Press Release

Astellas Reports Full Year FY2016 Financial Results

- Sales decreased (-4.4%) on a reported basis and increased approximately 2% excluding the factors associated with the transfer of the global dermatology business implemented in April 2016 and the impact of the foreign exchange; Increased core operating profit (+2.7%) and core profit (+7.3%)
- Sales of XTANDI® (enzalutamide) and overall overactive bladder ("OAB") treatments steadily increased on a constant currency basis
- Sales in the Americas, EMEA[1], Asia and Oceania decreased while increased on a constant currency basis. Sales in Japan decreased due to impacting factors such as a National Health Insurance ("NHI") drug price revision
- Astellas continues to create solid and resilient growth over the mid-to-long term
  - ✓ Astellas completed the acquisition of Ganymed Pharmaceuticals AG ("Ganymed") in December 2016
  - ✓ Astellas entered into a definitive agreement under which Astellas has agreed to acquire Ogeda SA ("Ogeda") in March 2017;
    The procedures required for this acquisition are still in progress (as of April 2017).

Tokyo, April 27, 2017 - Astellas Pharma Inc. (TSE: 4503, President and CEO: Yoshihiko Hatanaka, "Astellas") today announced the financial results for fiscal year 2016 ("FY2016") ended March 31, 2017.

"We achieved multiple milestones including the acquisition of Ganymed last December and an agreement with Ogeda shareholders to acquire Ogeda last month. These acquisitions and other alliances will expand Astellas' late-stage pipeline and contribute to its mid-to-long term growth," said Yoshihiko Hatanaka, President and CEO, Astellas. "We remain committed to creating innovative medical solutions and delivering value for patients and all stakeholders, as we continue to advance our strategic plan through maximizing the product value, creating innovation and pursuing operational excellence in the fiscal year 2017."

Consolidated Financial Results (April 1, 2016 – March 31, 2017) (core basis)

(Millions of yen)

	FY2015	**FY2016**	Change (%)
Sales	1,372,706	**1,311,665**	-61,041 (-4.4%)
Core operating profit	267,456	**274,554**	+7,098 (+2.7%)
Core profit for the year	198,802	**213,343**	+14,541 (+7.3%)
Basic core earnings per share (yen)	92.12	**101.15**	+9.03 (+9.8%)

Full-Year Financial Results

Sales for the full-year of FY2016 decreased by 4.4% compared to the previous fiscal year ("year-on-year") and resulted in 1,311.7 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. Sales increased by approximately 2% year-on-year excluding the factors associated with the transfer of the global dermatology business implemented in April 2016 and the impact of the foreign exchange.

In terms of global products, sales of XTANDI® marginally increased and sales of overall OAB treatments Vesicare® (solifenacin succinate) and Betanis® / Myrbetriq® / BETMIGA® (mirabegron) decreased due to the impact of foreign exchange, but sales of each product steadily increased on a local currency basis. Prograf® (tacrolimus) sales also decreased.

< Sales by Region[2] >

- Sales in **Japan** decreased by 3.3% year-on-year to 480.8 billion yen. Sales in the Japanese market decreased by 6.3% year-on-year to 452.7 billion yen mainly due to the impact of the NHI drug price revision. Sales growth continued for products such as 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 shipping restraints 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 9.4% year-on-year to 412.4 billion yen; however sales on a U.S. dollar basis increased by 0.5% year-on-year to 3,805 million 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 US dollar basis increased.

- **EMEA** saw a 0.5% increase in sales year-on-year to 330.8 billion yen, with growth driven by XTANDI®. Sales on a euro basis increased by 12.1% year-on-year to 2,785 million euros. Sales of overall OAB treatments (Vesicare® and BETMIGA®) and Prograf® declined due to the impact of foreign exchange.

- In **Asia and Oceania**, sales decreased by 3.8% year-on-year to 87.7 billion yen, while the sales on a constant currency basis increased by approximately 9%. 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.

Other Financial Highlights

Based on the transfer of the global dermatology business in April 2016, the sales and expenses of the transferred products were not included in 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 in FY2016.

Strategic Highlights in FY2016

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 throughout FY2016 including the following 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

- With respect to the update of the product label for XTANDI®, including the data from the head-to-head TERRAIN trial of enzalutamide versus bicalutamide, the Company obtained regulatory approvals in Europe and the U.S., and the product label was updated in April 2016 in Europe, and October 2016 in the U.S.

- Launched multiple products including Repatha® (evolocumab), PCSK9-inhibitor for the treatment of hypercholesterolemia in April 2016; Micatrio® Combination Tablets (telmisartan / amlodipine besylate / hydrochlorothiazide) for the treatment of hypertension in November 2016; Kiklin® Granules (bixalomer) for the treatment of hyperphosphatemia in December 2016; and guanylate cyclase-C receptor agonist, LINZESS (linaclotide), for the treatment of the irritable bowel syndrome with constipation in March 2017 were all launched in Japan.

Creating Innovation

- Completion of the acquisition of Ganymed.

- Definitive agreement under which Astellas has agreed to acquire Ogeda.
  The procedures required for this acquisition are still in progress (as of April 2017).

The following list highlights alliances with external partners announced during FY2016:

- Entered into a collaborative research agreement with the National Institute of Advanced Industrial Science and Technology to discover anti-protozoan parasite drugs for the treatment of Chagas' disease in April 2016.

- Announced the conclusion of a joint research agreement with Daiichi Sankyo Company, Limited and Takeda Pharmaceutical Company Limited to comprehensively acquire and analyze fundamental biomarker data in May 2016.

- Entered into a collaborative development agreement with the Institute of Medical Science, the University of Tokyo, to develop a rice-based oral vaccine in June 2016.

- Expanded its collaboration agreement in skeletal muscle activators with Cytokinetics, Inc. (U.S.) ("Cytokinetics") to include amyotrophic lateral sclerosis ("ALS") in July 2016. Through this amendment, the development of fast skeletal troponin activator, CK-2127107 for the potential treatment of ALS, will be conducted.

- Established DigiTx Partners LLC (U.S.), a digital health investment company in partnership with MPM Capital, Inc. (U.S.) in July 2016. DigiTx Partners LLC will invest in the digital health space broadly.

- Signed a memorandum of understanding to create a method for analyzing circulating tumor cells, with Sysmex Corporation and Daiichi Sankyo Company Limited in December 2016.

- Executed a license agreement with respect to an exclusive worldwide license for the AU-935 program for the treatment of chronic tympanic membrane perforation with Auration Biotech, Inc. (U.S.) in January 2017.

- Entered into an exclusive worldwide license agreement to develop and commercialize a vaccine targeting *Streptococcus pneumoniae* (pneumococcus) with Affinivax, Inc. in February 2017.

The following lists the main development advances achieved during FY2016:

- Submitted applications for approval of extended-release tablets of quetiapine fumarate (generic name, development code: FK949E) for the indication of the improvement of depressive symptoms associated with bipolar disorder in August 2016 in Japan.

- Obtained approval of Kiklin® Granules in September 2016 in Japan.

- Submitted applications for the approval of XTANDI® Tablets in September 2016 in Japan.

- Obtained marketing approval for a guanylate cyclase-C receptor agonist, LINZESS®, for the indication of irritable bowel syndrome with constipation in December 2016 in Japan.

- Submitted an application for the approval of romosozumab (generic name, development code: AMG 785) for the treatment of osteoporosis for those at high risk of fracture in December 2016 in Japan.

Pursuing Operational Excellence

The following lists the main operational excellence initiatives which occurred during FY2016:

- Transferred the global dermatology business to LEO Pharma S/A (headquarters: Denmark) in April 2016.
- Began operations for Malaysia-based subsidiary, Astellas Pharma Malaysia Sdn. Bhd. in April 2016. In addition, the SESA Umbrella Organization which is responsible for overseeing operations in the South East and South Asia regions was established and began operation in April 2016.
- Transferred the manufacturing subsidiary, Astellas Pharma Technologies, Inc. (U.S.) to Avara Norman Pharmaceutical Services, Inc. (U.S.) in August 2016.
- Decided to outsource facility and equipment management support in Japan, and dissolve Astellas Business Service Company Limited in November 2016.
- Transferred commercial rights for Qutenza® (capsaicin 8% patch) to Grünenthal in December 2016.
- Concluded a memorandum of understanding concering the extablishment of a new structure in Sapporo, Hokkaido with Takeda Pharmaceutical Company Limited, Teva Takeda Pharma Ltd. and Teva Takeda Yakuhin Ltd. in February 2017.
- Entered into an agreement providing Kyowa Pharmaceutical Industry Co., Ltd. the exclusive right to distribute and promote extended-release tablets of quetiapine fumarate in Japan in February 2017.
- Entered into an asset purchase agreement with LTL Pharma Co., Ltd., under which Astellas will transfer its marketing authorization of 16 long-listed products (the “Products”) in Japan, supply business of active pharmaceutical ingredients / bulk of the Products to third parties inside and outside of Japan and royalty business of the Products to LTL Pharma, in March 2017.

2017 Financial Guidance

The forecasts for the fiscal year ending March 31, 2018 ("FY2017") (core basis) are shown in the table below. The sales forecast is 1,279.0 billion yen (-2.5% year-on-year). While we anticipate continuous sales growth for XTANDI®, our mainstay product, and also for OAB treatments due to the growth of Betanis® / Myrbetriq® / BETMIGA®, we expect negative impact on sales and profit from the transfer of the global dermatology business implemented in April 2016 and the transfer of long-listed products in Japan for which an agreement was concluded in March 2017. We project a core operating profit of 254.0 billion yen (-7.5% year-on-year). However, we forecast core operating profit excluding the factors associated with the transfers of the dermatology business and long-listed products in Japan as stated above and the impact of the foreign exchange to be higher year-on-year.

Consolidated Full-year Business Forecasts (core basis)

(Millions of yen)

	FY2016 Full-year results	**FY2017 Full-year forecasts**	Change (%)
Sales	1,311,665	**1,279,000**	-32,665 (-2.5%)
Core Operating profit	274,554	**254,000**	-20,554 (-7.5%)
Core Profit for the year	213,343	**195,000**	-18,343 (-8.6%)
Basic earnings per share (yen)	101.15	**94.43**	-6.72 (-6.6%)

NOTE: For further information on the results, 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.

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1 Europe, the Middle East and Africa

2 Based on location of sellers