

Major R&D Pipeline: 5DXd ADCs

Phase 1		Phase 2		Phase 3		Regulatory phase	
(US/EU/Asia) HER2+ BC 2L+/1L DESTINY-Breast07	(JP/US/EU/Asia) NSCLC (w/o AGA, pembrolizumab combo) TROPION-Lung02	(CN) HER2 expressing solid tumors DESTINY-PanTumor03	(JP/US/EU/Asia) HER2+ BC adjuvant*1 DESTINY-Breast05	(JP/US/EU/Asia) in prep PD-L1 high nonsquamous NSCLC (w/o AGA, rilvegostomig combo) 1L TROPION-Lung10	(CN) HER2+ GC 3L DESTINY-Gastric06		
(US/EU/Asia) HER2 low BC Chemo naïve/post chemo DESTINY-Breast08	(JP/US/EU) NSCLC (w/o AGA, durvalumab, rilvegostomig, volrustomig and sabestomig combo) TROPION-Lung04	(JP/US/EU/Asia) solid tumors TROPION-PanTumor03	(JP/US/EU/Asia) HER2 low BC chemo naïve DESTINY-Breast06	(JP/US/EU/Asia) in prep EGFR mutated NSCLC (osimertinib combo) 1L TROPION-Lung14	(CN) HER2 mutant NSCLC 2L+ DESTINY-Lung05		
(JP/US/EU/Asia) HER2+ GC combo, 2L+/1L DESTINY-Gastric03	(US/EU/Asia) TNBC (durvalumab combo) BEGONIA	(JP/US/EU/Asia) EGFR mutated NSCLC (osimertinib combo) 2L ORCHARD	(JP/US/EU/Asia) HER2+ BC 1L DESTINY-Breast09	(JP/US/EU/Asia) TNBC (PD-1/PD-L1 inhibitor ineligible) 1L TROPION-Breast02	(US/EU) NSCLC 2/3L TROPION-Lung01		
(US/EU/Asia) HER2+ NSCLC (durvalumab, volrustomig combo) 1L DESTINY-Lung03	(JP/US/EU/Asia) solid tumors (saruparib combo) PETRA	(US/EU/Asia) resectable early-stage NSCLC (durvalumab combo) neoadjuvant NeoCOAST-2	(JP/US/EU/Asia) HER2+ BC neoadjuvant DESTINY-Breast11	(JP/US/EU/Asia) TNBC adjuvant*2 (mono or durvalumab combo) TROPION-Breast03	(JP/US/EU/CN) BC*3 2/3L TROPION-Breast01		
(US/EU) BC, NSCLC (pembrolizumab combo)	(JP/US/EU/Asia) NSCLC	(JP/US/EU/Asia) melanoma, SCCHN, HER2 negative GC, 2L+ HERTHENA-PanTumor01	(JP/EU/Asia) HER2+ GC 2L DESTINY-Gastric04	(JP/US/EU/Asia) TNBC neoadjuvant and adjuvant (durvalumab combo) TROPION-Breast04	(US) EGFR mutated NSCLC 3L HERTHENA-Lung01		
(US/EU/Asia) TNBC (durvalumab combo) BEGONIA	(JP/US/Asia) EGFR mutated NSCLC, 1/2L (osimertinib combo)	(JP/US/EU/Asia) ES-SCLC, 2L+ IDeate-Lung01	(JP/US/EU/Asia) NSCLC (w/ HER2 exon 19 or exon 20 mutation) 1L DESTINY-Lung04	(JP/US/EU/Asia) PD-L1 positive TNBC 1L (mono or durvalumab combo) TROPION-Breast05			
(US/EU/Asia) solid tumors (saruparib combo) PETRA	(JP/US) ESCC, CRPC, squamous NSCLC, SCLC, etc. IDeate-PanTumor01	(JP/US/EU/Asia) solid tumors, 2L+ REJOICE-Ovarian01	(JP/US/EU/Asia) nonsquamous NSCLC (w/o AGA, pembrolizumab combo) 1L TROPION-Lung07	(JP/US/EU/Asia) EGFR mutated NSCLC 2L HERTHENA-Lung02			
(JP/US) solid tumors TROPION-PanTumor01	(JP/US/EU/Asia) in prep ES-SCLC, 1L IDeate-Lung03	(JP/US/EU/Asia) NSCLC (w/o AGA, pembrolizumab combo) 1L TROPION-Lung08	(JP/US/EU/Asia) in prep ES-SCLC, 2L+ IDeate-Lung02				
(CN) NSCLC, TNBC TROPION-PanTumor02	(JP/US) renal cell carcinoma, ovarian cancer						

■ ENHERTU® (T-DXd)
 ■ Dato-DXd
 ■ HER3-DXd
 ■ I-DXd
 ■ DS-6000 (R-DXd)

□ Project in oncology that is planned to be submitted for approval in some countries/regions based on the results of phase 2 trials

★ Breakthrough Designation (US) ★ Orphan drug designation (designated in at least one country/region among JP, US and EU)

- * 1 Adjuvant therapy for HER2 positive breast cancer patients with residual invasive disease following neoadjuvant therapy
- * 2 Adjuvant therapy for TNBC patients with residual invasive disease following neoadjuvant therapy
- * 3 HR+, HER2 low or negative BC

AGA: actionable genomic alterations, BC: breast cancer, CRC: colorectal cancer, CRPC: castration-resistant prostate cancer, ESCC: esophageal squamous cell carcinoma, ES-SCLC: extensive stage-small cell lung cancer, GC: gastric cancer, NSCLC: non-small cell lung cancer, SCCHN: squamous cell carcinoma of head and neck, SCLC: small cell lung cancer, TNBC: triple negative breast cancer

Major R&D Pipeline: Next Wave

As of Apr 2024

Phase 1		Phase 2		Phase 3		Regulatory phase	
DS-1055 (JP/US) Anti-GARP antibody Solid tumors	DS-7011 (US) Anti-TLR7 antibody Systemic lupus erythematosus	Valemetostat (EU) EZH1/2 inhibitor BCL		Pexidartinib (JP/Asia) CSF-1/KIT/FLT3 inhibitor Tenosynovial giant cell tumor		Valemetostat (JP) EZH1/2 inhibitor PTCL	 
DS-9606 (US/EU) Target undisclosed ADC Solid tumors	DS-2325 (EU) KLK5 inhibitor Netherton syndrome	DS-1001 (JP) Mutant IDH1 inhibitor Glioma		Esaxerenone (JP) MR blocker Diabetic nephropathy		Mirogabalin (CN) α2δ ligands Diabetic peripheral neuropathic pain	
DS-1103 Anti-SIRPα antibody HER2 expressing or mutant solid tumors, HER2 low BC		DS-1211 (US/EU) TNAP inhibitor Pseudoxanthoma elasticum		DS-5670 (JP) COVID-19 mRNA vaccine (mutant strain), COVID-19 (booster vaccination, 5 to 11 aged children)		VN-0102/JVC-001 (JP) Mixed measles-mumps-rubella vaccine	
DS-3939 Anti-TA-MUC1 ADC Solid tumors		VN-0200 (JP) RS virus vaccine RS virus infection		DS-5670 (JP) COVID-19 mRNA vaccine (mutant strain), COVID-19 (single dose, 12 years old and over)			
DS-1471 Anti-CD147 antibody Solid tumors							
Valemetostat EZH1/2 inhibitor, HER2+ GC (ENHERTU® combo) and NSQ NSCLC (Dato-DXd combo)							

 Oncology

 Specialty medicine

 Vaccine

 Project in oncology that is planned to be submitted for approval in some countries/regions based on the results of phase 2 trials

 SAKIGAKE Designation (JP)  Orphan drug designation (designated in at least one country/region among JP, US and EU)  Rare Pediatric Disease Designation (US)

 Fast Track Designation (US)

ALL: acute lymphoblastic leukemia, BCL: B cell lymphoma, LBCL: large B cell lymphoma, PTCL: peripheral T-cell lymphoma