

Compounds in development

The following table provides an overview of key projects currently in the Confirmatory Development stage, and may also describe certain projects in the Early Development stage. Projects typically enter Confirmatory Development and become the responsibility of our Development organizational unit during Phase II testing. (For more information about our drug development program, see “—Research and development—Development program.”) Projects are listed in alphabetical order by compound code, or by product name where applicable. Included are projects seeking to develop potential uses of new molecular entities as well as potential additional indications or new formulations for already marketed products. The table below, entitled “Projects removed from the development table since 2024,” highlights changes to the table entitled “Selected development projects” from the previous year.

The year that each project entered the current phase of development refers to the year of the first patient’s first visit in the first clinical trial of that phase. For projects in Phase II, the year generally refers to the first patient’s first visit in the first trial in Confirmatory Development. In some cases, the first patient’s first visit in a Phase II trial can occur before the Confirmatory Development stage.

A reference to a project being in registration means that an application has been submitted to a health authority for marketing approval. Compounds and new indications in development are subject to required regulatory approvals, and, in certain instances, contractual limitations. These compounds and indications are in various stages of development throughout the world. It may not be possible to obtain regulatory approval for any or all of the new compounds and new indications referred to in the Form 20-F in any country or in every country. See “—Regulation” for more information on the approval process.

Selected development projects

Compound/ product	Common name	Mechanism of action	Potential indication	Category	Formulation/ route of administration	Year project entered current development phase	Planned filing dates/current phase
AAA817	actinium (²²⁵ Ac)- vipivotidium tetraxetan	Radioligand therapy targeting PSMA	Post-Lu metastatic castration-resistant prostate cancer ¹	Oncology	Intravenous infusion	2025	2028/III
			Metastatic castration-resistant prostate cancer, 1 st line ¹	Oncology	Intravenous infusion	2025	≥2029/III
Cosentyx	secukinumab	IL-17A inhibitor	Polymyalgia rheumatica	Immunology	Subcutaneous injection	2023	2026/III
DAK539	pelabresib	BET inhibitor	Myelofibrosis	Oncology	Oral	2024	2026/III
DII235	TBD	siRNA targeting Lp(a) mRNA	Risk reduction in cardiovascular disease w elevated Lp(a) ¹	Cardiovascular, Renal and Metabolic	Subcutaneous injection	2025	≥2029/II
Fabhalta (LNP023)	iptacopan	CFB inhibitor	IC-MPGN	Cardiovascular, Renal and Metabolic	Oral	2023	≥2029/III
			Atypical hemolytic uremic syndrome	Oncology	Oral	2021	≥2029/III
			Myasthenia gravis	Neuroscience	Oral	2024	2027/III
FUB523	zigakibart	Anti-APRIL monoclonal antibody	IgA nephropathy	Cardiovascular, Renal and Metabolic	Subcutaneous injection	2023	2027/III
GHZ339	TBD	TBD	Atopic dermatitis ¹	Immunology	Subcutaneous injection	2025	≥2029/II
JSB462	luxdegalu- tamide	Androgen receptor protein degradation	Prostate cancer ¹	Oncology	Oral	2025	≥2029/II
KAE609	cipargamin	PfATP4 inhibitor	Malaria, uncomplicated	Global Health	Oral	2017	≥2029/II
			Malaria, severe	Global Health	Intravenous infusion	2022	≥2029/II
Kesimpta	ofatumumab	Anti-CD20	Multiple sclerosis ¹	Neuroscience	Subcutaneous injection	2025	2027/III
KLU156	ganaplacide + lumefantrine	Non-artemisinin plasmodium falciparum inhibitor	Malaria, uncomplicated	Global Health	Oral	2024	2026/III
Leqvio	inclisiran	siRNA (regulation of LDL-C)	Secondary prevention of cardiovascular events in patients with elevated levels of LDL-C	Cardiovascular, Renal and Metabolic	Subcutaneous injection	2018	2027/III
			Primary prevention cardiovascular risk reduction	Cardiovascular, Renal and Metabolic	Subcutaneous injection	2023	≥2029/III

¹ Project added to selected development projects table in 2025 – entered Confirmatory Development

Item 4. Information on the Company

Compound/ product	Common name	Mechanism of action	Potential indication	Category	Formulation/ route of administration	Year project entered current development phase	Planned filing dates/current phase
LOU064	remibrutinib	BTK inhibitor	Chronic inducible urticaria	Immunology	Oral	2023	Registration
			Food allergy ¹	Immunology	Oral	2022	≥2029/II
			Multiple sclerosis	Neuroscience	Oral	2021	2027/III
			Myasthenia gravis	Neuroscience	Oral	2024	2028/III
			Hidradenitis suppurativa, Immunology ¹	Immunology	Oral	2025	2028/III
			Multiple sclerosis, secondary progressive ¹	Neuroscience	Oral	2025	≥2029/III
<i>Lutathera</i>	lutetium Lu 177 dotatate/ lutetium (¹⁷⁷ Lu) oxodotreotide	Radioligand therapy targeting SSTR	Gastroenteropancreatic neuroendocrine tumors ¹	Oncology	Intravenous infusion	2025	2028/III
LTP001	TBD	SMURF1 inhibitor	Pulmonary arterial hypertension ¹	Cardiovascular, Renal and Metabolic	Oral	2025	≥2029/II
LXE408	TBD	Proteasome inhibitor	Visceral leishmaniasis	Global Health	Oral	2022	≥2029/II
MAA868 ²	abelacimab	F11 inhibitor	Stroke prevention in atrial fibrillation	Cardiovascular, Renal and Metabolic	Subcutaneous injection	2025	2028/III
PAC001 ³	pacibekitug	Anti-IL-6 mAb	Atherosclerotic cardiovascular disease	Cardiovascular, Renal and Metabolic	Subcutaneous injection	2025	≥2029/II
<i>Pluvicto</i>	lutetium Lu 177 vipivotide tetraxetan/ lutetium (¹⁷⁷ Lu) vipivotide tetraxetan	Radioligand therapy targeting PSMA	Metastatic hormone-sensitive prostate cancer	Oncology	Intravenous infusion	2025	Registration
			Oligometastatic prostate cancer	Oncology	Intravenous infusion	2024	≥2029/III
QCZ484	TBD	TBD	Hypertension ¹	Cardiovascular, Renal and Metabolic	Subcutaneous injection	2025	≥2029/II
TQJ230	pelacarsen	ASO targeting lipoprotein(a)	Secondary prevention of cardiovascular events in patients with elevated levels of lipoprotein(a)	Cardiovascular, Renal and Metabolic	Subcutaneous injection	2019	2026/III
VAY736	ianalumab	BAFF-R inhibitor	Lupus nephritis	Immunology	Subcutaneous injection	2022	2028/III
			Sjögren's syndrome	Immunology	Subcutaneous injection	2022	2026/III
			Systemic lupus erythematosus	Immunology	Subcutaneous injection	2023	2028/III
			Systemic sclerosis	Immunology	Subcutaneous injection	2024	2028/II
			Immune thrombocytopenia, 1 st line	Oncology	Intravenous infusion	2023	2027/III
			Immune thrombocytopenia, 2 nd line	Oncology	Intravenous infusion	2023	2027/III
			Warm autoimmune hemolytic anemia (wAIHA)	Oncology	Intravenous infusion	2022	2027/III
VHB937	TBD	TREM2 stabilizer and activator	Alzheimer's disease ¹	Neuroscience	Intravenous infusion	2025	≥2029/II
			Amyotrophic lateral sclerosis ¹	Neuroscience	Intravenous infusion	2025	≥2029/II
<i>Vijoice</i>	alpelisib	PI3K-alpha inhibitor	Lymphatic malformations	Oncology	Oral	2023	≥2029/III
YTB323	rapcabtagene CD19 CAR-T autoleucel		Severe refractory lupus nephritis/ systemic lupus erythematosus	Immunology	Intravenous infusion	2023	2028/II
			High-risk large B-cell lymphoma, 1 st line	Oncology	Intravenous infusion	2023	≥2029/II
			Systemic sclerosis	Immunology	Intravenous infusion	2024	≥2029/II
			Myositis	Immunology	Intravenous infusion	2024	≥2029/II
			ANCA associated vasculitis ¹	Immunology	Intravenous infusion	2025	≥2029/II

¹ Project added to selected development projects table in 2025 – entered Confirmatory Development

² Entered Confirmatory Development following the acquisition of Anthos Therapeutics in 2025

³ Entered Confirmatory Development following the acquisition of Tourmaline Bio in 2025

Projects removed from the development table since 2024

Compound/product	Potential indication	Change	Reason
<i>Coartem</i>	Malaria (<5 kg patients)	Commercialized	
<i>Beovu</i>	Diabetic retinopathy	Commercialized	
<i>Fabhalta</i>	C3 glomerulopathy	Commercialized	
<i>Itivisma</i>	Spinal muscular atrophy (IT formulation)	Commercialized	
<i>Pluvicto</i>	Metastatic castration-resistant prostate cancer, pre-taxane	Commercialized	
<i>Rhapsido</i>	Chronic spontaneous urticaria	Commercialized	
<i>Vanrafia</i>	IgA nephropathy	Commercialized	
<i>Cosentyx</i>	Giant cell arteritis	Removed	Development discontinued

Principal markets

Novartis sells products in approximately 120 countries worldwide. Net sales are primarily concentrated in the US and Europe. The following table sets forth aggregate net sales by region for each of the last three years:

	2025 net sales		2024 net sales		2023 net sales	
	USD millions	%	USD millions	%	USD millions	%
United States	23 331	43	21 146	42	17 959	40
Europe	16 729	31	15 557	31	14 997	33
Asia, Africa, Australasia	10 797	20	10 021	20	9 308	20
Canada and Latin America	3 675	6	3 593	7	3 176	7
Total	54 532	100	50 317	100	45 440	100
Of which in established markets ¹	40 555	74	37 371	74	33 725	74
Of which in emerging growth markets ¹	13 977	26	12 946	26	11 715	26

¹ Emerging growth markets comprise all markets other than the established markets of the US, Canada, Western Europe, Japan, Australia and New Zealand. Novartis definition of Western Europe includes Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, The Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, and the United Kingdom.

Many of our products are used for chronic conditions that require patients to continue dosing of the product over long periods of time, ranging from months to years. However, certain of our marketed products and development projects, such as cell and gene therapies, are administered only once. Net sales of the vast majority of our products are not subject to material changes in seasonal demand.

Production

Our primary goal is to ensure the uninterrupted and timely supply of medicines that meet all product specifications and quality standards, and that are manufactured in the most cost-effective and sustainable manner. The manufacturing of our products is highly regulated by governmental health authorities around the world, including the FDA and the EMA. In addition to regulatory requirements, many of our products involve technically complex manufacturing processes or require highly specialized raw materials.

We manufacture our products across the following technologies at facilities worldwide: chemistry, biopharmaceuticals, cell and gene therapy, xRNA therapy and radioligand therapy (see also “—Item 4.D Property, plants and equipment”). In addition, we generate contract manufacturing sales from chemistry, biopharmaceuticals, xRNA, and cell and gene therapy, including fill and finish activities, which we include under “established brands” in our consolidated financial statements (see “Item 18.

Financial Statements—Note 4. Revenues and geographic information”).

In our manufacturing network, we maintain state-of-the-art processes, with quality as a priority, and require our suppliers to adhere to the same high standards we expect from our own people and processes. These processes include chemical and biological syntheses; radioisotope handling; sterile processing in the area of formulation and delivery; CAR-T cell processing and gene modification; and packaging. We are continually working to improve our existing manufacturing processes, develop new and innovative technologies, and review and adapt our manufacturing network to maintain quality in our manufacturing processes and supply of products to customers and patients.

We produce raw materials for manufacturing in-house or purchase them from third-party suppliers. Where possible, we maintain multiple supply sources so that the business is not dependent on a single or limited number of suppliers. However, our ability to do so may at times be limited by regulatory or other requirements. We monitor market developments that could have an adverse effect on the supply of essential materials. Our suppliers of raw materials are required to comply with applicable regulations and Novartis quality standards.

Because the manufacturing of our products is complex and highly regulated by governmental health authorities and other regulators, uninterrupted supply cannot be guaranteed. If we or our third-party suppliers fail to comply with applicable regulations, there could be a product recall or other disruption to our production