News Release

Astellas Reports First Quarter Financial Results of FY2016

- Sales slightly decreased (-1.7%) on reported basis and increased approx. 6% on a constant currency basis; Increased core operating profit (+38.5%) and core profit (+49.1%)
- Sales in Americas, EMEA, Asia/Oceania increased on their local currency basis while sales in Japan decreased due to the impacts such as a National Health Insurance (NHI) drug price revision
- Sales of XTANDI® (enzalutamide) and overall overactive bladder (OAB) treatments grew
- Guidance for FY2016 is unchanged from the consolidated full-year business forecasts announced in May 2016
- Astellas continues to create a solid and resilient continuity of growth over the mid - to long-term through the pursuit of three main strategies

Tokyo, July 29, 2016 – Astellas Pharma Inc. (TSE:4503, President and CEO: Yoshihiko Hatanaka, "Astellas") today announced financial results for the first quarter of fiscal year 2016 ending March 31, 2017 ("FY2016").

"We are pleased with our solid performance and ability to achieve sustainable growth through increasing sales of XTANDI® and overall OAB treatments, new product introductions and focused investment in innovation and strengthening our base," said Yoshihiko Hatanaka, President and CEO, Astellas. "We remain confident in our ability to deliver value for patients and for our stakeholders as we continue to advance our strategic plan of maximizing the product value, creating innovation and pursuing operational excellence."

Consolidated Financial Results (April 1, 2016 – June 30, 2016) (core basis)

(Millions of yen)

	Q1 FY2015	**Q1 FY2016**	Change (%)
Sales	343,659	**337,752**	-5,907 (-1.7%)
Core operating profit	67,820	**93,951**	+26,131 (+38.5%)
Core profit for the period	45,031	**67,148**	+22,117 (+49.1%)
Basic core earnings per share (yen)	20.57	**31.60**	+11.03 (+53.6%)

Impact of Foreign Exchange Rate on Financial Results

The foreign exchange rates for the yen in the first three months of FY2016 are shown in the table below. The resulting impacts were a 25.6 billion yen decrease in sales and a 0.4 billion yen increase in core operating profit compared with if the exchange rates of the three months of FY2015 were applied.

Average rate	Q1 FY2015	Q1 FY2016	Change
USD/yen	121	108	13 yen (Strengthening of yen)
Euro/yen	134	122	12 yen (Strengthening of yen)

Change from beginning to end of period	As of June 30, 2015	As of June 30, 2016
USD/yen	2 yen (Weakening of yen)	10 yen (Strengthening of yen)
Euro/yen	7 yen (Weakening of yen)	13 yen (Strengthening of yen)

Quarterly Revenue Highlights

Sales in the first three months of FY2016 decreased by 1.7% compared to those in the corresponding period of the previous fiscal year ("year-on-year") to 337.8 billion yen.

Sales decreased due to the impacts such as the NHI drug price revision in Japan enforced in April 2016 as well as the impact of foreign exchange. On a constant currency basis, however, sales increased by approximately 6 % year-on-year.

In terms of global products, sales of XTANDI® and overall OAB treatments Vesicare® (solifenacin succinate) and Betanis® / Myrbetriq® / BETMIGA® (mirabegron) grew, while sales of Prograf® (tacrolimus) decreased due to foreign exchange while sales of Prograf® increased on a constant currency exchange rate basis.

< Sales by Region[1]>

Sales in **Japan** decreased by 1.1% year-on-year to 124.2 billion yen mainly due to the NHI drug price revision. This reflected underlying growth in sales of products including overall OAB treatments (Vesicare® and Betanis®), Celecox® (celecoxib) and Symbicort® (budesonide and formoterol fumarate dihydrate). Sales of XTANDI® decreased due to the NHI drug price revision. Sales of vaccines declined mainly due to the continued impact of the restrain of shipment by the manufacturer in FY2015 (shipments of some of products have already been recommenced). Revenues were impacted by the decline in sales of products including Lipitor® (atorvastatin calcium) and Gaster® (famotidine) mainly due to the impact of generics.

Sales in the **Americas** decreased by 6.3% year-on-year to 107.6 billion yen; however sales on a USD basis increased by 5.2% year-on-year to 995 million USD. This was driven by an increase in sales of XTANDI® and CRESEMBA® (isavuconazonium sulfate). Sales of products including overall OAB treatments (VESIcare® and Myrbetriq®), Prograf® and Lexiscan® (regadenosan) decreased due to the impact of foreign exchange. The sales of each product on a USD basis increased.

EMEA[2] saw a 4.4% increase in sales year-on-year to 85.3 billion yen, with growth from XTANDI®. Sales of overall OAB treatments (Vesicare® and BETMIGA®) and Prograf® declined due to foreign exchange. Sales on a Euro basis increased by 14.8% year-on-year to 699 million Euros.

In **Asia and Oceania**, sales decreased by 3.8% year-on-year to 20.7 billion yen. XTANDI®, overall OAB treatments (Vesicare® and BETMIGA®) and Harnal® (tamsulosin hydrochloride) contributed to the

[1] Based on location of sellers
[2] EMEA: Europe, the Middle East and Africa

revenue growth. Sales of Prograf® declined mainly due to the foreign exchange impact. Sales on a constant currency exchange rate basis increased by 14.7% year-on-year.

Expense and Other Financial Highlights

- Gross profit increased by 5.0% year-on-year to 266.3 billion yen, because a decrease in cost of sales exceeded a decrease in sales. The cost-to-sales ratio fell 5.1 percentage points year-on-year to 21.2%, owing to changes in the product mix and the foreign exchange rate impact from the elimination of unrealized gains in intra-group transactions.
- Selling, general and administrative expenses decreased by 5.7% year-on-year to 111.9 billion yen mainly due to the foreign exchange rate impact.
- Research and development ("R&D") expenses decreased by 8.9% year-on-year to 51.0 billion yen partly due to the impact of foreign exchange, although steady progress of development was shown. The R&D cost-to-sales ratio was down 1.2 percentage points year-on-year to 15.1%.
- Amortization of intangible assets was 9.0 billion yen, down 17.5% year-on-year.

As a result of the above, core operating profit increased by 38.5% year-on-year to 94.0 billion yen. Meanwhile, core profit for the period increased by 49.1% year-on-year to 67.1 billion yen and basic core earnings per share increased by 53.6% year-on-year to 31.60 yen.

Resulting from the transfer of the global dermatology business in April 2016, the sales and the expenses of the transferred products were not included in the first three month of FY2016. On the other hand, consideration of the business transfer was recognized as revenue over certain periods. As a result, there were certain positive impacts on sales and profit for the first three months of FY2016.

FY2016 Guidance

The company has chosen to leave its business forecasts unchanged from the consolidated full-year business forecasts announced in May 2016 as it does not expect large deviations from the forecasts.

Strategic Quarterly Highlights

Astellas continues to create a solid and resilient continuity of growth over the mid - to long-term through the pursuit of three main strategies – "Maximizing the Product Value," "Creating Innovation" and "Pursuing Operational Excellence."

Maximizing the Product Value

- Received a marketing authorization from the European Medicines Agency (EMA) to include data from the TERRAIN trial in the XTANDI® label
- XTANDI® and Myrbetriq® / BETMIGA® newly launched across multiple countries; Repatha® (evolocumab) launched in Japan

Creating Innovation

- Progressed the pipeline with several products entering Phase III including enzalutamide (MDV3100) for triple-negative breast cancer for the US/EU/Japan/Asia; ipragliflozin (ASP1941) for Type 1 diabetes in Japan; and linaclotide (ASP0456) for chronic constipation in Japan
- Entered into several strategic collaborations including:
  - As one of the activation plans for Ocata Therpeutics, Inc. acquired in previous fiscal year, the company name was changed to Astellas Institute for Regenerative Medicine
  - Biomarker database on healthy adults with Takeda Pharmaceutical Company Limited and Daiichi-Sankyo Company, Limited
  - Developing a rice-based oral vaccine with the Institute of Medicine Science, the University of Tokyo

Pursuing Operational Excellence

- Compliance was structurally divided from legal and introduced as a new function "Ethics & Compliance" which globally integrates and manages the regional Ethics & Compliance functions across regions
- Transferred the global dermatology business to LEO Pharma S/A (headquarter: Demark)
- Enhanced our organizational structure by establishing a subsidiary in Colombia

NOTE: For further information on the results and their drivers, please refer to the reference documents: Financial Results, Supplementary Documents, Overview of R&D Pipeline and Presentation Material for Information Meeting available on the Astellas website.

Cautionary Statement Regarding Forward-Looking Information

In this press release, statements made with respect to current plans, estimates, strategies and beliefs and other statements that are not historical facts are forward-looking statements about the future performance of Astellas. These statements are based on management's current assumptions and beliefs in light of the information currently available to it and involve known and unknown risks and uncertainties. A number of factors could cause actual results to differ materially from those discussed in the forward-looking statements. Such factors include, but are not limited to: (i) changes in general economic conditions and in laws and regulations, relating to pharmaceutical markets, (ii) currency exchange rate fluctuations, (iii) delays in new product launches, (iv) the inability of Astellas to market existing and new products effectively, (v) the inability of Astellas to continue to effectively research and develop products accepted by customers in highly competitive markets, and (vi) infringements of Astellas' intellectual property rights by third parties.

Information about pharmaceutical products (including products currently in development) which is included in this press release is not intended to constitute an advertisement or medical advice.

About Astellas

Astellas Pharma Inc., based in Tokyo, Japan, is a company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. We focus on Urology, Oncology, Immunology, Nephrology and Neuroscience as prioritized therapeutic areas while advancing new therapeutic areas and discovery research leveraging new technologies/modalities. We are also creating new value by combining internal capabilities and external expertise in the medical/healthcare business. Astellas is on the forefront of healthcare change to turn innovative science into value for patients. For more information, please visit our website at www.astellas.com/en.

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