Results Presentation
Fiscal 2019 Third Quarter

Kyowa Kirin Co., Ltd.

Agenda

Financial Review

Executive Officer, Head of Finance Dept Motohiko Kawaguchi

R&D Review

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Q&A

This document contains certain forward-looking statements relating to such items as the company's (including its domestic and overseas subsidiaries) forecasts, targets and plans. These forward-looking statements are based upon information available to the company at the present time and upon reasonable assumptions made by the company in making its forecasts, but the actual results in practice may differ substantially due to uncertain factors.

These uncertain factors include, but are not limited to, potential risks of the business activities in the pharmaceutical industry in Japan and overseas, intellectual property risks, risk of side effects, regulatory risks, product defect risks, risks of changes to the prices for raw materials, risks of changes to market prices, as well as risks of changes to foreign exchange rates and financial markets.

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Financial Review

Summary of Q3 Results

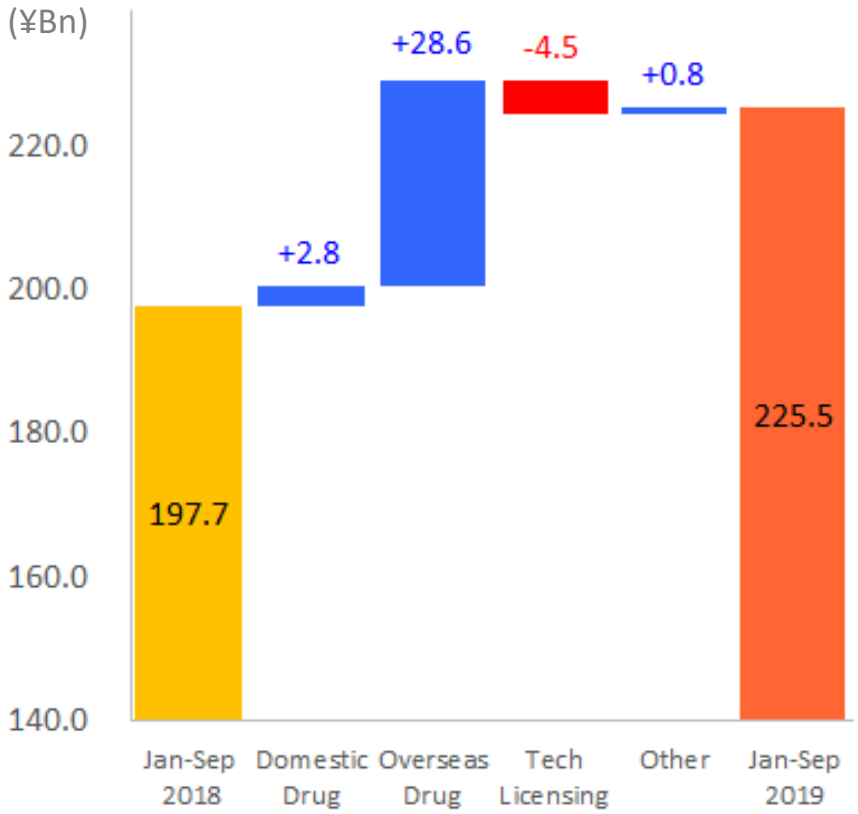
(Billion Yen / Rounded)

	2018Q3 Results [Cumulative]	2019Q3 Results [Cumulative]	Changes	2019Q4 Plan* [Cumulative]	Progress
Revenue *[Overseas Ratio]*	197.7 *[32%]*	225.5 *[38%]*	+27.7 (+14%)	305.0 *[39%]*	74%
Gross Profit *[Gross Profit margin]*	143.8 *[73%]*	168.4 *[75%]*	+24.6 (+17%)	224.0 *[73%]*	75%
Core OP *[Core OP margin]*	39.5 *[20%]*	45.8 *[20%]*	+6.2 (+16%)	53.0 *[17%]*	86%
Profit from continued operation	42.8	26.9	-15.9 (-37%)	37.0	73%
Profit from discontinued operation	4.6	29.4	+24.8 (+537%)	31.0	95%
Profit	47.4	56.3	+8.9(+19%)	68.0	83%

*Announced on February 5, 2019

YoY Analysis -Revenue-

+27.7 billion yen
(incl. forex effect -3.2)



● Domestic Drug +2.8

- **Positive:** Rituximab BS (+4.3), Orkedia (+3.7), G-Lasta (+3.5), Dovobet (+0.8), Romiplate(+0.6), Nouriast (+0.5) and Lumicef (+0.5) maintained steady growth.
- **Negative:** There were negative impacts by the drug price revision in April 2018. ESAs* shrunk due to switch to the authorized version of Nesp launched in Aug (-1.6). In addition, Regpara (-5.4) dropped due to the presence of a competing product and switch to Orkedia. Long-listed products such as Allelock (-1.3), Coniel (-0.7) and Depakene (-0.6) decreased mainly due to the penetration of generic drugs.

* ESA: Erythropoiesis Stimulating Agent

● Overseas Drug +28.6 (incl. forex effect -3.0)

- **EU/US:** Crysvita (+18.4) and Poteligeo (+8.0), launched last year, are strongly penetrating into the market.
- **Asia:** Regpara (+1.5) recorded favorable sales mainly in China . Neulasta/Peglasta (+1.0) also increased due to the launch in Middle Eastern countries.

● Tech Licensing -4.5 (incl. forex effect -0.1)

- **Benralizumab:** Increased sales royalties were not able to offset the absence of milestone revenue booked last year.
- **Other:** There was a gain on sale of Priority Review Voucher (US$80.6M × 50%) last year.

● Other +0.8

- Increase in the sales of FKB327 (Hulio) API.

Revenue of Major Items (Japan)

(Billion yen / Rounded)

Item	2018Q3 Results [Cumulative]	2019Q3 Results [Cumulative]	Changes	Reason	2019Q4 Plan [Cumulative]	Progress
Nesp+Authorized ver.	39.2	37.6	-1.6 (-4%)	Switch to the authorized ver. launched in Aug 2019	48.4	78%
Nesp	39.2	32.0	-7.2 (-18%)			
Authorized version*	–	5.6	+5.6			
Regpara	10.7	5.2	-5.4 (-51%)	A competitor's penetration & switch to Orkedia	5.1	103%
Orkedia	1.1	4.8	+3.7 (+324%)	Launched in May 2018	9.5	51%
G-Lasta	14.8	18.3	+3.5 (+24%)	Steady market penetration	22.8	80%
Rituximab BS	2.4	6.8	+4.3 (+177%)	Launched in Jan 2018	8.4	81%
Allelock	9.7	8.5	-1.3 (-13%)	Generic drugs' market penetration	9.3	91%
Patanol	11.5	11.7	+0.2 (+2%)		11.3	103%
Nouriast	6.8	7.3	+0.5 (+7%)	Steady market penetration	10.0	73%
Technology licensing	2.2	3.7	+1.5 (+66%)		4.4	84%

* Official product name is Darbepoetin Alfa Injection Syringe [KKF]. Kyowa Kirin Frontier is a marketing authorization holder; Kyowa Kirin is a distributor.

Revenue of Major Items (Overseas)

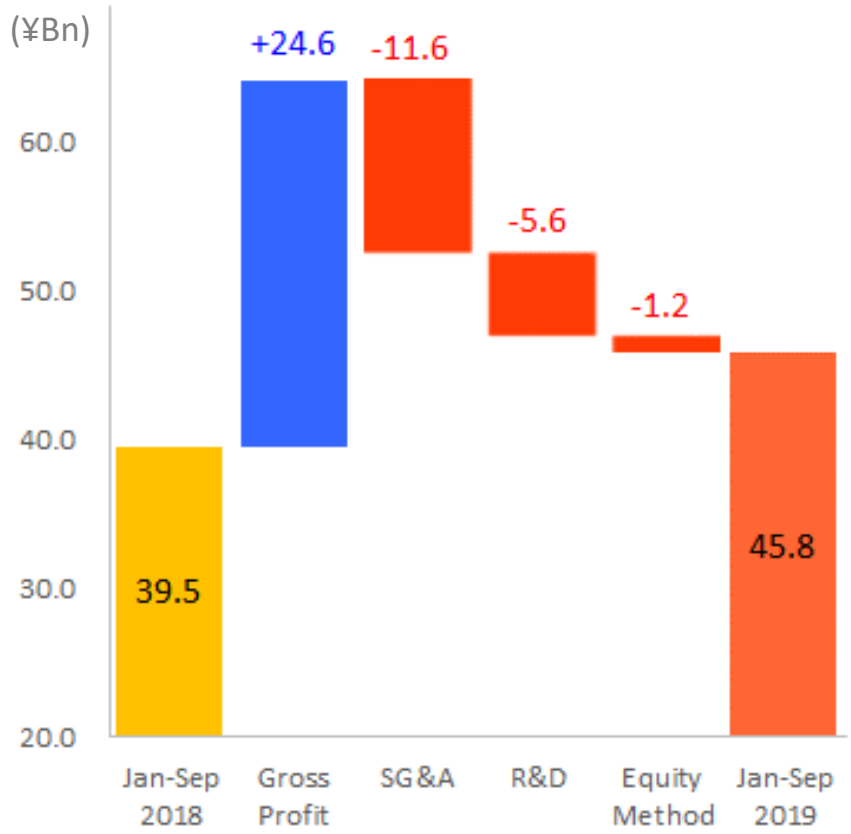
(Billion yen / Rounded)

Item	2018Q3 Results [Cumulative]	2019Q3 Results [Cumulative]	Changes	Reason	2019Q4 Plan [Cumulative]	Progress
Crysvita*1	3.2	21.6	+18.4 (+572%)	Launched in Apr 2018	Undisclosed	—
North America		16.3				
Europe & others		5.3				
Poteligeo	—	8.0	+8.0	Launched in Oct 2018	10.0	80%
Abstral	9.5	8.3	-1.2 (-12%)	Preparation for Brexit	12.3	68%
Technology licensing	13.9	7.9	-6.0 (-43%)	Benralizumab milestone & Crysvita PRV*3 in 2018	12.9	62%
Benralizumab Royalty*2	1.7	6.1	+4.4 (+254%)	Launched in 2018		

*1 -In January, sales started in England at the list price of GBP2,992 per 10mg vial.
-Since May, the List price in Germany has been revised to €2,550 per 10mg vial (from €3,388).
-Launched countries as of September 30, 2019:
USA, Canada, Germany, Netherland, Luxembourg, England, Wales, North Ireland, Slovakia, Sweden, Israel, UAE
*2 Sales royalties of “Fasenra” marketed by AstraZeneca. Includes our own estimation.
*3 PRV = Priority Review Voucher

YoY Analysis -Core OP-

+6.2 billion yen (incl. forex effect -0.7)



- **Gross Profit +24.6 (incl. forex effect -2.6)**
  - Increased in conjunction with the rise in the revenue. Gross profit margin up by 2 points, from 73% to 75%.

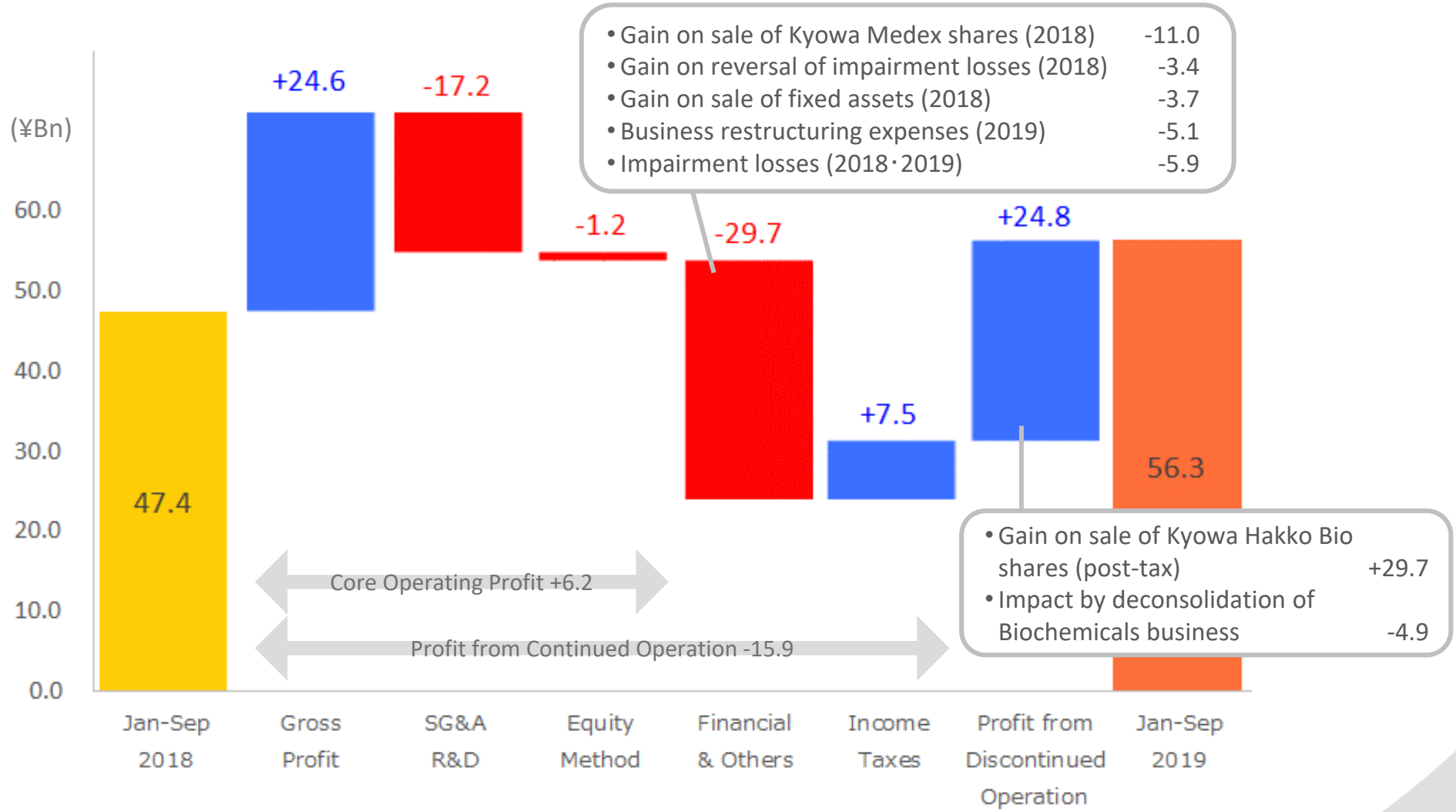
- **SG&A -11.6 (incl. forex effect +1.6)**
  - Increased selling and launch readiness expenses in the EU/US, including Crysvita's profit sharing expenses in North America.

- **R&D -5.6 (incl. forex effect +0.3)**
  - **Negative:** KHK4083 (P2 initiated in Oct 2018), RTA402 (P3 initiated in May 2018), KW-6356 (P2 initiated in Nov 2018), etc.

- **Gain/Loss on Equity Method -1.2**
  - Decreased due to the absence of FKB327-related revenue from the license-out of EU commercial rights and the achieved development milestone booked last year.

YoY Analysis -Profit-

Profit (Jan-Sep) +8.9 billion yen



- Gain on sale of Kyowa Medex shares (2018) -11.0
- Gain on reversal of impairment losses (2018) -3.4
- Gain on sale of fixed assets (2018) -3.7
- Business restructuring expenses (2019) -5.1
- Impairment losses (2018･2019) -5.9

- Gain on sale of Kyowa Hakko Bio shares (post-tax) +29.7
- Impact by deconsolidation of Biochemicals business -4.9

R&D Review

Key development updates in 19Q3

- **Initiation of the phase 3 clinical study of KHK4827 for the treatment of palmoplantar pustulosis in Japan (August)**

- **Approval of KW-6002 for the treatment of Parkinson's disease in the U.S. (August)**

  → The marketing strategy to be elaborated at the investor event on November 19th

- **Approval of KRN23 for the treatment of FGF23-related hypophosphatemic rickets and osteomalacia in Japan (September)**

Key development updates after September

- **Results of the phase 2 study of KHK4083 for the treatment of ulcerative colitis in the US and European countries:**

  There was no significant difference in efficacy endpoints

Appendix

FOREX Information

Average FOREX Rate

(Yen)

Currency	2018Q3 Results	2019Q3 Results	Changes	2019Q4 Plan
USD/JPY	109	109	—	110
GBP/JPY	149	140	-9	145

YoY FOREX Impact

(Billion yen)

Currency	On Revenue	On Core OP
USD	-0.2	-0.2
GBP	-2.1	+0.0

Key progress in development (2019 Q1-Q3)

Note: Listed events were completed between January 1st ,2019 and September 30th, 2019.

Month	Generic name Code	Indication	Country/region	Event
Jan.	Burosumab KRN23	FGF23-related hypophosphatemic rickets and osteomalacia	JP	Filed
Feb.	Tenapanor KHK7791	Hyperphosphatemia under maintenance dialysis	JP	Initiated phase 2 study
Apr.	Istradefylline KW-6002	Parkinson's disease	US	Accepted resubmission
Apr.	Evocalcet KHK7580	Hypercalcemia in patients with parathyroid carcinoma or primary hyperparathyroidism	JP	Filed additional indications
Jun.	Brodalumab KHK4827	Systemic sclerosis	JP	Initiated phase 3 study
Jun.	Romiplostim AMG531	Aplastic anemia in patients with inadequate response to conventional therapy	JP	Approved additional indication
Aug.	Brodalumab KHK4827	Palmoplantar Pustulosis	JP	Initiated phase 3 study
Aug.	Istradefylline KW-6002	Parkinson's disease	US	Approved
Sep.	Burosumab KRN23	FGF23-related hypophosphatemic rickets and osteomalacia	JP	Approved

Submission plan of major pipeline

As of September 30th, 2019

Generic name Code	Indication	Country/region	2019	2020	2021~
Burosumab[1] KRN23	XLH (adult)	EU	Submission	+	
Burosumab KRN23	XLH[2]	JP	Filed	+	
Burosumab KRN23	XLH[2]	AS	Filed[3]	+	
Evocalcet KHK7580	PHPT	JP	Filed	+	
Istradefylline KW-6002	Parkinson's disease	US	Filed	+	
Romiplostim AMG531	Aplastic anemia	JP	+		
Romiplostim AMG531	Aplastic anemia	KR	Submission / +		
Romiplostim AMG531	ITP	CN	Submission	+	
Brodalumab KHK4827	Psoriasis	AS	Filed[3]	+	
Brodalumab KHK4827	Axial spondyloarthritis	JP, AS	Phase 3	Submission / +	
Mogamulizumab KW-0761	HAM	JP	Phase 3	Submission / +	

+ Estimated time of regulatory decisions
Completed
On going
Planned

[1] Jointly developed with Ultragenyx
[2] Filed/approved indications are FGF23-related hypophosphatemic rickets and osteomalacia in JP and KR
[3] Korea and China
AS: Asia, CN: China, EU: Europe, JP: Japan, KR: Korea, US: United States

Development plan of major pipeline

As of September 30th, 2019

Generic name Code	Indication	Country/region	2019	2020	2021~
Bardoxolone methyl RTA 402	Diabetic Kidney disease	JP	Phase 3		
Bleselumab[1] ASKP1240	Recurrence of FSGS in *de novo* kidney transplant	US	Phase 2		
Entinostat KHK2375	Breast cancer	JP	Phase 2		
Evocalcet KHK7580	SHPT	AS	FPI	Phase 3	
KHK4083	Atopic dermatitis	JP US EU	Phase 2		Phase 3
KW-6356	Parkinson's disease	JP	Phase 2		Phase 3
Tenapanor KHK7791	Hyperphosphatemia under maintenance dialysis	JP	FPI	Phase 2	Phase 3
KHK4827 Brodalumab	Systemic sclerosis	JP	FPI	Phase 3	
KHK4827 Brodalumab	Palmoplantar Pustulosis	JP		FPI Phase 3	
Romiplostim AMG531	Aplastic anemia[2]	JP	FPI	Phase 3	
Pegfilgrastim KRN125	Mobilization of HSCs into peripheral blood	JP	FPI	Phase 2	

[1] Jointly developed with Astellas

[2] Aplastic anemia who were previously untreated with immunosuppressive therapy

AS: Asia, EU: Europe, JP: Japan, US: United States

Completed
On going
Planned

Estimated annual incidence/prevalence

Disease	Country /region	Estimated # of Incidence (i) or Prevalence (p)	Source
ATL	Japan	i: 1,150 per year p: 2,000	i: Survey and countermeasures to HTLV-1 infection and related diseases in Japan. 2009 summary research report (Yamaguchi, 2010) p: Ministry of Health, Labour and Welfare: 2017 Patient survey (illness classification)
ATL	U.S.	i: 180 per year	US Lymphoid Malignancy Statistics by World Health Organization Subtypes (Lauren R et al., CA Cancer J Clin., 2016)
PTCL	Japan	p: 1,000	Ministry of Health, Labour and Welfare: 2017 Patient survey (illness classification)
CTCL	Japan	p: 2,000	Ministry of Health, Labour and Welfare: 2017 Patient survey (illness classification)
CTCL	U.S.	i: 1,500 per year	SEER Data (2001-2007)
XLH	Japan	p: 5,000 (adult), 1,000 (ped.)	Estimate based on reported prevalence of 1 in 20,000 people; Nationwide survey of fibroblast growth factor 23 (FGF23)-related hypophosphatemic diseases in Japan: prevalence, biochemical data and treatment. (Endo I et al., Endocr J., 2015)
XLH	Europe	p: 12,000 (adult), 3,000 (ped.)	Estimate based on reported prevalence of 1 in 20,000 people
XLH	U.S.	p: 12,000 (adult), 3,000 (ped.)	Estimate based on reported prevalence of 1 in 20,000 people; New perspectives on the biology and treatment of X-linked hypophosphatemic rickets. (Carpenter TO, Pediatr Clin North Am., 1997)
TIO/ENS	Japan	p: 30 (TIO)	2010 Ministry of Health, Labour and Welfare Epidemiological Research on abnormalities in Hormone Receptor Mechanisms
TIO/ENS	U.S.	p: 500 - 1,000	Survey by Ultragenyx Pharmaceutical
PD	Japan	p: 162,000	Ministry of Health, Labour and Welfare: 2017 Patient survey (illness classification)
PD	U.S.	p: more than 570,000	Study by Decision Resources
AD	U.S.	p: 9,000,000 - 17,000,000	Studies by Decision Resources and Global Data
CKD	Japan	p: 13,300,000	Clinical Practice Guidebook for Diagnosis and Treatment of Chronic Kidney Disease (2012)
AA	Japan	i: 1,000 per year	Cited from the website of Japan Intractable Diseases Information Center (as of July, 2019) http://www.nanbyou.or.jp/entry/106
HAM	Japan	i: 30 per year p: 3,000 - 3,600	HTLV-1 associated myelopathy (HAM) practice guideline 2019

Crysvita - Collaboration with Ultragenyx -

	Kyowa Kirin Group	Ultragenyx
U.S.A /Canada	● Books sales ● For first 5 years, splits profits in half ● After 5 years, pays mid to high 20% range sales royalty	● For first 5 years, splits profits in half ● After 5 years, receives mid to high 20% range sales royalty from Kyowa Kirin International (KKI)
Europe	● Books sales ● Pay up to 10% sales royalty to Ultragenyx	● Receives up to 10% sales royalty from KKI
Latin America	● Receives low single-digit sales royalty from Ultragenyx	● Books sales ● Pays low single-digit sales royalty to Kyowa Kirin
Turkey	● Receives up to 20% sales royalty from Ultragenyx ● Retains an option to take over commercialization rights after a certain period	● Books sales ● Pays up to 20% sales royalty to KKI
Japan/Asia /ROW	● Books sales	

* Kyowa Kirin supplies commercial products in all regions.

List of acronyms

AA	Aplastic Anemia
AD	Atopic Dermatitis
ATL	Adult T-Cell Leukemia/Lymphoma
BS	Biosimilar
CKD	Chronic Kidney Disease
CTCL	Cutaneous T-Cell Lymphoma
DKD	Diabetic Kidney Disease
ENS	Epidermal Nevus Syndrome
FSGS	Focal Segmental Glomerulosclerosis
HAM	HTLV-1 Associated Myelopathy
HSC	Hematopoietic Stem Cell
ITP	Idiopathic (immune) Thrombocytopenic Purpura
PD	Parkinson’s Disease
PHPT	Primary Hyperparathyroidism
PTCL	Peripheral T-Cell Lymphoma
SHPT	Secondary Hyperparathyroidism
TIO	Tumor Induced Osteomalacia
XLH	X-linked Hypophosphatemia

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