Daiichi Sankyo Cancer Enterprise

Daiichi-Sankyo cancerenterprise

The vision of Daiichi Sankyo Cancer Enterprise is to leverage our world-class, innovative science and push beyond traditional thinking in order to create meaningful treatments for patients with cancer. We are dedicated to transforming science into value for patients, and this sense of obligation informs everything we do.

Caliber of Science

Driven by an obligation to translate high-quality science into value for patients, the Daiichi Sankyo Cancer Enterprise is committed to becoming a world-class leader in oncology. Our teams of exceptional scientists share a passion for innovation and meticulous execution to advance the next generation of precision medicines.

Dynamic and Sustainable R&D Engine

The Daiichi Sankyo Cancer Enterprise portfolio is powered by our research engines:

- Two laboratories for biologic/immuno-oncology and small molecules in Japan.
- Plexxikon Inc. – small molecule structure-guided R&D center in Berkeley, California.

Focused and Prioritized Pipeline

Anchored by our Antibody Drug Conjugate (ADC) and Acute Myeloid Leukemia (AML) Franchises, the Daiichi Sankyo Cancer Enterprise prioritized portfolio includes more than 20 ADCs, monoclonal antibodies and small molecules.

Enhanced Capabilities Through Collaboration

To complement and expand our premier cadre of internal scientists, we are collaborating with leading academic and business partners to leverage cutting-edge science in new treatment modalities, disease biology, diagnostics and pipeline prioritization:

Research & Technology

zymeworks · Darwin Health · sysmex · Glycotope Biotechnology · 国立がん研究センター National Cancer Center Japan · JVCKENWOOD · Max-Planck-Innovation · LDC

Translational & Development

AgonOx · Bristol-Myers Squibb · Dana-Farber Cancer Institute · Kite Pharma · MD Anderson Cancer Center

Pipeline at a Glance

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Care. Compassion. Science. It's Our Obligation.

More than 20 ADCs, monoclonal antibodies and small molecules

These are investigational agents and have not been approved by the FDA or any other regulatory agency worldwide as a treatment for any indication. Safety and efficacy have not been established.

Antibody Drug Conjugate (ADC) Franchise

ADCs are targeted cancer medicines that deliver cytotoxic chemotherapy ("payload") to cancer cells via a linker attached to a monoclonal antibody that binds to a specific target expressed on cancer cells. Daiichi Sankyo's proprietary ADC technology is designed to target and deliver chemotherapy inside cancer cells and reduce systemic exposure to the cytotoxic payload (or chemotherapy) compared to the way chemotherapy is commonly delivered.

COMPOUND	TUMOR TYPE	TUMOR EXPRESSING	FURTHEST PHASE OF DEVELOPMENT (REGION)
DS-8201	Breast Cancer (DESTINY-Breast01) *FDA Breakthrough Therapy Designation* *FDA Fast Track Designation*	HER2	Phase 2 (US, EU, Japan)
	Gastric Cancer (DESTINY-Gastric01)		Phase 2 (Japan, Asia)
	Solid Tumors		Phase 1 (US, Japan)
DS-8201 [in combination with nivolumab]	Breast Cancer, Bladder Cancer	HER2	Phase 1 preparation (US, EU)
U3-1402	Breast Cancer	HER3	Phase 1 (Japan)
	Non-Small Cell Lung Cancer		Phase 1 preparation (US, EU)
DS-1062	Solid Tumors	TROP2	Preclinical
DS-7300	Solid Tumors	B7-H3	Preclinical
Project 5	Solid Tumors	Undisclosed	Preclinical
Project 6	Solid Tumors	Undisclosed	Preclinical

Acute Myeloid Leukemia (AML) Franchise

Our AML Franchise is developing a portfolio of therapies that leverage three distinct strategies for the treatment of AML, including quizartinib in phase 3 clinical development, DS-3032, DS-3201 and PLX51107 in phase 1 clinical development, and DS-1001 in preclinical development. Our AML Franchise will evaluate combination regimens including these and other compounds for their potential to change the standard of care for patients with AML.

COMPOUND	TUMOR TYPE	RELEVANT PATHWAY (CLASS OF TARGET)	FURTHEST PHASE OF DEVELOPMENT (REGION)
Quizartinib (AC220)	Newly-Diagnosed AML (QuANTUM-First)	FLT3 (growth factor receptor inhibition)	Phase 3 (US, EU, Asia)
	Relapsed/Refractory AML (QuANTUM-R) *FDA Fast Track Designation* *Orphan Drug Designation*		Phase 3 (US, EU, Asia)
	Relapsed/Refractory AML		Phase 2 (Japan)
DS-3032	AML, Acute Lymphocytic Leukemia (ALL), Chronic Myeloid Leukemia (CML), Myelodysplastic Syndrome (MDS)	MDM2 (tumor suppressor p53 reactivation)	Phase 1 (US)
	Solid Tumors, Lymphoma		Phase 1 (US)
	Solid Tumors, Lymphoma		Phase 1 (Japan)
DS-3201	AML/ALL	EZH1/2 (epigenetic regulation)	Phase 1 (US)
	Non-Hodgkin's Lymphoma		Phase 1 (Japan)
PLX51107	AML, MDS, Lymphoma, Solid Tumors	BRD4 (epigenetic regulation)	Phase 1 (US)
DS-1001	AML	IDH1 (epigenetic regulation)	Preclinical

Additional Late and Early Stage Programs

Daiichi Sankyo Cancer Enterprise is also developing compounds with high clinical promise for additional conditions with unmet medical needs, such as tenosynovial giant cell tumor (TGCT), which includes pigmented villonodular synovitis (PVNS) and giant cell tumor of the tendon sheath (GCT-TS), glioblastoma, and non-small cell lung cancer (NSCLC).

COMPOUND	TUMOR TYPE	RELEVANT PATHWAY	FURTHEST PHASE OF DEVELOPMENT (REGION)
Pexidartinib (PLX3397)	TGCT (ENLIVEN) *FDA Breakthrough Therapy Designation* *Orphan Drug Designation*	CSF-1R	Phase 3 (US,EU)
	Glioblastoma	CSF-1R, c-KIT	Phase 2 (US)
	Melanoma	c-KIT	Phase 1/2 (Asia)
	Solid Tumors	CSF-1R	Phase 1 (Asia)
Pexidartinib (PLX3397) [in combination with pembrolizumab]	Solid Tumors, Melanoma	CSF-1R	Phase 1 (US)
Patritumab (U3-1287)	Head and Neck Cancer	HER3	Phase 2 (EU)
DS-1647	Glioblastoma *SAKIGAKE Designation*	Oncolytic HSV-1	Phase 2 (Japan)
DS-1205 [in combination with osimertinib]	Non-Small Cell Lung Cancer	AXL	Phase 1 preparation (US)
DS-8273	Solid Tumors	DR5	Phase 1 (US)
DS-1123	Solid Tumors	FGFR2	Phase 1 (Japan)
DS-1001	Gliomas	IDH1	Phase 1 (Japan)
PLX2853	Solid Tumors	BRD4	Phase 1 (US)
PLX73086	TGCT	CSF-1R	Phase 1 (US)
PLX7486	Solid Tumors	FMS/TRK	Phase 1 (US)
PLX8394	Solid Tumors	BRAF	Phase 1 (US)
PLX9486	Solid Tumors	KIT	Phase 1 (US)