Major R&D Pipeline

As of October 2014

Daiichi-Sankyo

Therapeutic area	Phase 1	Phase 2	Phase 3	Application
Cardiovascular-Metabolics	■ DS-1040 (Acute ischemic stroke / TAFIa inhibitor)	■ CS-3150 (JP) (Hypertensive / DM nephropathy / MR antagonist) ■ DS-8500 (JP) (Diabetes / GPR119 agonist)	■ Prasugrel (JP) (CS-747 / ischemic stroke / anti-platelet agent) ■ Prasugrel (US) (CS-747 / sickle Cell Disease / anti-platelet agent)	■ Edoxaban (US/EU/Others) (DU-176b / AF / oral factor Xa inhibitor) ■ Edoxaban (US/EU/Others) (DU-176b / VTE / oral factor Xa inhibitor)
Oncology	■ U3-1565 (US/JP) (Anti-HB-EGF antibody) ■ DS-7423 (US/JP) (PI3K / mTOR inhibitor) ■ DS-3078 (US/EU) (mTOR inhibitor) ■ DS-3032 (US) (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)	■ Patritumab (US/EU) (U3-1287 / anti-HER3 antibody) ■ Vemurafenib (US/EU) (PLX4032 / BRAF inhibitor) ■ PLX3397 (US) (Fms / Kit/Flt3-ITD inhibitor)	■ 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)* (PLX4032 / melanoma adjuvant / BRAF inhibitor	
Others	■ PLX5622 (Rheumatoid arthritis / FMS kinase inhibitor) ■ DS-1093 (Anemia of chronic kidney disease / HIF-PH inhibitor) ■ DS-3801 (Chronic obstipation / GPR 38 agonist) ■ DS-1971 (Chronic pain)	■ Mirogabalin (JP) (DS-5565 / chronic pain / α2δ ligand) ■ SUN13837 (US/EU) (Spinal cord injury / modulator of bFGF signaling system) ■ Laninamivir (US/EU) (CS-8958 / anti-influenza / out-licensing with Biota) ■ Ioforminol (JP) (GE-145 / X-ray contrast media / angiography)	■ Mirogabalin (US/EU) (DS-5565 / Fibromyalgia / α2δ ligand) ■ Levofloxacin (JP) (DR-3355 / anti-infection / New quinolone) ■ Denosumab (JP) (AMG 162 / rheumatoid arthritis / anti-RANKL anti-body) ■ Hydromorphone (JP) (DS-7113 / narcotic analgesic / opioid μ-receptor regulator) ■ CHS-0214 (JP) (Etanercept BS / rheumatoid arthritis / TNFα inhibitor) ■ CL-108 (US) (Acute pain / opioid μ-receptor regulator)	

Underlined: stage-up project after the 1Q financial announcement on July 31, 2014

*: newly cited in line with Roche's description

13. Major R&D Pipeline (Innovative pharmaceuticals)

As of October 2014

◆ Launched/Approved

Generic Name	Class	Indication	Region	Status	Remarks
Edoxaban	Factor Xa inhibitor	Atrial Fibrillation（AF）	JP	Approved	Sep 2014
		Venous thromboembolism (VTE)	JP	Approved	

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.

Underline: change after FY2014 1Q Financial Announcement in July 2014

◆ Filed

	Class	Target indication	Region	Filing year/month
Edoxaban	Factor Xa inhibitor	Atrial Fibrillation（AF）	US/EU	Jan 2014
			Others	CH (14/2*), BR (14/6) TW (14/7), KR (14/9) * means February, 2014, ditto
		Venous thromboembolism (VTE)	US/EU	Jan 2014
			Others	CH (14/2), 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. 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.

Underline: change after FY2014 1Q Financial Announcement in July 2014

◆ **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
Levofloxacin	New quinolone	Infection disease	JP	P3	Injection, 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 (newly included in align with the description of Roche)
		Colorectal cancer	US/EU	P2	additional indication
Mirogabalin	α2δ ligand	Fibromyalgia	US/EU	P3	
		Chronic pain	JP	P2	P3 to be started in FY2014
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	P2	
		Diabetic nephropathy	JP	P2	
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	
PLX3397	Fms/Kit/Flt3-ITD inhibitor	Acute myeloid leukemia	US	P2	
		Glioblastoma	US	P2	
		Melanoma	US	P2	
		Pigmented villonodular synovitis	US	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-licenseing with Biota
DS-1040	TAFIa inhibitor	Acute ischemic stroke	-	P1	
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 1QFinancial Announcement in July 2014

◆ 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	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	
PLX5622	FMS kinase inhibitor	Rheumatoid arthritis	-	P1	
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	

Underline: change after FY2014 1QFinancial Announcement in July 2014

◆ Stage-up (major changes from the FY2014 1Q financial announcement in July 2014)

Generic Name / Project code number	Class	Target indication	Current stage	
Edoxaban	FXa inhibitor	Atrial Fibrillation（AF）	JP	Approval
			Others	Filed (KR)
		Venous thromboembolism (VTE)	JP	Approved
			Others	Filed (KR)
Mirogabalin / DS-5565	α2δ ligand	Fibromyalgia	US/EU	P3
CHS-0214	TNFα inhibitor	Rheumatoid Arthritis	JP	P3
CL-108	opioid mu-receptor agonist	Acute Pain	US	P3
DS-6051	NTRK/ROS1 inhibitor	Solid Cancer	US	P1

◆ Discontinue (major changes from the FY2014 1Q financial announcement in July 2014)

Generic Name / Project code number	Class	Target indication	Stage	
DS-7309	Glucokinase activator	Diabetes	-	P1
< Reason for discontinuation> Daiichi Sankyo decided not to develop this compound by ourselves in order to concentrate management resources on promising business areas.				