



## R&D Update: World Class Innovation FY2015 Q2

October 30, 2015

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## Clear Focus on Priorities

1

**ENTYVIO  
&  
ixazomib**

2

**OUR RECENTLY  
LAUNCHED  
PRODUCTS**

*ADCETRIS  
AZILVA  
BRINTELLIX  
CONTRAVE  
NESINA/ZAFATEK  
TAKECAB*

3

**FUTURE  
TAKEDA  
PIPELINE**

*Dengue vaccine  
Norovirus vaccine  
Pre-POC pipeline  
External  
opportunities*

## Ixazomib Filed with Priority Review

Status		Remarks
<b>US: Filed</b>	New Drug Application (NDA)	<ul style="list-style-type: none"> <li>Filed for relapsed/refractory multiple myeloma in July 2015</li> <li>FDA granted Priority Review</li> </ul>
<b>EU: Filed</b>	Marketing Authorization Application (MAA)	<ul style="list-style-type: none"> <li>EMA accepted for relapsed/refractory multiple myeloma in August 2015</li> <li>CHMP granted Accelerated Assessment</li> </ul>
<b>Upcoming Milestone</b>	TOURMALINE-MM1	<ul style="list-style-type: none"> <li>Interim analysis data to be presented at American Society of Hematology (ASH) in December 2015</li> </ul>
<b>Ongoing Phase 3</b>	TOURMALINE-MM1 <i>Filed US/EU, EM from FY2015, JP target: FY2016</i> TOURMALINE-MM2 <i>Filing target: US/EU/JP FY2017</i> TOURMALINE-MM3 <i>Filing target: US/EU/JP FY2018</i> TOURMALINE-MM4 <i>Filing target: US/EU/JP FY2019</i> TOURMALINE-AL1 <i>Filing target: US/EU FY2018</i>	<ul style="list-style-type: none"> <li>Relapsed/refractory multiple myeloma US/EU/JP</li> <li>Previously untreated multiple myeloma US/EU/JP</li> <li>Maintenance therapy in patients with newly diagnosed multiple myeloma following autologous stem cell transplant US/EU/JP</li> <li>Maintenance therapy in patients with newly diagnosed multiple myeloma not treated with stem cell transplantation US/EU/JP</li> <li>Relapsed or refractory systemic light-chain (AL) amyloidosis US/EU</li> <li>Breakthrough Therapy status, US</li> </ul>

# Focusing on Recently Launched Products and Building a Future Pipeline

	Phase 2	Phase 3	Filed
<b>GI</b>	TAK-114 (ulcerative colitis) US/EU	<b>ENTYVIO</b> (ulcerative colitis, Crohn's disease) JP (head to head with adalimumab) US <b>AMITIZA</b> (new formulation) US (pediatric functional constipation) US	<b>ENTYVIO</b> (ulcerative colitis, Crohn's disease) EM <b>TAKECAB</b> ( <i>H. pylori</i> triple pack) JP <b>DEXILANT</b> (orally dissolving tablet) US (acid-related diseases in adolescents) US*/EU*
<b>ONC</b>	<b>MLN8237</b> (small cell lung cancer) US/EU <b>TAK-385</b> (prostate cancer) US/EU <b>TAK-228</b> (breast cancer, renal cancer) US/EU (endometrial cancer) US	<b>AMG386</b> (ovarian cancer) JP <b>ixazomib</b> (previously untreated multiple myeloma) US/EU/JP (multiple myeloma maintenance post-ASCT) US/EU/JP (multiple myeloma maintenance without ASCT) US/EU/JP (R/R AL amyloidosis) US/EU <b>ADCETRIS</b> (front line Hodgkin lymphoma) EU/JP (front line mature T-cell lymphoma) EU/JP (relapsed cutaneous T-cell lymphoma) EU	<b>ixazomib</b> (R/R multiple myeloma) US/EU* <b>ADCETRIS</b> (post-ASCT Hodgkin lymphoma) EU
<b>Other</b>	<b>TAK-003</b> (dengue fever) <b>TAK-214</b> (norovirus) <b>TAK-063</b> (schizophrenia) US* <b>TAK-272</b> (diabetic nephropathy) JP <b>TAK-385</b> (endometriosis) JP (uterine fibroids) JP <b>MT203</b> (rheumatoid arthritis) EU/JP* (psoriasis) EU <b>BRINTELLIX</b> (attention deficit hyperactivity disorder) US <b>TAK-850</b> (seasonal influenza) JP*	<b>AD4833/TOMM40</b> (delay of onset of mild cognitive impairment due to Alzheimer's disease) US/EU <b>AZILECT</b> (Parkinson's disease) JP <b>BRINTELLIX</b> (major depressive disorder) JP (generalized anxiety disorder) US <b>AZILVA FDC</b> (+amlodipine and hydrochlorothiazide) JP <b>BENET</b> (additional formulation; change of the dosage and administration) JP <b>ULORIC</b> (extended release formulation) US	<b>BRINTELLIX</b> (addition of data of effect on cognitive function to label) US* <b>NESINA FDC</b> (+metformin) JP* <b>TAK-816</b> (Hib vaccine) JP

New Molecular Entity  
Life Cycle Management

*Better Health, Brighter Future*

**THANK YOU**

