

Major R&D Pipeline

As of Jan 2014



Therapeutic area	Phase 1	Phase 2	Phase 3	Application
Cardiovascular-Metabolics	■ DS-7309 (Anti-diabetes / Glucokinase activator) ■ DS-8500 (Anti-diabetes / GPR119 agonist) ■ DS-1442 (Dyslipidemia / CETP inhibitor) ■ DS-1040 (Acute ischemic stroke / TAFIa inhibitor)	■ CS-3150 (JP) (Anti-hypertensive/DM nephropathy / MR antagonist)	■ CS-747 (JP) (prasugrel / ischemic stroke / anti-platelet agent) ■ CS-747 (US) (prasugrel / Sickle Cell Disease / anti-platelet agent)	■ CS-747 (JP) (prasugrel / PCI / anti-platelet agent) ■ DU-176b (Global) (edoxaban / AF / oral factor Xa inhibitor) ■ DU-176b (Global) (edoxaban / VTE / oral factor Xa inhibitor)
Oncology	■ U3-1565 (US/JP) (Anti-HB-EGF antibody) ■ DS-2248 (US) (HSP90 inhibitor) ■ 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(日) (Anti-EPHA2 antibody)	■ U3-1287 (US/EU) (patritumab / anti-HER3 antibody) ■ PLX4032 (US/EU) (vemurafenib / BRAF inhibitor) ■ PLX3397 (US) (Fms/Kit/Flt3-ITD inhibitor)	■ ARQ 197 (US/EU) (tivantinib / HCC / Met inhibitor) ■ AMG 162 (JP) (denosumab / breast cancer adjuvant / anti-RANKL antibody) ■ DE-766 (JP) (nimotuzumab / NSCLC / anti-EGFR antibody) ■ DE-766 (JP) (nimotuzumab / Gastric cancer / anti-EGFR antibody)	■ AMG 162 (JP) (denosumab / Giant Cell tumor / anti-RANKL antibody)
Others	■ DS-8587 (Anti-bacterial / Topoisomerase inhibitor) ■ CS-4771 (Anti-sepsis / TLR4 inhibitor) ■ PLX5622 (Rheumatoid arthritis / FMS kinase inhibitor) ■ CS-0777 (Immunomodulator / S1P receptor modulator) ■ DS-1093 (Anemia of chronic kidney disease/HIF-PH inhibitor)	■ DS-5565 (Global) (Chronic pain / $\alpha 2\delta$ ligand) ■ SUN13837 (US/EU) (Spinal cord injury / Modulator of bFGF signaling system) ■ ASB17061 (US) (Atopic Dermatitis / chymase inhibitor) ■ CS-8958 (US/EU) (laninamivir / anti-influenza / Outlicensing with Biota)	■ DR-3355 (JP) (levofloxacin / anti-infection / New quinolone) ■ AMG 162 (JP) (denosumab / rheumatoid arthritis / anti-RANKL anti-body) ■ DS-7113 (hydromorphone / Narcotic analgesic / opioid mu-receptor regulator)	

◆ Change of stage from announcement in Oct 2013

◆ Launched/Approved

Project code Number	Generic Name	Class	Target indication	Stage	Remarks
AMG 162	denosumab	Anti-RANKL antibody	Osteoporosis	JP Launched	Launched in Jun 2013
The fully human monoclonal antibody to target RANK Ligand, an essential mediator of osteoclast formation. Launched in Japan in April 2012 as treatment for bone complications stemming from multiple myeloma and bone metastases from solid tumors, and in June 2013 as treatment for osteoporosis.					
CS-8958	laninamivir	Neuraminidase inhibitor	Anti-influenza, prophylactic	JP Approved/ Launched	Approved/Launched in Dec 2013
The long-acting neuraminidase inhibitor developed and produced by Daiichi Sankyo. This is an inhalant that will act directly on the pulmonary and tracheal sites of infection. Launched in Japan in October 2010 as treatment for influenza A and influenza B viruses.					

◆ Filed

Project code Number	Generic Name	Class	Target indication	Stage	Remarks
CS-747	prasugrel	Anti-platelet agent	Ischemic heart disease undergoing PCI	JP Filed	Filed in Jun 2013
The oral antiplatelet agent discovered by Daiichi Sankyo and its Japanese research partner, Ube Industries, Ltd. Prasugrel helps keep blood platelets from clumping together and developing a blockage in an artery					
AMG 162	denosumab	Anti-RANKL antibody	Giant cell tumor of bone	JP Filed	Filed in Aug 2013
Application to manufacture and market RANMARK®. Denosumab obtained orphan drug designation for GCTB indication in June 2013					
DU-176b	edoxaban	Factor Xa inhibitor	Atrial Fibrillation (AF)	JP/US/EU Filed	Filed in Dec 2013(JP) Filed in Jan 2014(US/EU)
			Venous thromboembolism (VTE)	JP/US/EU Filed	Filed in Dec 2013(JP) Filed in Jan 2014(US/EU)
The once daily oral anti coagulant (Fxa inhibitor) doscovered 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.					

◆ Under development (Phase1-3)

Project code Number	Generic Name	Class	Target indication	Stage		Remarks
CS-747	prasugrel	Anti-platelet agent	Ischemic Stroke	JP	P3	Study to be completed in FY2014
			Sickle cell disease	US	P3	
AMG 162	denosumab	Anti-RANKL antibody	Breast cancer adjuvant	JP	P3	
			Rheumatoid arthritis	JP	P3	
DR-3355	levofloxacin	New quinolone	Anti-infection	JP	P3	
ARQ 197	tivantinib	MET inhibitor	Hepatocellular cancer	US/EU	P3	
DE-766	nimotuzumab	Anti-EGFR antibody	Gastric cancer	JP	P3	
			Non small cell lung cancer	JP	P3	
			Esophageal cancer	JP	P1	
DS-7113	hydromorphone	opioid mu-receptor agonist	Cancer pain	JP	P3	
CS-3150	-	MR antagonist	Hypertension	JP	P2	
			Diabetic nephropathy	JP	P2	
U3-1287	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	
PLX4032	vemurafenib	BRAF inhibitor	Thyroid cancer	US/EU	P2	
PLX3397	-	Fms/Kit/Flt3-ITD inhibitor	Hodgkin lymphoma	US	P2	
			Acute myeloid leukemia	US	P2	
			Glioblastoma	US	P2	
			Prostate Caner	US	P2	
DS-5565	-	α2δ ligand	Chronic pain	Global	P2	
SUN13837	-	Modulator of bFGF signaling system	Spinal cord injury	US/EU	P2	
ASB17061	-	Chymase inhibitor	Atopic Dermatitis	US	P2	
CS-8958	laninamivir	Neuraminidase inhibitor	Anti-influenza	US/EU	P2	

◆ Under development (Phase1-3)

Project code Number	Generic Name	Class	Target indication	Stage	Remarks
DS-7309	-	Glucokinase activator	Diabetes	- P1	
DS-8500	-	GPR119 agonist	Diabetes	- P1	
DS-1442	-	CETP inhibitor	Dyslipidemia	- P1	
DS-1040	-	TAFIa inhibitor	Acute ischemic stroke	- P1	
U3-1565	-	Anti-HB-EGF antibody	Solid cancer	US/JP P1	
DS-2248	-	HSP90 inhibitor	Solid cancer	US P1	
DS-7423	-	PI3K/mTOR inhibitor	Solid cancer	US/JP P1	
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-8587	-	Topoisomerase inhibitor	Anti-bacterial	- P1	
CS-4771	-	TLR4 inhibitor	Anti-sepsis	- P1	
PLX5622	-	FMS kinase inhibitor	Rheumatoid arthritis	- P1	
CS-0777	-	S1P receptor modulator	Immunomodulator	- P1	
DS-1093	-	HIF-PH inhibitor	Anemia of chronic kidney disease	- P1	

◆ Change of stage from announcement in Oct 2013

Project code Number	Generic Name	Class	Target indication	Stage	
CS-8958	laninamivir	Neuraminidase inhibitor	Anti-influenza, prophylactic	JP	Approved/ Launched
DU-176b	edoxaban	Factor Xa inhibitor	Atrial Fibrillation (AF)	JP/US/EU	Filed
			Venous thromboembolism (VTE)	JP/US/EU	Filed
AMG 162	denosumab	Anti-RANKL antibody	Rheumatoid arthritis	JP	P3
DS-7113	hydromorphone	opioid mu-receptor agonist	Cancer pain	JP	P3
DS-8895	-	Anti-EPHA2 antibody	Solid cancer	JP	P1

◆ Discontinue

Project code Number	Generic Name	Class	Target indication	Stage	
ARQ 197	tivantinib	MET inhibitor	Colorectal cancer	US/EU	P2
<Reason for discontinue> Daiichi Sankyo decided to discontinue the development of ARQ 197 after reviewing its clinical studies results.					