

Annual Flash Report (unaudited)

Fiscal Year ended March 31, 2013

Supplemental Information

Status of Development Pipeline

as of May 13, 2013

Developments in Japan

NDA filed (New Formulations):

- **Orencia® SC (ONO-4164 SC / BMS-188667SC)**
(Co-development with Bristol-Myers Squibb Company)
Rheumatoid Arthritis [T-cell activation inhibitor]
- **Glactiv® Tablets 12.5mg (ONO-5435 / MK-0431)**
(Co-development with Merck & Co., Inc.)
Type II diabetes with severe renal dysfunction [DPP-4 inhibitor]

NDA filed (Additional Indication):

- **Onoact® 50 for Injection (ONO-1101) *1**
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-2745 / CNS 7056 (injection)**
(In-licensed from PAION AG)
ICU sedation (Phase II)
[GABA_A receptor modulator]
- **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) *2**
Parkinson's disease (Phase I) [levodopa pro-drug]

Ongoing clinical studies (Additional Indications):

- **Glactiv® Tablets (ONO-5435 / MK-0431)**
(Co-development with MSD KK)
Type II diabetes: combination therapy with a rapid-acting insulin secretagogue (Phase III) [DPP-4 inhibitor]
- **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) *3**
(Co-development with Bristol-Myers Squibb KK)
Juvenile idiopathic arthritis [T-cell activation inhibitor]
- **Orencia® IV (ONO-4164IV / BMS-188667IV) *4**
(Co-development with Bristol-Myers Squibb Company)
Lupus nephritis [T-cell activation inhibitor]

Ongoing clinical studies (Additional Dosing Regimen):

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

Ongoing clinical studies (New Formulations):

- **Glactiv® and Metformin Combination Tablets (ONO-5435A / MK-0431A)**
(Co-development with MSD KK)
Type II diabetes (Phase III) / Combination product with Glactiv and biguanide

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]