | | Results | Increase/Decrease | | Forecast |
| Glactiv | Agent for type II diabetes | ¥ 182 | ¥ + 12 | 7.4 % | ¥ 400 |
| Opalmon | Circulatory system agent | 167 | Δ 7 | Δ 3.8 % | 310 |
| Onon | Agent for bronchial asthma and allergic rhinitis | 61 | Δ 10 | Δ 14.5 % | 125 |
| Recalbon | Agent for osteoporosis | 51 | + 18 | 55.3 % | 105 |
| Emend/Proemend | Agent for Chemotherapy-induced nausea and vomiting | 42 | + 3 | 7.2 % | 95 |
| Foipan | Agent for chronic pancreatitis and postoperative reflux esophagitis | 42 | Δ 4 | Δ 9.0 % | 80 |
| Kinedak | Agent for diabetic peripheral neuropathy | 38 | Δ 8 | Δ 17.5 % | 80 |
| Staybla | Agent for overactive bladder (pollakiuria and urinary incontinence) | 31 | Δ 2 | Δ 5.6 % | 70 |
| Onon dry syrup | Agent for pediatric bronchial asthma and allergic rhinitis | 30 | Δ 1 | Δ 3.9 % | 70 |
| Rivastach | Agent for Alzheimer's disease | 29 | + 12 | 71.2 % | 65 |
| Onoact | Agent for tachyarrhythmia during and post operation | 19 | + 1 | 7.9 % | 45 |
| Elaspol | Agent for acute lung injury associated with SIRS | 17 | Δ 2 | Δ 11.1 % | 35 |
| Orencia SC | Agent for rheumatoid arthritis | 1 | — | — | 12 |

Note: 1 Sales of products are shown in a gross sales basis.

2 Orencia SC was launched in Fiscal 2013, and year-on-year changes in value and percentage are therefore not available.

First-Second Quarter (April 1 – September 30, 2013) Flash Report (unaudited)

Six months ended September 30, 2013

Supplemental Information

Status of Development Pipeline

as of November 5, 2013

Developments in Japan

NDA approved (New Formulations):

- **Glactiv® Tablets 12.5mg (ONO-5435 / MK-0431) *1**
(Co-development with Merck & Co., Inc.)
Type 2 diabetes with severe renal dysfunction [DPP-4 inhibitor]

NDA filed (New Formulations):

- **Opalmon® Tablets (Co-development with Daiinippon Sumitomo Pharma Co., Ltd.) *2**
Thromboangitis obliterans and lumbar spinal canal stenosis [Blood vessel dilation]

NDA filed (Additional Indication):

- **Glactiv® Tablets (ONO-5435 / MK-0431) *3**
(Co-development with Merck & Co., Inc.)
Type 2 diabetes: combination therapy with a rapid-acting insulin secretagogue [DPP-4 inhibitor]

- **Onoact® 50 for Injection (ONO-1101)**
Tachyarrhythmia in low cardiac function [Short acting beta-1 blocker]

Ongoing clinical studies (New Chemical Entities):

- **ONO-4538 / BMS-936558 (injection)**
Renal cell cancer (Phase III) [Fully human anti-PD-1 antibody]
- **ONO-2745 / CNS 7056 (injection)**
(In-licensed from PAION AG)
Short acting general anesthetic (Phase II / III)
[GABA_A receptor modulator]
- **ONO-7165 / EMD531444 (injection)**
(Co-development with Merck KGaA)
Non-small cell lung cancer (Phase II) [Therapeutic cancer peptide vaccine targeting the tumor antigen MUC-1]
- **ONO-4641 (tablet)**
Multiple sclerosis (Phase II) [S1P receptor agonist]
- **ONO-3849 / Methylnaltrexone bromide (injection)**
(In-licensed from Progenics Pharmaceuticals, Inc.)
Opioid-induced constipation (Phase II)
[Mu-opioid receptor antagonist]
- **ONO-7643 / RC-1291 (tablet)**
(In-licensed from Helsinn Therapeutics (U.S.), Inc.)
Cancer anorexia / cachexia (Phase II)
[Ghrelin mimetic]
- **ONO-4538 / BMS-936558 (injection)**
Melanoma (Phase II) [Fully human anti-PD-1 antibody]
- **ONO-4538 / BMS-936558 (injection)**
Non-small cell lung cancer (Phase II) [Fully human anti-PD-1 antibody]
- **ONO-7057 / Carfilzomib (injection)**
(In-licensed from Onyx Pharmaceuticals, Inc.)
Multiple Myeloma (Phase I / II) [Proteasome inhibitor]
- **ONO-5163 / AMG-416 (injection)**
(In-licensed from Amgen Inc.)
Secondary hyperparathyroidism (Phase I / II) [Calcium sensing receptor agonist]
- **ONO-6950 (tablet)**
Bronchial asthma (Phase I) [LT receptor antagonist]

- **ONO-7056 / Salirasib (tablet)**
(In-licensed from Kadmon Corporation LLC)
Solid tumor (Phase I) [Ras signal inhibitor]
- **ONO-7268 MX1 (injection)**
(In-licensed from OncoTherapy Science, Inc.)
Hepatocellular carcinoma (Phase I) [Therapeutic cancer peptide vaccines]
- **ONO-1162 / Ivabradine (tablet)**
(In-licensed from Les Laboratoires Servier)
Chronic heart failure (Phase I) [If channel inhibitor]
- **ONO-2160/CD (tablet)**
Parkinson's disease (Phase I) [levodopa pro-drug]

Ongoing clinical studies (Additional Indications):

- **Proemend® for i.v. infusion (ONO-7847 / MK-0517)**
(In-licensed from Merck & Co., Inc.)
Chemotherapy-induced nausea and vomiting in pediatric patients (Phase III) [NK1 receptor antagonist]
- **Orencia® IV (ONO-4164IV / BMS-188667IV)**
(Co-development with Bristol-Myers Squibb Company)
Juvenile Rheumatoid Arthritis (Phase III) [T-cell activation inhibitor]
- **Orencia® IV (ONO-4164IV / BMS-188667IV)**
(Co-development with Bristol-Myers Squibb Company)
Lupus nephritis (Phase III) [T-cell activation inhibitor]

Ongoing clinical studies (Additional Dosing Regimen):

- **Rivastach® Patch (ONO-2540 / ENA713D)**
(Co-development with Novartis Pharma AG)
Alzheimer's disease (Phase III) [dual inhibitor of AChE and BuChE]

Developments abroad

Ongoing clinical studies (New Chemical Entities):

- **ONO-4538 / BMS-936558 (injection)**
(Out-licensed to Bristol-Myers Squibb Company)
Renal cell cancer (Phase III) [Fully human anti-PD-1 antibody]
- **ONO-4538 / BMS-936558 (injection)**
(Out-licensed to Bristol-Myers Squibb Company)
Non-small cell lung cancer (Phase III) [Fully human anti-PD-1 antibody]
- **ONO-4538 / BMS-936558 (injection)**
(Out-licensed to Bristol-Myers Squibb Company)
Melanoma (Phase III) [Fully human anti-PD-1 antibody]
- **ONO-4641 (tablet)**
(Out-licensed to Merck KGaA)
Multiple sclerosis (Phase II) [S1P receptor agonist]
- **ONO-6950 (tablet)**
Bronchial asthma (Phase II) [LT receptor antagonist]
- **ONO-4053 (tablet)**
Allergic rhinitis (Phase II) [PGD2 receptor antagonist]
- **ONO-2952 (tablet)**
Irritable bowel syndrome (Phase II) [TSPO antagonist]

- **ONO-4538 / BMS-936558 (injection) *4**
(Out-licensed to Bristol-Myers Squibb Company)
Solid tumors (triple negative breast cancer, stomach cancer, pancreatic cancer, small cell lung cancer (Phase I/II) [Fully human anti-PD-1 antibody]
- **ONO-4538 / BMS-936558 (injection)**
(Out-licensed to Bristol-Myers Squibb Company)
Hematological cancer (Phase I) [Fully human anti-PD-1 antibody]
- **ONO-4538 / BMS-936558 (injection)**
(Out-licensed to Bristol-Myers Squibb Company)
Hepatocellular carcinoma (Phase I) [Fully human anti-PD-1 antibody]
- **ONO-4538 / BMS-936558 (injection)**
(Out-licensed to Bristol-Myers Squibb Company)
Hepatitis C (Phase I) [Fully human anti-PD-1 antibody]
- **ONO-7746 (capsule)**
(In-licensed from Nissan Chemical Industries, Ltd.)
Thrombocytopenia (Phase I) [TPO receptor agonist]
- **ONO-9054 (eye drop)**
Glaucoma, ocular hypertension (Phase I) [PG receptor (FP / EP3) agonist]
- **ONO-4059 (capsule)**
B cell lymphoma (Phase I) [Bruton's tyrosine kinase (Btk) inhibitor]
- **ONO-8055 (tablet)**
Underactive bladder (Phase I) [PG receptor (EP2 / EP3) agonist]
- **ONO-8539 (tablet)**
Gastroesophageal reflux disease (GERD) (Phase I) [PG receptor (EP1) antagonist]
- **ONO-1266 (capsule)**
Portal hypertension (Phase I) [S1P receptor antagonist]
- **ONO-4232 (injection) *5**
Acute heart failure (Phase I) [PG receptor (EP4) agonist]

Changes from First Quarter Flash Report for the Fiscal Year ending March 2014 announced on August 2, 2013

- *1: Marketing authorization of new formulation of Glactiv[®] Tablets 12.5mg (ONO-5435 / MK0431) was obtained which can be administered at a dose of 12.5mg of sitagliptin once daily. Type 2 diabetic patients with severe renal dysfunction, or terminal renal failure necessary for hemodialysis or peritoneal dialysis can be treated by this new tablet.
- *2: New formulation of Opalmon[®] was filed for the purpose of stability improvement.
- *3: Additional indication of Glactive[®] was filed for the indication of type 2 diabetes.
- *4: Phase I/II clinical study of ONO-4538/BMS-936558 (Fully human anti-PD-1 antibody) was initiated for the treatment of solid tumors (triple negative breast cancer, stomach cancer, pancreatic cancer, small cell lung cancer)
- *5: Phase I clinical study of ONO-4232 (PG receptor (EP4) agonist) was initiated for the treatment of acute heart failure.
- *: Phase III clinical study of Glactive[®] and Metformin Combination Tablets (ONO-5435A / MK-031A) for type 2 diabetes was discontinued because expected efficacy as combination drug was not obtained.

First-Second Quarter (April 1 – September 30, 2013) Flash Report (unaudited) Six months ended September 30, 2013

Supplemental Information

New Drugs in Development

as of November 5, 2013

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:

Glactiv[®] Tablet (ONO-5435 / MK-0431)

Japan: J-NDA approved / type 2 diabetes with severe renal dysfunction (12.5 mg, new formulation, co-development with Merck & Co., Inc.), J-NDA filed / combination therapy with a rapid-acting insulin secretagogue for type 2 diabetes (additional indication, co-development with Merck & Co., Inc.)

Onoact[®] for Injection (ONO-1101)

Japan: J-NDA filed / tachyarrhythmia in low cardiac function

Proemend[®] Intravenous Infusion (ONO-7847 / MK-0517) (In-licensed from Merck & Co., Inc.)

Japan: Phase III / chemotherapy-induced nausea and vomiting in pediatric patients (additional indication)

Rivastach[®] Patch(ONO-2540 / ENA713D)

Japan: Phase III / alzheimer' disease (administration change) (co-development with Novartis Pharma AG)

Opalmon[®] Tablets (OP-1206 · α -CD)

Japan: J-NDA filed / thromboangitis obliterans, lumbar spinal canal stenosis (new formulation, co-development with Dainippon Sumitomo Pharma Co., Ltd.)

ONO-4538 / BMS-936558 (injection)

ONO-4538, a fully human anti-PD-1 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.

Japan: Phase III / renal cell cancer (global clinical trial), Phase II / melanoma, Phase II / non-small cell lung cancer

Overseas: Phase III / renal cell cancer (Bristol-Myers Squibb Company, global clinical trial), Phase III /

melanoma (Bristol-Myers Squibb Company), Phase I/II /solid tumors (triple negative breast cancer, stomach cancer, pancreatic cancer, small cell lung cancer)(Bristol-Myers Squibb Company)

US & Other Countries: Phase III / non-small cell lung cancer(Bristol-Myers Squibb Company), Phase I /hematological cancer (Bristol-Myers Squibb Company)

US: Phase I / Hepatitis C (Bristol-Myers Squibb Company), Phase I / Hepatocellular carcinoma (Bristol-Myers Squibb Company)

ONO-4164IV / BMS-188667IV (injection)(In-licensed from Bristol-Myers Squibb Company)

ONO-4164IV is an intravenous preparation of Orenicia[®] 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)

ONO-2745 / CNS 7056 (injection)(In-licensed from PAION AG)

ONO-2745 is a GABA_A receptor modulator, an innovative short-acting general anaesthetic and sedative, and is under clinical development as a sedative agent during the induction and maintenance of general anesthesia and during mechanical ventilation in the Intensive Care Unit (ICU). The sedative effects rapidly disappear after cessation of administration due to its metabolism by esterase enzymes, and therefore it is expected to be a drug with improved controllability and safety profile.

Japan: Phase II / III / general anesthesia,
Europe: Phase II / general anesthesia (PAION AG)
US: Phase II / procedural sedation (PAION AG)

ONO-7165 / EMD531444 (injection) (In-licensed from Merck KGaA)

ONO-7165 is a liposome vaccine being developed for non-small cell lung cancer. ONO-7165 is a cancer immunotherapy targeting the tumor antigen, MUC-1. It is thought that an immune cell recognizes MUC-1 as tumor antigen, and then attacks cancer cells expressing MUC-1.

Japan: Phase II / non-small cell lung cancer (co-development with Merck KGaA)

Overseas: Phase III / non-small cell lung cancer (Merck KGaA)

ONO-4641 (tablet)

ONO-4641 is a sphingosine-1-phosphate (S1P) receptor agonist, being developed for the treatment of multiple sclerosis. ONO-4641 is a low molecular weight substance that keeps lymphocytes in lymph nodes and reduces the lymphocyte count in the blood, thereby inhibiting the infiltration of lymphocytes into lesions. ONO-4641 is therefore expected to be an innovative drug for the treatment of auto-immune diseases such as multiple sclerosis, which is regarded as an intractable disease.

Japan: Phase II / multiple sclerosis (global clinical trial)

US and Europe: Phase II / multiple sclerosis (Merck KGaA, global clinical trial)

ONO-3849 / Methylnaltrexone bromide (injection) (In-licensed from Progenics Pharmaceuticals, Inc.)

ONO-3849 is a peripherally acting mu-opioid receptor antagonist, and is developed for intractable opioid induced constipation. Opioid pain medications are often used for the treatment of pain in cancer and other advanced illnesses, but cause constipation in many of these patients. ONO-3849 is expected to decrease the constipating effects of opioid analgesics in the gastrointestinal tract without affecting their ability to relieve pain.

Japan: Phase II / opioid-induced constipation

Overseas: Marketed (Salix Pharmaceuticals, Inc.)

ONO-7643 / RC-1291 (tablet) (In-licensed from Helsinn Therapeutics (US), Inc.)

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

US & Other Countries: Phase III / cancer anorexia / cachexia (Helsinn Therapeutics (U.S.), Inc.)

ONO-7057 / Carfilzomib (injection) (In-licensed from Onyx Pharmaceuticals, Inc.)

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 poor prognosis multiple myeloma.

Japan: Phase I / II / multiple myeloma

Overseas: Approved under Accelerated Drug Approval Program in US / multiple myeloma (launched in August 2012)

Phase III in Europe / multiple myeloma (Onyx Pharmaceuticals, Inc.).

ONO-5163 / AMG-416 (injection) (In-licensed from Amgen Inc.)

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

Japan: Phase I / II / secondary hyperparathyroidism

US: Phase III / secondary hyperparathyroidism (Amgen Inc.)

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 I / bronchial asthma

US: Phase II / bronchial asthma

ONO-7056 / Salirasib (tablet) (In-licensed from Kadmon Pharmaceuticals, Inc.)

ONO-7056 is a Ras signal inhibitor which is expected to be effective in the cancers, such as pancreatic cancer, in which high RAS genetic mutation is found.

Japan: Phase I / solid tumor

US: Phase I / pancreatic cancer (Kadmon Pharmaceuticals, Inc.)

ONO-7268MX1 (injection) (In-licensed from OncoTherapy Science, Inc.)

ONO-7268 is a peptide vaccine and is expected to have effects on cancers such as hepatocarcinoma.

Japan: Phase I / hepatocarcinoma

ONO-1162 (tablet) (In-licensed from Servier)

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 I / chronic heart failure

Overseas: Marketed / stable angina, chronic heart failure (Servier)

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-4053 (tablet)

ONO-4053 is a PGD2 receptor antagonist and is under clinical development for allergic rhinitis. It is expected to improve particularly nasal congestion, one of the three major symptoms of allergic rhinitis such as nasal congestion, sneezing and nasal discharge.

Europe: Phase II / allergic rhinitis

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.

US: Phase II / IBS

ONO-8539 (tablet)

ONO-8539 is a prostaglandin receptor (EP1) antagonist being developed for the treatment of gastroesophageal reflux disease (GERD).

Europe: Phase I /GERD

ONO-7746 (capsule) (In-licensed from Nissan Chemical Industries, Ltd.)

ONO-7746 is an orally active low molecule compound which may increase platelet count by activating a receptor of thrombopoietin, which is a hematopoietic factor to accelerate platelet production. It is therefore expected to be developed as a new drug which may reduce the risk of bleeding in various diseases with thrombocytopenia and overcome the risk of infection associated with platelet transfusion. Nissan Chemical is participating in co-development by process development and manufacture of the drug substance.

US: Phase I / thrombocytopenia

ONO-9054 (eye drop)

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

US: Phase I / glaucoma and ocular hypertension

ONO-4059 (capsule)

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

Europe: Phase I / B cell lymphoma

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 (SIP) antagonist being developed for the treatment of portal hypertension.

US: Phase I /portal hypertension

ONO-4232 (injection)

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

US: Phase I /acute heart failure

ONO-2370/BIA9-1067 (tablet) (In-licensed from Bial)

ONO-2370 is a long acting COMT inhibitor being developed for the treatment of Parkinson's disease. Bial is currently conducting the Phase III trials overseas 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.

Europe: Phase III /Parkinson's disease (Bial)