

Innovation Review

Benefiting from our continued focus on innovation, Novartis has one of the industry's most innovative and inventive pipelines with ~150 projects in clinical development.

Selected Innovative Medicines approvals: US, EU and Japan in Q4

Product	Active ingredient/ Descriptor	Indication	Region
<i>Pluvicto</i>	lutetium (¹⁷⁷ Lu) vipivotide tetraxetan	Metastatic castration-resistant prostate cancer, post-taxane	EU – Dec

Selected Innovative Medicines projects awaiting regulatory decisions

Product	Indication	Completed submissions			News update
		US	EU	Japan	
<i>Cosentyx</i>	300mg auto-injector and pre-filled syringe	Q4 2022	Approved	Approved	– US resubmission
<i>Cosentyx</i>	Intravenous formulation for psoriatic arthritis (PsA), ankylosing spondylitis (AS), and non-radiographic axial SpA (nr-axSpA)	Q4 2022			
<i>Cosentyx</i>	Hidradenitis suppurativa	Q3 2022	Q2 2022		
<i>Jakavi</i>	Acute graft-versus-host disease (GvHD)		Approved	Q1 2021	– US filing by Incyte
	Chronic GvHD		Approved	Q1 2021	– US filing by Incyte
SEG101 (crizalizumab)	Sickle cell disease, pediatrics				– Results from the ongoing global Ph3 STAND study did not show superiority compared to placebo; health authorities have been informed
VDT482 (tislelizumab)	2L Esophageal cancer (ESCC)	Q3 2021	Q1 2022		– FDA deferred action pending completion of required inspections
	NSCLC		Q1 2022		

Selected Innovative Medicines pipeline projects

Compound/ product	Potential indication/ Disease area	First planned submissions	Current Phase	News update
<i>Aimovig</i>	Migraine, pediatrics	≥2026	3	
AVXS-101 (OAV101)	Spinal muscular atrophy (IT formulation)	2025	3	
<i>Beovu</i>	Diabetic retinopathy	2025	3	
CFZ533 (iscalimab)	Sjögren's syndrome	≥2026	2	
<i>Coartem</i>	Malaria, uncomplicated (<5 kg patients)	2024	3	– Submission will use the MAGHP procedure in Switzerland to facilitate rapid approval in developing countries
<i>Cosentyx</i>	Giant cell arteritis	2025	3	
	Lupus nephritis	≥2026	3	

Compound/ product	Potential indication/ Disease area	First planned submissions	Current Phase	News update
JDQ443	Non-small cell lung cancer, 2/3L	2024	3	
	Non-small cell lung cancer (combos)	≥2026	2	
KAE609 (cipargamin)	Malaria, uncomplicated	≥2026	2	
	Malaria, severe	≥2026	2	
KAF156 (ganaplacide)	Malaria, uncomplicated	≥2026	2	- FDA Orphan Drug designation - FDA Fast Track designation for the ganaplacide-containing combination therapy
<i>Kisqali</i> + endocrine therapy	Hormone receptor-positive (HR+)/human epidermal growth factor receptor 2-negative (HER2-) early breast cancer (adjuvant)	2023	3	
<i>Leqvio</i>	Secondary prevention of cardiovascular events in patients with elevated levels of LDL-C	≥2026	3	
LMI070 (branaplam)	Huntington's disease		2	- Program discontinued based on an overall assessment of potential benefit-risk from the Ph2b VIBRANT-HD study
LNA043	Osteoarthritis	≥2026	2	- FDA Fast Track designation
LNP023 (iptacopan)	Paroxysmal nocturnal hemoglobinuria	2023	3	- FDA, EU Orphan Drug designation - FDA Breakthrough Therapy designation - Ph3 APPLY-PNH full data presentation at ASH - Ph3 APPOINT-PNH trial met primary endpoint
	IgA nephropathy	2024	3	- EU Orphan Drug designation - Few months submission delay but readout confirmed for 2023 (Slightly slower recruitment than planned)
	C3 glomerulopathy	2024	3	- EU Orphan Drug designation - EU PRIME designation - FDA Rare Pediatric designation - China Breakthrough Therapy designation - Few months submission delay but readout confirmed for 2023 (Slightly slower recruitment than planned)
	Membranous nephropathy		2	- Program discontinued (uncompelling competitive profile)
	IC-MPGN	≥2026	3	- Ph3 start planned in H2 2023
	Atypical haemolytic uraemic syndrome	≥2026	3	- Recruitment slower than anticipated
LOU064 (remibrutinib)	Chronic spontaneous urticaria	2024	3	
	Multiple sclerosis	≥2026	3	
	Sjögren's syndrome	≥2026	2	
<i>Lutathera</i>	Gastroenteropancreatic neuroendocrine tumors, 1L in G2/3 tumors	2023	3	
¹⁷⁷ Lu-NeoB	Multiple solid tumors	≥2026	1	
LXE408	Visceral leishmaniasis	≥2026	2	
MBG453 (sabatolimab)	Myelodysplastic syndrome	2024	3	- FDA Fast Track designation - EU Orphan Drug designation
	Unfit acute myeloid leukemia	≥2026	2	
MIJ821 (onfasprodil)	Depression	≥2026	2	
NIS793	1L Pancreatic cancer	2025	3	- FDA Orphan Drug designation
<i>Piqray</i>	Triple negative breast cancer		3	- Project will be discontinued to prioritize other key programs in portfolio
	Human epidermal growth factor receptor 2-positive (HER2+) advanced breast cancer		3	- Project will be discontinued to prioritize other key programs in portfolio
	Ovarian cancer	2023	3	
<i>Pluvicto</i>	Metastatic castration-resistant prostate cancer pre-taxane	2023	3	- Ph3 PSMAfore trial met primary endpoint
	Metastatic hormone sensitive prostate cancer	2024	3	
PPY988 (GT005)	Geographic atrophy	≥2026	2	- Gyroscope acquisition

Compound/ product	Potential indication/ Disease area	First planned submissions	Current Phase	News update
QGE031 (ligelizumab)	Food allergy	≥2026	3	- Optimized clinical program strategy to maximize potential
SAF312 (libvatrep)	Chronic ocular surface pain	≥2026	2	
Scemblix	1L Chronic myeloid leukemia	2025	3	- Ph3 ASC4FIRST trial completed enrollment
TQJ230 (pelacarsen)	Secondary prevention of cardiovascular events in patients with elevated levels of lipoprotein(a)	2025	3	- FDA Fast Track designation - China Breakthrough Therapy designation
VAY736 (ianalumab)	Auto-immune hepatitis	≥2026	2	
	Sjögren's syndrome	≥2026	3	- FDA Fast Track designation
	Lupus nephritis	≥2026	3	
	Systemic lupus erythematosus	≥2026	2	
	1L Immune thrombocytopenia	≥2026	3	- Ph3 study VAYHIT1 initiating
	2L Immune thrombocytopenia	≥2026	3	- Ph3 study VAYHIT2 initiating
	warm Autoimmune hemolytic anemia	≥2026	3	- Ph3 study VAYHIA initiated
VDT482 (tislelizumab)	1L Nasopharyngeal carcinoma	2023	3	- FDA Orphan designation
	1L Gastric cancer	2023	3	
	1L ESCC	2023	3	
	Localized ESCC	2024	3	- Protocol amendment
	1L Hepatocellular carcinoma	2023	3	
	1L Small cell lung cancer	2024	3	
	1L Urothelial cell carcinoma	≥2026	3	
	Adj/Neo adj. NSCLC	≥2026	3	
VPM087 (gevokizumab)	Colorectal cancer, 1L	≥2026	1	
Xolair	Food allergy	2023	3	
YTB323	1L High-risk large B-cell lymphoma	≥2026	2	- Development plan update
XXB750	Hypertension	≥2026	2	- Ph2b initiated

Selected Sandoz approvals and pipeline projects

Project/ Compound	Potential indication/ Disease area	News update
GP2411 (denosumab)	Osteoporosis (same as originator)	- In Ph3
SOK583 (afibercept)	Ophthalmology (same as originator)	- In Ph3
Insulin glargine, lispro, aspart	Diabetes	- Collaboration with Gan & Lee
Natalizumab	Multiple sclerosis and Crohn's disease	- Collaboration Polpharma Biologics - In registration
Trastuzumab	HER2-positive cancer tumors	- Collaboration EirGenix - In registration
Bevacizumab	Solid tumors	- Collaboration Bio-Thera Solutions - In registration