Press Release

Astellas Reports First Half FY2016 Financial Results, Revises Fiscal Year Outlook

- Sales decreased (-5.2%) on reported basis and increased approximately 4% on a constant currency basis; Increased core operating profit (+14.7%) and core profit (+16.0%)
- Sales of XTANDI® (enzalutamide) grew while overall overactive bladder (OAB) treatments decreased due to foreign exchange
- Sales in EMEA increased, and sales in Americas and Asia and Oceania decreased while increased on a constant currency basis. Sales in Japan decreased due to the impacts such as a National Health Insurance ("NHI") drug price revision
- Guidance for FY2016 is revised from the consolidated full-year business forecasts announced in May 2016 (sales downwardly revised, core operating profit and core profit for the period upwardly revised)
- Astellas continues to create a solid and resilient growth over the mid-to long-term

Tokyo, October 28, 2016 - Astellas Pharma Inc. (TSE: 4503, President and CEO: Yoshihiko Hatanaka, "Astellas") today announced financial results for the first six months of fiscal year 2016 ending March 31, 2017 ("FY2016").

"Our results continue to demonstrate sustainable growth by increasing sales of key global products, XTANDI® and Betanis® / Myrbetriq® / BETMIGA® (mirabegron), launching new products and investment for innovation," said Yoshihiko Hatanaka, President and CEO, Astellas. "We remain committed to delivering value for patients as we reinforce in our strategic plan through maximizing the product value, creating innovation and pursuing operational excellence."

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

(Millions of yen)

	First six months of FY2015	First six months of FY2016	Change (%)
Sales	687,501	**651,673**	-35,828 (-5.2%)
Core operating profit	145,170	**166,455**	+21,285 (+14.7%)
Core profit for the period	103,938	**120,569**	+16,631 (+16.0%)
Basic core earnings per share (yen)	47.76	**56.75**	+8.99 (+18.8%)

Impact of Foreign Exchange Rate on Financial Results

The foreign exchange rates for the yen in the first six months of FY2016 are shown in the table below. The resulting impacts were a 64.1 billion yen decrease in sales and a 12.5 billion yen decrease in core operating profit compared to if the exchange rates of the first six months of FY2015 were applied.

Average rate	First six months of FY2015	First six months of FY2016	Change
USD/yen	122	105	17 yen (Strengthening of yen)
Euro/yen	135	118	17 yen (Strengthening of yen)

Change from beginning to end of period	As of September 30, 2015	As of September 30, 2016
USD/yen	0 yen (Strengthening of yen)	12 yen (Strengthening of yen)
Euro/yen	5 yen (Weakening of yen)	14 yen (Strengthening of yen)

Revenue Highlights for First Six Months

Sales in the first six months of FY2016 decreased by 5.2% compared to those in the corresponding period of the previous fiscal year ("year-on-year") and resulted in 651.7 billion yen. Sales decreased due to the impact of foreign exchange as well as the impact of the NHI drug price revision in Japan enforced in April 2016. On a constant currency basis, however, sales increased by approximately 4% year-on-year.

In terms of global products, sales of XTANDI® grew while sales of overall OAB treatments Vesicare® (solifenacin succinate) and Betanis® / Myrbetriq® / BETMIGA® decreased due to the impact of foreign exchange. Prograf® (tacrolimus) sales also decreased.

< Sales by Region[1] >

- Sales in **Japan** decreased by 4.0% year-on-year to 237.2 billion yen. Sales in the Japanese market decreased by 7.6% year-on-year to 221.8 billion yen mainly due to the impact of the NHI drug price revision. There was growth in sales of products including overall OAB treatments (Vesicare® and Betanis®), Celecox® (celecoxib), Symbicort® (budesonide and formoterol fumarate dihydrate) and Suglat® (ipragliflozin). Sales of XTANDI® decreased due to the impact of the NHI drug price revision. Sales of vaccines declined due to the continued impact of the restraints of shipment by the manufacturer in FY2015 (shipments of some of the products have already 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 11.3% year-on-year to 206.6 billion yen; however sales on a U.S. dollar basis increased by 2.6% year-on-year to 1.963 billion USD. The increase in sales of CRESEMBA® (isavuconazonium sulfate) contributed to the sales growth. Sales of products including XTANDI®, overall OAB treatments (VESIcare® and Myrbetriq®) and Lexiscan® (regadenoson) decreased due to the impact of foreign exchange, while the sales of each product on a U.S. dollar basis increased. Sales of Prograf® decreased.

- **EMEA**[2] saw a 2.3% increase in sales year-on-year to 166.1 billion yen, with growth from XTANDI®. Sales on a euro basis increased by 17.0% year-on-year to 1.406 billion euro. Sales of overall OAB treatments (Vesicare® and BETMIGA®) and

[1] Based on location of sellers

[2] EMEA: Europe, the Middle East and Africa

Prograf® declined due to the impact of foreign exchange; however sales of Prograf® on a euro basis increased.

- In **Asia and Oceania**, sales decreased by 7.6% year-on-year to 41.8 billion yen. XTANDI® and overall OAB treatments (Vesicare® and BETMIGA®) contributed to the revenue growth. Sales of Prograf® and Harnal® (tamsulosin hydrochloride) declined mainly due to the foreign exchange impact.

Expense and Other Financial Highlights

- Gross profit decreased by 2.6% year-on-year to 505.5 billion yen along with a decrease in sales. The cost-to-sales ratio fell by 2.1 percentage points year-on-year to 22.4%, based on 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 7.9% year-on-year to 220.8 billion yen mainly due to the foreign exchange impact.

- Research and development ("R&D") expenses decreased by 11.0% year-on-year to 99.7 billion yen partly due to the impact of foreign exchange. The R&D cost-to-sales ratio was down 1.0 percentage points year-on-year to 15.3%.

- Amortization of intangible assets was 17.7 billion yen, down 19.2% year-on-year.

As a result of the above, core operating profit increased by 14.7% year-on-year to 166.5 billion yen.

Meanwhile, core profit for the period increased by 16.0% year-on-year to 120.6 billion yen and basic core earnings per share increased by 18.8% year-on-year to 56.75 yen.

Based on 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 six months of FY2016; however the consideration for 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 six months of FY2016.

FY2016 Guidance Revisions

The company has downwardly revised its forecasts for sales, and upwardly revised its forecasts for core operating profit and core profit for the year from the figures announced in May 2016 ("initial forecast") based on the situation of financial results for the first six months of FY2016 and the trend of foreign exchange rates. Revised expected exchange rates are anticipated to cause a 56.8 billion yen decrease in sales and a 10.0 billion yen decrease in core operating profit compared to if the expected exchange rates of the initial forecast were applied.

Consolidated Full-year Business Forecasts (core basis)

(Millions of yen)

	FY2015 Full-year results	**FY2016 Full-year forecasts**	Change (%)
Sales	1,372,706	**1,300,000**	-72,706 (-5.3%)
Core Operating profit	267,456	**274,000**	+6,544 (+2.4%)
Core Profit for the year	198,802	**202,000**	+3,198 (+1.6%)
Basic earnings per share (yen)	92.12	**95.07**	+2.96 (+3.2%)

Latest Strategic Highlights

Astellas continues to create sustainable growth over the mid-to long-term through the pursuit of three main strategies – “Maximizing the Product Value,” ” Creating Innovation” and “Pursuing Operational Excellence.” The company achieved multiple accomplishments during the second quarter of FY2016 (July 1, 2016 – September 30, 2016) including the most recent highlights outlined below.

Maximizing the Product Value

- Continued to maximize the growth of the oncology franchise centered on XTANDI® and the OAB franchise comprised of Vesicare® and Betanis® / Myrbetriq® / BETMIGA® with new launches across various countries and growth in sales.

Creating Innovation

- Advanced multiple strategic collaborations including:
  - Amended its existing agreement with Cytokinetics, Inc. (USA) to expand its collaboration in skeletal muscle activators. Through this amendment, the development of fast skeletal troponin activation, CK-2127107 for the potential treatment of amyotrophic lateral sclerosis will be included.

- Established DigiTx Partners LLC (USA), a digital health investment company in partnership with MPM Capital, Inc. (USA).

Pursuing Operational Excellence

- Transferred the manufacturing subsidiary, Astellas Pharma Technologies, Inc. (USA) to Avara Norman Pharmaceutical Services, Inc. (USA)

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.

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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.

Cautionary Notes
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.

Contacts for inquiries or additional information:

Astellas Pharma Inc.
Corporate Communications
TEL: +81-3-3244-3201 FAX: +81-3-5201-7473

US Media:
Tarsis Lopez
Astellas US LLC
TEL: 224-205-8833
tarsis.lopez@astellas.com