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Financial Results of Astellas for the First Six Months of FY2021

Japan, October 29, 2021 – Astellas Pharma Inc. (TSE: 4503, President and CEO: Kenji Yasukawa, "the Company") today announced the financial results for the first six months (April 1, 2021 – September 30, 2021) of the fiscal year 2021 (FY2021) ending March 31, 2022.

Consolidated financial results for the first six months of FY2021 (core basis)

			(IVIIIIONS OF yen)
	First six months	First six months	Change
	of FY2020	of FY2021	(%)
Revenue	615,480	651 666	+36,186
Revenue	015,460	651,666	(+5.9%)
Core operating profit	100.070	405 000	-4,985
Core operating profit	130,278	125,293	(-3.8%)
Coro profit	106 159	98,756	-7,402
Core profit	106,158		(-7.0%)

(Millions of yen)

Cautionary Notes

In this material, 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 material is not intended to constitute an advertisement or medical

advice.

1. Qualitative information on consolidated financial results for the first six months of FY2021

(1) Business performance

<Consolidated financial results (core basis (Note))>

Consolidated financial results (core basis) in the first six months of FY2021 are shown in the table below. While revenue increased, core operating profit and core profit decreased.

Consolidated financial results (core basis)

(Millions of yen) First six months First six months Change of FY2021 of FY2020 (%) +36,186 Revenue 615,480 651,666 (+5.9%)+5,186119,549 124,736 Cost of sales (+4.3%)Selling, general and +28,372 242,135 270,506 (+11.7%)administrative expenses +7,359 111,700 119,060 **R&D** expenses (+6.6%)+829 Amortisation of 12,379 11,550 (+7.2%)intangible assets Share of profit (loss) of +576 investments accounted -268 308 (-) for using equity method -4,985 Core operating profit 130,278 125,293 (-3.8%) -7,402 Core profit 106,158 98,756 (-7.0%) Basic core earnings per -3.85 57.15 53.30 (-6.7%)share (yen)

(Note) The Company discloses financial results on a core basis as an indicator of its recurring profitability. Certain items reported in financial results on a full basis that are deemed to be non-recurring items by the Company are excluded as non-core items from these financial results on a core basis. These adjusted items include impairment losses, gain/loss on sales of property, plant and equipment, restructuring costs, loss on disaster, a large amount of losses on compensation or settlement of litigations and other legal disputes, and other items that are deemed to be excluded based on the Company's judgment. A reconciliation table between results on a full basis and results on a core basis is provided in the "Supplementary Documents for Q2/FY2021 Financial Results."

<u>Revenue</u>

- Main products XTANDI for the treatment of prostate cancer, XOSPATA for the treatment of acute myeloid leukemia and PADCEV for the treatment of urothelial cancer showed steady growth as expected. In addition, the sales growth of EVRENZO for the treatment of renal anemia and Betanis / Myrbetriq / BETMIGA for the treatment of overactive bladder ("OAB") contributed to revenue as well.
- Moreover, other factor for the increase in sales in the first six months of FY2021 was the sales of pharmacologic stress agent Lexiscan returning to pre-pandemic level which decreased mainly in the first quarter of the previous fiscal year because of the impact of the spread of COVID-19.
- The sales growth of the products above offset the sales decrease mainly due to the termination of sales and distribution for Celecox for the treatment of inflammation and pain and Lipitor for the treatment of hypercholesterolemia, and the divestiture of Eligard for the treatment of prostate cancer.

As a result of the above, revenue in the first six months of FY2021 increased by 5.9% compared to those in the corresponding period of the previous fiscal year ("year-on-year") to ¥651.7 billion.

Core operating profit / Core profit

- Gross profit increased by 6.3% year-on-year to ¥526.9 billion. The cost-to-revenue ratio fell by 0.3 percentage points year-on-year to 19.1%, mainly due to changes in product mix.
- Selling, general and administrative expenses increased by 11.7% year-on-year to ¥270.5 billion. The total amount increased mainly due to the increase of copromotion fees associated with the growth of sales of XTANDI in the United States (increase of ¥10.2 billion year-on-year), investment in systems associated with globalization (increase of approximately ¥5.0 billion year-on-year), the increase in sales promotion expenses for new product launch readiness (increase of approximately ¥3.0 billion year-on-year), and the impact of the foreign exchange rates (increase of ¥8.4 billion year-on-year).

Excluding co-promotion fees of XTANDI in the United States, selling, general and administrative expenses increased by 10.0% year-on-year to ¥199.4 billion.

- Research and development (R&D) expenses increased by 6.6% year-on-year to ¥119.1 billion. While there was a decrease in development expenses for fezolinetant, a selective neurokinin-3 receptor antagonist, for which patient enrollment in Phase III trials in the United States and Europe has been completed, the total amount increased mainly due to increases in development expenses for zolbetuximab, an anti-Claudin 18.2 monoclonal antibody and R&D investment for Rx+ business (related to iota).
- Amortisation of intangible assets increased by 7.2% year-on-year to ¥12.4 billion.

As a result of the above, core operating profit decreased by 3.8% year-on-year to ¥125.3 billion, and core profit decreased by 7.0% year-on-year to ¥98.8 billion.

Impact of exchange rate on financial results

The exchange rates for the yen in the first six months of FY2021 are shown in the table below. The resulting impacts were a ¥24.5 billion increase in revenue and a ¥11.5 billion increase in core operating profit compared with if the exchange rates of the first six months of FY2020 were applied.

Average rate	First six months of FY2020	First six months of FY2021	Change
US\$/¥	107	110	¥3 (Weakening of yen)
€⁄¥	121	131	¥10 (Weakening of yen)

Change from beginning to end of period	As of September 30, 2020	As of September 30, 2021
	¥3	¥1
US\$/¥	(Strengthening of yen)	(Weakening of yen)
CN	¥5	¥1
€/¥	(Weakening of yen)	(Strengthening of yen)

Consolidated financial results on a full basis in the first six months of FY2021 are shown in the table below. While revenue and operating profit increased, profit decreased.

The full basis financial results include "Other income," "Other expenses," which are excluded from the core basis financial results. In the first six months of FY2021, "Other income" was ¥2.8 billion (¥4.3 billion in the corresponding period of the previous fiscal year) and "Other expenses" was ¥38.0 billion (¥47.7 billion in the corresponding period of the previous fiscal year).

The increase of the fair value on the contingent consideration recorded at the time of the acquisition of Ganymed was booked as "Other expenses" (¥8.7 billion) in the first six months of FY2021 as a result of the revision of the development plan for zolbetuximab for pancreatic adenocarcinoma.

Consolidated financial results (full basis)

First six months First six months Change of FY2020 of FY2021 (%) +36,186 Revenue 615,480 651,666 (+5.9%) +3,296Operating profit 86,872 90,169 (+3.8%)-5 Profit before tax 89,091 89,085 (-0.0%) -1,229 Profit 72,838 71,609 (-1.7%) Basic earnings per -0.57 39.21 38.65 share (yen) (-1.4%) Comprehensive -8,023 78,100 70,077 (-10.3%)income

(Millions of yen)

(Billions of yen)

	First six months of FY2020	First six months of FY2021	Change
XTANDI	225.5	267.6	+18.7%
XOSPATA	11.0	16.5	+50.3%
PADCEV	6.0	9.1	+51.5%
EVRENZO	0.3	1.4	+319.1%
Betanis / Myrbetriq / BETMIGA	80.0	84.4	+5.5%
Prograf*	89.6	92.3	+3.0%

* Prograf: Includes Advagraf, Graceptor, and ASTAGRAF XL.

<XTANDI>

 Sales grew in all regions. In Europe, where additional indication was approved for "metastatic hormone-sensitive prostate cancer (M1 HSPC)" in April 2021, reimbursement started in some countries, contributing to sales growth. In addition, in China, where reimbursement started in March 2021, sales expanded as the demand grew higher than expected.

<XOSPATA>

- Sales expanded in all regions, mainly in the United States and Europe, where sales grew compared to the corresponding period of the previous fiscal year. In addition, sales in China also contributed, where the product was launched in April 2021.

<PADCEV>

In the United States, revenue from co-promotion grew as expected, as the additional indication for "locally advanced or metastatic urothelial cancer patients who are ineligible for cisplatin-containing chemotherapy and have previously received one or more prior lines of therapy" was approved in July 2021. In addition, in September 2021, it was approved in Japan for the indication for "radically unresectable urothelial carcinoma that has progressed after anti-cancer chemotherapy."

<EVRENZO>

- In addition to increased sales in Japan, the product was launched in Europe in September 2021.

<Betanis / Myrbetriq / BETMIGA>

- While sales decreased in the United States, sales increased in other regions, resulting in an increase in global sales.

<Prograf>

- Global sales were in line with the full-year forecasts, although there were differences in increases and decreases by region, such as growth in Europe and China, while sales decreased in other regions.

<Revenue by region>

Revenue by region is shown in the table below. Revenue in United States, Established Markets and Greater China increased, while in Japan and International Markets decreased.

(Billions	of	yen))
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	First six months of FY2020	First six months of FY2021	Change
Japan	144.2	130.5	-9.5%
United States	236.7	270.1	+14.1%
Established Markets	138.9	157.4	+13.3%
Greater China	29.6	33.1	+11.8%
International Markets	56.7	55.3	-2.5%

Established Markets: Europe, Canada, Australia.

Greater China: China, Hong Kong, Taiwan.

International Markets: Russia, Latin America, Middle East, Africa, South East Asia, South Asia, Korea, Export sales, etc.

(2) Financial position

1) Assets, equity and liabilities

An overview of the consolidated statement of financial position as of September 30, 2021 and the main changes from the end of the previous fiscal year are shown below.

<u>Assets</u>

Total assets saw a decrease of ¥12.1 billion compared to the end of the previous fiscal year to ¥2,261.5 billion.

<Non-current assets> As of September 30, 2021: ¥1,385.1 billion (a decrease of ¥16.0

- billion)
- Property, plant and equipment increased by ¥2.0 billion compared to the end of the previous fiscal year to ¥266.7 billion.
- Goodwill increased by ¥1.0 billion compared to the end of the previous fiscal year to ¥285.0 billion, and intangible assets decreased by ¥10.4 billion compared to the end of the previous fiscal year to ¥641.0 billion. In the first three months of FY2021, intangible assets decreased mainly due to the recognition of impairment losses in relation to the termination of the development of the DNA vaccine ASP0892 and the anti-CD40 monoclonal antibody bleselumab.

<Current assets> As of September 30, 2021: ¥876.5 billion (an increase of ¥3.9 billion)

- Cash and cash equivalents decreased by ¥7.8 billion compared to the end of the previous fiscal year to ¥318.3 billion.

Equity

Total equity as of September 30, 2021 saw an increase of \pm 31.5 billion compared to the end of the previous fiscal year to \pm 1,417.6 billion, making the ratio of equity attributable to owners of the parent to total assets 62.7%.

- While profit stood at ¥71.6 billion, the Company paid ¥38.9 billion of dividends of surplus.

Liabilities

Total liabilities decreased by ¥43.6 billion compared to the end of the previous fiscal year to ¥843.9 billion.

<Non-current liabilities> As of September 30, 2021: ¥289.1 billion (a decrease of ¥6.0 billion)

- <Current liabilities> As of September 30, 2021: ¥554.8 billion (a decrease of ¥37.6 billion)
 - As of September 30, 2021, the balance of bonds amounted to ¥80.0 billion (a decrease of ¥40.0 billion).

2) Cash flow

Cash flows from operating activities

Net cash flows from operating activities in the first six months of FY2021 increased by ¥24.4 billion year-on-year to ¥139.4 billion.

- Income tax paid increased by ¥17.9 billion year-on-year to ¥24.1 billion.

Cash flows from investing activities

Net cash flows used in investing activities in the first six months of FY2021 was ¥55.7 billion, an increase in outflow of ¥17.5 billion year-on-year.

Cash flows from financing activities

Net cash flows used in financing activities in the first six months of FY2021 was ¥89.9 billion, a decrease in outflow of ¥19.8 billion year-on-year.

The balance of bonds and short-term borrowings decreased by ¥40.0 billion.
Dividends paid increased by ¥1.8 billion year-on-year to ¥38.9 billion.

As a result, cash and cash equivalents totaled ¥318.3 billion as of September 30, 2021, a decrease of ¥7.8 billion compared to the end of the previous fiscal year.

(3) Consolidated business forecasts for FY2021 and other forward-looking statements

The Company's business forecasts are presented on a core basis and full basis. The consolidated full-year business forecasts for FY2021 are shown below.

Regarding business forecasts on a core basis, the Company has left its business forecasts unchanged from the consolidated full-year business forecasts announced in April 2021. On the other hand, regarding business forecasts on a full basis, the Company has downwardly revised the operating profit, profit before tax and profit for the year, considering the increase of the fair value on the contingent consideration recorded at the time of the acquisition of Ganymed which was booked as "Other expenses" (¥8.7 billion) in the first six months of FY2021 as a result of the revision of the development plan for zolbetuximab for pancreatic adenocarcinoma.

			(M	illions of yen)
	Previous forecasts	Latest forecasts	Change	Results
	(FY2021)	(FY2021)	Change	(FY2020)
Revenue	1,323,000	1,323,000	_	1,249,528
Selling, general and administrative expenses	541,000	541,000	_	504,316
R&D expenses	242,000	242,000	_	224,489
Core operating profit	270,000	270,000	_	251,375
Core profit for the year	213,000	213,000	_	209,906
Basic core earnings per share (yen)	114.95	114.95	_	113.03

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Consolidated full-year business forecasts (core basis)

Consolidated full-year business forecasts (full basis)

(Millions of yen)

			· ·	
	Previous forecasts	Latest forecasts	Change	Results
	(FY2021)	(FY2021)		(FY2020)
Revenue	1,323,000	1,323,000	-	1,249,528
Operating profit	227,000	218,000	-9,000	136,051
Profit before tax	225,000	216,000	-9,000	145,324
Profit for the year	183,000	174,000	-9,000	120,589
Basic earnings per share (yen)	98.76	93.90	-4.86	64.93

Expected exchange rate for

FY2021 (Forecast)	¥110/US\$	¥130/€
FY2020 (Result)	¥106/US\$	¥124/€

2. Condensed Interim Consolidated Financial Statements and Notes

(1) Condensed Interim Consolidated Statement of Income

	(Millions of yen
Six months ended 30 September 2020	Six months ended 30 September 2021
615,480	651,666
(119,549)	(124,736)
495,931	526,931
(242,135)	(270,506)
(111,700)	(119,060)
(11,550)	(12,379)
(268)	308
4,263	2,847
(47,668)	(37,972)
86,872	90,169
3,445	1,888
(1,227)	(2,972)
89,091	89,085
(16,253)	(17,476)
72,838	71,609
72,838	71,609
39.21	38.65
39.19	38.63
	30 September 2020 615,480 (119,549) 495,931 (242,135) (111,700) (11,550) (268) 4,263 (47,668) 86,872 3,445 (1,227) 89,091 (16,253) 72,838 39.21

	·	(Millions of yen)
	Six months ended 30 September 2020	Six months ended 30 September 2021
Profit	72,838	71,609
Other comprehensive income		
Items that will not be reclassified to profit or loss		
Financial assets measured at fair value through other comprehensive income	6,585	(6,369)
Remeasurements of defined benefit plans	(844)	1,573
Subtotal	5,741	(4,796)
Items that may be reclassified to profit or loss		
Exchange differences on translation of foreign operations	(479)	3,264
Subtotal	(479)	3,264
Other comprehensive income	5,262	(1,532)
Total comprehensive income	78,100	70,077
Total comprehensive income attributable to:		
Owners of the parent	78,100	70,077

(2) Condensed Interim Consolidated Statement of Comprehensive Income

. ,		(Millions of yen)
	As of 31 March 2021	As of 30 September 2021
Assets		
Non-current assets		
Property, plant and equipment	264,623	266,671
Goodwill	284,011	284,993
Intangible assets	651,427	640,981
Trade and other receivables	33,924	32,376
Investments accounted for using equity method	7,117	8,580
Deferred tax assets	54,176	55,089
Other financial assets	95,850	87,094
Other non-current assets	9,913	9,270
Total non-current assets	1,401,040	1,385,054
Current assets		
Inventories	164,080	148,732
Trade and other receivables	343,178	357,801
Income tax receivable	13,984	17,569
Other financial assets	5,560	9,993
Other current assets	19,658	24,063
Cash and cash equivalents	326,128	318,295
Total current assets	872,588	876,454
Total assets	2,273,628	2,261,508

(3) Condensed Interim Consolidated Statement of Financial Position

		(Millions of yen)
	As of 31 March 2021	As of 30 September 2021
Equity and liabilities		
Equity		
Share capital	103,001	103,001
Capital surplus	177,830	178,531
Treasury shares	(15,377)	(15,605
Retained earnings	953,289	985,231
Other components of equity	167,373	166,464
Total equity attributable to owners of the parent	1,386,115	1,417,622
Total equity	1,386,115	1,417,622
Liabilities		
Non-current liabilities		
Trade and other payables	400	444
Deferred tax liabilities	18,161	9,371
Retirement benefit liabilities	38,982	37,075
Provisions	5,796	4,129
Other financial liabilities	199,021	204,838
Other non-current liabilities	32,782	33,261
Total non-current liabilities	295,141	289,118
Current liabilities		
Trade and other payables	124,777	111,568
Income tax payable	8,395	12,381
Provisions	22,187	15,342
Other financial liabilities	148,163	106,117
Other current liabilities	288,851	309,359
Total current liabilities	592,372	554,768
Total liabilities	887,513	843,886
Total equity and liabilities	2,273,628	2,261,508

(4) Condensed Interim Consolidated Statement of Changes in Equity

(Millione	of yon)
(Millions	or yen)

	Equity attributable to owners of the parent					
					Other compo	onents of equity
	Share capital	Capital surplus	Treasury shares	Retained earnings	Subscription rights to shares	Exchange differences on translation of foreign operations
As of 1 April 2020	103,001	177,506	(7,178)	905,851	899	93,277
Comprehensive income						
Profit	—	_	_	72,838	_	_
Other comprehensive income	_	_	_	_	_	(479)
Total comprehensive income	—	_	_	72,838	_	(479)
Transactions with owners						
Acquisition of treasury shares	_	_	(881)	—	_	—
Disposals of treasury shares	—	(444)	748	(225)	(79)	—
Dividends	_	_	_	(37,150)	_	—
Share-based payments	—	391	_	—	_	—
Transfers	_	_	_	533	_	—
Total transactions with owners	_	(53)	(133)	(36,842)	(79)	_
As of 30 September 2020	103,001	177,452	(7,311)	941,847	820	92,798

As of 1 April 2021	103,001	177,830	(15,377)	953,289	745	147,024
Comprehensive income						
Profit	_	_	—	71,609	—	_
Other comprehensive income	_	_	_	_	_	3,264
Total comprehensive income	_	_	—	71,609	—	3,264
Transactions with owners						
Acquisition of treasury shares	-	_	(715)	—	—	_
Disposals of treasury shares	_	(357)	487	(87)	(44)	_
Dividends	-	_	_	(38,914)	_	_
Share-based payments	-	1,058	_	_	_	_
Transfers	_	_	_	(666)	_	_
Total transactions with owners	_	702	(227)	(39,667)	(44)	_
As of 30 September 2021	103,001	178,531	(15,605)	985,231	701	150,288

(Millions of yen)

	Equity attributable to owners of the parent				
	Other	components of equ			
	Financial assets measured at fair value through other comprehensive income	Remeasurements of defined benefit plans	Total	Total	Total equity
As of 1 April 2020	15,813	_	109,989	1,289,168	1,289,168
Comprehensive income					
Profit	-	_	_	72,838	72,838
Other comprehensive income	6,585	(844)	5,262	5,262	5,262
Total comprehensive income	6,585	(844)	5,262	78,100	78,100
Transactions with owners					
Acquisition of treasury shares	-	_	_	(881)	(881)
Disposals of treasury shares	-	_	(79)	0	0
Dividends	-	_	_	(37,150)	(37,150)
Share-based payments	-	—	—	391	391
Transfers	(1,377)	844	(533)		_
Total transactions with owners	(1,377)	844	(613)	(37,640)	(37,640)
As of 30 September 2020	21,022		114,639	1,329,628	1,329,628

As of 1 April 2021	19,604	_	167,373	1,386,115	1,386,115
Comprehensive income					
Profit	_	_	_	71,609	71,609
Other comprehensive income	(6,369)	1,573	(1,532)	(1,532)	(1,532)
Total comprehensive income	(6,369)	1,573	(1,532)	70,077	70,077
Transactions with owners					
Acquisition of treasury shares	_	_	_	(715)	(715)
Disposals of treasury shares	_	_	(44)	0	0
Dividends	_	_	_	(38,914)	(38,914)
Share-based payments	_	_	_	1,058	1,058
Transfers	2,239	(1,573)	666	_	_
Total transactions with owners	2,239	(1,573)	623	(38,570)	(38,570)
As of 30 September 2021	15,474	_	166,464	1,417,622	1,417,622

		(Millions of yen)
	Six months ended 30 September 2020	Six months ended 30 September 2021
Cash flows from operating activities		
Profit before tax	89,091	89,085
Depreciation and amortisation	35,941	37,081
Impairment losses (reversal of impairment losses)	34,560	26,054
Finance income and expenses	(2,218)	1,083
(Increase) decrease in inventories	(2,938)	15,423
(Increase) decrease in trade and other receivables	17,865	(13,254)
Increase (decrease) in trade and other payables	(50,805)	(8,791)
Other	(328)	16,768
Subtotal	121,167	163,451
Income tax paid	(6,207)	(24,066)
Net cash flows from operating activities	114,960	139,385
Cash flows from investing activities		
Purchases of property, plant and equipment	(13,955)	(17,493)
Proceeds from sales of property, plant and equipment	22	256
Purchase of intangible assets	(29,086)	(30,382)
Payments for acquisition of subsidiaries	(1,707)	(649)
Interest and dividends received	500	292
Other	5,941	(7,768)
Net cash flows provided by (used in) investing activities	(38,285)	(55,744)
Cash flows from financing activities		
Increase (decrease) in bonds and short-term borrowings	(142,000)	(40,000)
Proceeds from long-term borrowings	80,000	_
Acquisition of treasury shares	(881)	(715)
Dividends paid to owners of the parent	(37,150)	(38,914)
Repayments of lease liabilities	(8,528)	(9,083)
Other	(1,177)	(1,224)
Net cash flows provided by (used in) financing activities	(109,736)	(89,936)
Effect of exchange rate changes on cash and cash equivalents	1,404	(1,539)
Net increase (decrease) in cash and cash equivalents	(31,657)	(7,834)
Cash and cash equivalents at the beginning of	318,391	326,128
the year Cash and cash equivalents at the end of the period	286,734	318,295
	200,104	510,200

(5) Condensed Interim Consolidated Statement of Cash Flows

(6) Notes to condensed interim consolidated financial statements Notes on going concern assumption Not applicable.