

Major R&D pipeline

As of May 2015



Therapeutic area	Phase 1	Phase 2	Phase 3	Application
Cardiovascular- Metabolics	<ul style="list-style-type: none"> ■ DS-1040 (Acute ischemic stroke / TAF1a inhibitor) ■ DS-8312 (<u>Hypertriglyceridemia</u>) 	<ul style="list-style-type: none"> ■ CS-3150 (JP) (Hypertension · DM nephropathy / MR antagonist) ■ DS-8500 (JP) (Diabetes / GPR119 agonist) 	<ul style="list-style-type: none"> ■ Prasugrel (JP) (CS-747 / ischemic stroke / anti-platelet agent) ■ Prasugrel (US) (CS-747 / sickle cell disease / anti-platelet agent) 	<ul style="list-style-type: none"> ■ Edoxaban (EU/Others) (DU-176b / AF / oral factor Xa inhibitor) ■ Edoxaban (EU/Others) (DU-176b / VTE / oral factor Xa inhibitor)
Oncology	<ul style="list-style-type: none"> ■ U3-1565 (US/JP) (Anti-HB-EGF antibody) ■ DS-7423 (US/JP) (PI3K / mTOR inhibitor) ■ DS-3078 (US/EU) (mTOR inhibitor) ■ DS-3032 (US/JP) (MDM2 inhibitor) ■ PLX7486 (US) (FMS / TRK inhibitor) ■ DS-8895 (JP) (Anti-EPHA2 antibody) ■ DS-8273 (US) (Anti-DR5 antibody) ■ PLX8394 (US) (BRAF inhibitor) ■ DS-6051 (US) (NTRK / ROS1 inhibitor) ■ DS-5573 (JP) (Anti-B7-H3 antibody) ■ PLX9486 (US) (<u>KIT inhibitor</u>) 	<ul style="list-style-type: none"> ■ Patritumab (US/EU) (U3-1287 / anti-HER3 antibody) ■ Vemurafenib (US/EU) (PLX4032 / BRAF inhibitor) ■ PLX3397 (US) (FMS/KIT/FLT3-ITD inhibitor) 	<ul style="list-style-type: none"> ■ Tivantinib (US/EU) (ARQ 197 / HCC / MET inhibitor) ■ Denosumab (JP) (AMG 162 / breast cancer adjuvant / anti-RANKL antibody) ■ Nimotuzumab (JP) (DE-766 / gastric cancer / anti-EGFR antibody) ■ Vemurafenib (US/EU) (PLX4032 / melanoma adjuvant / BRAF inhibitor) ■ Quizartinib (US/EU) (AC220 / AML / FLT3-ITD inhibitor) ■ PLX3397 (US/EU) (<u>TGCT / FMS/KIT/FLT3-ITD inhibitor</u>) 	
Others	<ul style="list-style-type: none"> ■ DS-1093 (Anemia of chronic kidney disease / HIF-PH inhibitor) ■ DS-3801 (Chronic obstipation / GPR38 agonist) ■ DS-1971 (Chronic pain) ■ DS-1501 (Osteoporosis / Anti-Siglec-15 antibody) 	<ul style="list-style-type: none"> ■ SUN13837 (US/EU) (Spinal cord injury / modulator of bFGF signaling system) ■ Laninamivir (US/EU) (CS-8958 / anti-influenza / out-licensing with Biota) ■ Ioforninol (JP) (GE-145 / X-ray contrast media / angiography) 	<ul style="list-style-type: none"> ■ Mirogabalin (US/EU) (DS-5565 / fibromyalgia / $\alpha 2\delta$ ligand) ■ Mirogabalin (JP/Asia) (DS-5565 / DPNP/ $\alpha 2\delta$ ligand) ■ Mirogabalin (JP/Asia) (DS-5565 / PHN / $\alpha 2\delta$ ligand) ■ Denosumab (JP) (AMG 162 / rheumatoid arthritis / anti-RANKL anti-body) ■ Hydromorphone (JP) (DS-7113 / cancer pain / opioid μ-receptor regulator) ■ CHS-0214 (JP) (Etanercept BS / rheumatoid arthritis / TNFα inhibitor) ■ CL-108 (US) (Acute pain / opioid μ-receptor regulator) 	<ul style="list-style-type: none"> ■ Levofloxacin (JP) (DR-3355 / anti-infection / New quinolone)

Red: Change from FY2014 Q3 financial announcement

11. Major R&D Pipeline (Innovative pharmaceuticals)**◆ Launched/Approved**

Generic Name	Class	Indication	Region	Status	Remarks
Edoxaban	Factor Xa inhibitor	Atrial Fibrillation (AF)	US	<u>Launched</u>	Approved Jan 2015, <u>Feb 2015</u>
			CH	<u>Launched</u>	Approved Mar 2015, <u>May 2015</u>
		Venous thromboembolism (VTE)	US	<u>Launched</u>	Approved Jan 2015, <u>Feb 2015</u>
			CH	<u>Launched</u>	Approved Mar 2015, <u>May 2015</u>
The once daily oral anti coagulant (FXa inhibitor) discovered by Daiichi Sankyo. Edoxaban specifically, reversibly and directly inhibits the enzyme, Factor Xa, a clotting factor in the blood. Launched in Japan in July 2011 as the prevention of venous thromboembolism (VTE) in patients with total knee arthroplasty, total hip arthroplasty and hip fracture surgery. Additional indications for AF/VTE was approved in September 2014 and 60 mg tablet was launched in December 2014.					

Underline: change after FY2014 3Q Financial Announcement in January 2015

◆ Filed

Generic Name	Class	Target indication	Region	Filing year/month
Edoxaban	Factor Xa inhibitor	Atrial Fibrillation (AF)	EU	Jan 2014 <u>Apr 2015 CHMP recommendation for approval</u>
			Others	BR (14/6*) TW (14/7), KR (14/9) * means June, 2014, ditto
		Venous thromboembolism (VTE)	EU	Jan 2014 <u>Apr 2015 CHMP recommendation for approval</u>
			Others	BR (14/6) TW (14/7), KR (14/9)
The once daily oral anti coagulant (FXa inhibitor) discovered by Daiichi Sankyo. Edoxaban specifically, reversibly and directly inhibits the enzyme, Factor Xa, a clotting factor in the blood.				
Levofloxacin	New quinolone	Infection disease	JP	Injection, additional indication Nov 2014
Levofloxacin injection formation, which was launched in 2011 for the treatment in respiratory tract infection. As LCM programme, the trials for urinary tract infection, surgical infection and gynecological infection are completed.				

Underline: change after FY2015 3Q Financial Announcement in January 2015

◆ Under development (Phase1-3)

Generic Name / Project code number	Class	Target indication	Stage	Remarks
Prasugrel	Anti-platelet agent	Ischemic stroke	JP P3	additional indication
		Sickle cell disease	US P3	additional indication
Denosumab	Anti-RANKL antibody	Breast cancer adjuvant	JP P3	additional indication
		Rheumatoid arthritis	JP P3	additional indication
Tivantinib	MET inhibitor	Hepatocellular cancer	US/EU P3	
Nimotuzumab	Anti-EGFR antibody	Gastric cancer	JP P3	
		Esophageal cancer	JP P1	
Vemurafenib	BRAF inhibitor	Melanoma adjuvant	US/EU P3	additional indication
		Colorectal cancer	US/EU P2	additional indication
Quizartinib	FLT3-ITD inhibitor	Acute myeloid leukemia	US/EU P3	
PLX3397	FMS/KIT/FLT3-ITD inhibitor	<u>Tenosynovial Giant Cell Tumor (TGCT)</u>	<u>US/EU P3</u>	including pigmented villonodular synovitis
		Acute myeloid leukemia	US P2	
		Glioblastoma	US P2	
		Melanoma	US P2	
Mirogabalin	α2δ ligand	Fibromyalgia	US/EU P3	
		Diabetic peripheral neuropathic pain	JP/Asia P3	
		Postherpetic neuralgia	JP/Asia P3	
Hydromorphone	Opioid mu-receptor agonist	Cancer pain	JP P3	
CHS-0214	TNFα inhibitor	Rheumatoid Arthritis	JP P3	etanercept biosimilar
CL-108	Opioid mu-receptor agonist combination	Acute pain	US P3	co-develop with Charleston Laboratories
CS-3150	MR antagonist	Hypertension	JP P2b	
		Diabetic nephropathy	JP P2b	
DS-8500	GPR119 agonist	Diabetes	JP P2	
Patritumab	Anti-HER3 antibody	Non small cell lung cancer	US/EU P2	
		Non small cell lung cancer	JP P1	
		Breast cancer	US P2	
		Breast cancer	JP P1	
		Head & Neck cancer	EU P1	
SUN13837	Modulator of bFGF signaling system	Spinal cord injury	US/EU P2	
GE-145	X-ray contrast media	Angiography	JP P2	
Laninamivir	Neuraminidase inhibitor	Influenza	US/EU P2	out-licensing with Biota
DS-1040	TAF1a inhibitor	Acute ischemic stroke	- P1	
<u>DS-8312</u>	<u>Hypertriglyceridemia treatment</u>	<u>Hypertriglyceridemia</u>	- <u>P1</u>	
U3-1565	Anti-HB-EGF antibody	Solid cancer	US/JP P1	
DS-7423	PI3K/mTOR inhibitor	Solid cancer	US/JP P1	

Underline: change after FY2014 3QFinancial Announcement in January 2015

◆ Under development (Phase1-3)

Generic Name / Project code number	Class	Target indication	Stage	Remarks
DS-3078	mTOR inhibitor	Solid cancer, lymphoma	US/EU P1	
DS-3032	MDM2 inhibitor	Solid cancer, lymphoma	US/JP P1	
PLX7486	FMS/TRK inhibitor	Solid cancer	US P1	
DS-8895	Anti-EPHA2 antibody	Solid cancer	JP P1	
DS-8273	Anti-DR5 antibody	Solid cancer	US P1	
PLX8394	BRAF inhibitor	Solid cancer, leukemia	US P1	
DS-6051	NTRK/ROS1 inhibitor	Solid cancer	US P1	
DS-5573	Anti-B7-H3 antibody	Solid cancer	JP P1	
<u>PLX9486</u>	<u>KIT inhibitor</u>	<u>Solid cancer</u>	<u>US</u> <u>P1</u>	
DS-1093	HIF-PH inhibitor	Anemia of chronic kidney disease	- P1	
DS-3801	GPR 38 agonist	Chronic obstipation	- P1	
DS-1971	Pain	Chronic pain	- P1	
DS-1501	Anti-Siglec-15 antibody	Osteoporosis	- P1	

Underline: change after FY2014 3QFinancial Announcement in January 2015

◆ Stage-up (major changes from the FY2014 3Q financial announcement in January 2015)

Generic Name / Project code number	Class	Target indication	Current stage	Remarks
Edoxaban	FXa inhibitor	Atrial Fibrillation (AF)	US	Launched
			CH	Approved Launched
		Venous thromboembolism (VTE)	US	Launched
			CH	Approved Launched
PLX3397	FMS/KIT/FLT3-ITD inhibitor	Tenosynovial Giant Cell Tumor	US/EU P3	including pigmented villonodular synovitis
DS-8312	Hypertriglyceridemia treatment	Hypertriglyceridemia	- P1	
PLX9486	KIT inhibitor	Solid cancer	US P1	

◆ Discontinue (major changes from the FY2014 3Q financial announcement in January2015)

Generic Name / Project code number	Class	Target indication	Stage
PLX5622	FMS kinase inhibitor	Rheumatoid arthritis	- P1
< Reason for discontinuation > Plexxikon decided to discontinue the development of PLX5622 after reviewing its study result.			