Press Release

Astellas Reports First Half FY2017 Financials Results, Revises Fiscal Year Outlook

- Sales (-1.8%) and core operating profit (-18.1%) decreased due to the impact of certain items such as the transfer of the global dermatology business in April 2016 and the transfer of long-listed products in Japan in April 2017. Excluding these items as well as the foreign exchange rate impact, sales were -1.9% and core operating profit was -2.7% respectively.
- Sales of key global products such as XTANDI® (enzalutamide) for the treatment of prostate cancer and overactive bladder ("OAB") treatments Betanis® / Myrbetriq® / BETMIGA® (mirabegron) grew.
- Astellas continues to create solid and resilient growth.

Tokyo, October 31, 2017 - Astellas Pharma Inc. (TSE: 4503, President and CEO: Yoshihiko Hatanaka, "Astellas") today announced the financial results for the first six months of fiscal year 2017, ending March 31, 2018 ("FY2017").

"Key global products XTANDI and Betanis / Myrbetriq / BETMIGA (mirabegron) continued to demonstrate steady growth in the first six months of FY2017, and milestones such as the positive results from the Phase 3 PROSPER trial of enzalutamide in non-metastatic castration resistant prostate cancer patients demonstrate that our development activities are progressing steadily. Furthermore, continuous resource allocation is being made with the aim of realizing sustainable growth over the medium- and long-terms," 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."

Consolidated Financial Results (April 1, 2017 – September 30, 2017) (core basis)

(Millions of yen)

	First six months of FY2016	**First six months of FY2017**	Change (%)
Sales	651,673	**639,754**	-11,919 (-1.8%)
Core operating profit	166,455	**136,353**	-30,102 (-18.1%)
Core profit for the period	120,569	**106,638**	-13,932 (-11.6%)

Quarterly Revenue Highlights

Sales in the first six months of FY2017 decreased by 1.8% compared to those in the corresponding period of the previous fiscal year ("year-on-year") to ¥639.8 billion due to the impact of certain items such as the transfer of the global dermatology business in April 2016 and the transfer of long-listed products in Japan in April 2017.

- Oncology franchise

Sales of XTANDI® increased by 11.4% year-on-year to ¥140.3 billion. Sales in the United States ("U.S.") remained largely unchanged year-on-year, but sales grew steadily in Japan, the Americas excluding the U.S., EMEA[1] and the Asia and Oceania region.

- Urology OAB franchise

Sales of Betanis® / Myrbetriq® / BETMIGA® increased by 26.0% year-on-year to ¥57.6 billion. Sales increased in all regions: Japan, the Americas, EMEA and the Asia and Oceania region. Sales of Vesicare®, however, decreased by 16.9% year-on-year to ¥49.7 billion.

- Transplantation franchise

Sales of Prograf® (tacrolomis) increased by 5.4% year-on-year to ¥99.3 billion, and continued to grow in the EMEA and the Asia and Oceania regions.

- Other new and key products

In the Japanese market, continued growth was achieved for products such as Celecox® (celecoxib) for the treatment of inflammation and pain, Symbicort® (budesonide and formoterol fumarate dihydrate) for the treatment of bronchial asthma, Suglat® (ipragliflozin) for the treatment of type 2 diabetes, and Cimzia® (certolizumab pegol) for the treatment of adult patients with rheumatoid arthritis. Meanwhile, we have been steadily working to penetrate the market with our launch of Repatha® (evolocumab) for the treatment of hypercholesterolemia, which occurred in April 2016, and of LINZESS® (linaclotide) for the treatment of irritable bowel syndrome with constipation, which occurred in March 2017. In the Americas, sales of azole antifungal CRESEMBA® (isavuconazonium sulfate) grew.

(Billions of yen)

	First six months of FY2016	**First six months of FY2017**	Change
Oncology franchise	153.9	**167.8**	+9.1%
XTANDI®	126.0	**140.3**	+11.4%
Urology OAB franchise	105.5	**107.3**	+1.7%
Vesicare®	59.8	**49.7**	-16.9%
Betanis® / Myrbetriq® / BETMIGA®	45.7	**57.6**	+26.0%
Transplantation franchise	94.2	**99.3**	+5.4%

Sales by Region[2]

Sales in Japan, the Americas and EMEA decreased, while sales in Asia and Oceania increased. As for the Japanese market, sales decreased by 12.5% year on year to ¥194.1 billion largely due to the impact of transferring 16 long-listed products in April 2017, and the introduction of generics for Micardis® (telmisartan) for the treatment of hypertension in June 2017. Meanwhile in EMEA, sales decreased due to the impact of transferring the dermatology business in April 2016, yet sales showed an increase when calculated excluding this impact.

FY2017 Guidance

The company has upwardly revised its forecasts for sales, core operating profit and core profit for the year from the figures announced in April 2017 ("initial forecast") based on the financial results for the first six months of FY2017 and the trend of foreign exchange rates. Revised expected exchange rates are anticipated to cause a ¥20.2 billion increase in sales and a ¥3.8 billion increase 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)

	FY2016 Full-year results	**FY2017 Full-year forecasts**	Change (%)
Sales	1,311,665	**1,297,000**	-14,665 (-1.1%)
Core Operating profit	274,554	**258,000**	-16,554 (-6.0%)
Core Profit for the year	213,343	**201,000**	-12,343 (-5.8%)

NOTE: For further information on the results including on a full basis, please refer to the reference documents: Financial Results, Supplementary Documents, Overview of R&D Pipeline and Presentation Material for the Financial Information Meeting available on the Astellas website.https://www.astellas.com/en/investors/ir-library

Strategic Quarterly 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 as outlined below.

Maximizing the Product Value

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

Creating Innovation

The following lists the main development advances achieved during the first six months of FY2017:

- Announced the Phase 3 PROSPER trial evaluating XTANDI® (enzalutamide) plus androgen deprivation therapy (ADT) versus ADT alone in patients with non-metastatic castration-resistant prostate cancer met its primary endpoint of improved metastasis-free survival in September 2017.

- Submitted an application for marketing approval of fidaxomicin for the treatment of infectious enteritis caused by *Clostridium difficile* in Japan in July 2017.

- Repatha® SC Injection 420 mg Auto mini doser was approved in Japan in August 2017.

- Submitted a supplemental new drug application for marketing approval of linaclotide (generic name, brand name: Linzess® Tablets 0.25 mg), for the additional indication of chronic constipation (other than constipation associated with organic disorders) in Japan in September 2017

Pursuing Operational Exellence

- Announced that as of October 1, 2017, Maruho Co., Ltd will succeed the marketing approval in Japan from Astellas, for anti-atopic dermatitis agent Protopic® Ointment(July 2017).

- Announced the decision to wind down the research operations of Agensys, Inc.(U.S.) (July 2017).

(1) EMEA: Europe, the Middle East and Africa
(2) Sales by Region: based on location of sellers

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 https://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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