# Innovation Review

Benefiting from our continued focus on innovation, Novartis has one of the industry's most innovative and inventive pipelines with more than 160 projects in clinical development.

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

| Product | Active ingredient/ Descriptor | Indication | Region |
|---|---|---|---|
| *Scemblix* | asciminib | 3L Chronic myeloid leukemia | US – Oct |
| *Cosentyx* | secukinumab | JPsA & ERA | US – Dec |
| *Leqvio* | inclisiran | Hyperlipidemia | US – Dec |

## Selected Innovative Medicines projects awaiting regulatory decisions

| | | Completed submissions | | | |
|---|---|---|---|---|---|
| **Product** | **Indication** | **US** | **EU** | **Japan** | **News update** |
| *Cosentyx* | JPsA & ERA | Approved | Q2 2021 | | |
| *Cosentyx* | *Cosentyx* 300mg auto-injector and pre-filled syringe | Q4 2020 | Approved | Q3 2021 | – CRL issued by FDA |
| *Jakavi* | Acute graft-versus-host disease (GvHD) | | Q1 2021 | Q1 2021 | – US filing by Incyte |
| | Chronic GvHD | | Q1 2021 | Q1 2021 | – US filing by Incyte |
| ABL001 (asciminib) | 3L Chronic myeloid leukemia | Approved | Q2 2021 | Q3 2021 | |
| *Beovu* | Diabetic macular edema | Q3 2021 | Q3 2021 | Q3 2021 | |
| $^{177}$Lu-PSMA-617 | Metastatic castration-resistant prostate cancer, post-taxane | Q3 2021 | Q4 2021 | | – FDA priority review |
| VDT482 (tislelizumab) | 2L Esophageal cancer (ESCC) | Q3 2021 | | | – BLA submitted by BeiGene to FDA |
| *Kymriah* | Relapsed/refractory follicular lymphoma | Q3 2021 | Q3 2021 | Q4 2021 | – FDA priority review granted |
| BYL719 (alpelisib) | PIK3CA-related overgrowth spectrum | Q4 2021 | | | – US filing based on RWE data<br>– FDA priority review granted |

## Selected Innovative Medicines pipeline projects

| Compound/ product | Potential indication/ Disease area | First planned submissions | Current Phase | News update |
|---|---|---|---|---|
| ABL001 (asciminib) | 1L Chronic myeloid leukemia | 2025 | 3 | |
| ACZ885 (canakinumab) | Adjuvant NSCLC | 2023 | 3 | – Enrollment completed |
| *Aimovig* | Migraine, pediatrics | ≥2026 | 3 | |
| AVXS-101 (OAV101) | Spinal muscular atrophy (IT formulation) | 2025 | 3 | –Pivotal confirmatory study initiating |
| *Beovu* | Diabetic retinopathy | 2025 | 3 | |
| BYL719 (alpelisib) | Triple negative breast cancer | 2023 | 3 | |
| | Human epidermal growth factor receptor 2-positive (HER2+) advanced breast cancer | 2025 | 3 | |
| | Ovarian cancer | 2023 | 3 | |
| CEE321 | Atopic dermatitis | | 1 | – Program discontinued unfavorable benefit/risk profile |
| CFZ533 (iscalimab) | Liver transplantation | ≥2026 | 2 | |
| | Sjögren's syndrome | ≥2026 | 2 | |
| *Coartem* | Malaria, uncomplicated (<5 kg patients) | 2024 | 3 | – Submission planned in Switzerland |

| Compound/ product | Potential indication/ Disease area | First planned submissions | Current Phase | News update |
|---|---|---|---|---|
| *Cosentyx* | Ankylosing spondylitis head-to-head study versus Sandoz biosimilar *Hyrimoz* (adalimumab) | 2022 | 3 | |
| | Hidradenitis suppurativa | 2022 | 3 | |
| | Giant cell arteritis | 2024 | 3 | |
| | Lichen planus | 2025 | 2 | |
| | Lupus nephritis | ≥2026 | 3 | |
| | Psoriatic arthritis (IV formulation) | 2022 | 3 | |
| | Ankylosing spondylitis (IV formulation) | 2023 | 3 | |
| CPK850 | Retinitis pigmentosa | ≥2026 | 2 | |
| CSJ117 | Asthma | ≥2026 | 2 | |
| JDQ443 | Non-small cell lung cancer, 2/3L | 2024 | 3 | – Ph3 to be initiated in H2 2022 |
| | Non-small cell lung cancer (combos) | ≥2026 | 2 | |
| KAE609 (cipargamin) | Malaria, uncomplicated | ≥2026 | 2 | |
| | Malaria, severe | ≥2026 | 2 | |
| KAF156 (ganaplacide) | Malaria, uncomplicated | ≥2026 | 2 | |
| *Kisqali* + endocrine therapy | Hormone receptor-positive (HR+)/human epidermal growth factor receptor 2-negative (HER2-) early breast cancer (adjuvant) | 2023 | 3 | |
| *Leqvio* | Secondary prevention of cardiovascular events in patients with elevated levels of LDL-C | ≥2026 | 3 | – Ph3 VICTORION-2P initiated |
| LJN452 (tropifexor + licogliflozin) | Nonalcoholic steatohepatitis | ≥2026 | 2 | |
| LMI070 (branaplam) | Huntington's disease | ≥2026 | 2 | – FDA Orphan Drug designation<br>– FDA Fast Track designation granted |
| LNA043 | Osteoarthritis | ≥2026 | 2 | – FDA Fast Track designation |
| LNP023 (iptacopan) | Paroxysmal nocturnal hemoglobinuria | 2023 | 3 | – FDA, EU Orphan Drug designation<br>– FDA Breakthrough Therapy designation |
| | IgA nephropathy | 2023 | 3 | – EU Orphan Drug designation |
| | C3 glomerulopathy | 2023 | 3 | – EU Orphan Drug designation<br>– EU PRIME designation<br>– FDA Rare Pediatric designation |
| | Membranous nephropathy | ≥2026 | 2 | |
| | Atypical haemolytic uraemic syndrome | 2025 | 3 | |
| LOU064 (remibrutinib) | Chronic spontaneous urticaria | 2024 | 3 | – Ph3 initiated |
| | Multiple sclerosis | 2025 | 3 | – Ph3 initiated |
| | Sjögren's syndrome | ≥2026 | 2 | |
| *Lutathera* | Gastroenteropancreatic neuroendocrine tumors, 1st line in G2/3 tumors | 2023 | 3 | |
| $^{177}$Lu-PSMA-617 | Metastatic castration-resistant prostate cancer pre-taxane | 2023 | 3 | |
| | Metastatic hormone sensitive prostate cancer | 2024 | 3 | |
| $^{177}$Lu-NeoB | Multiple solid tumors | ≥2026 | 1 | |
| LXE408 | Visceral leishmaniasis | ≥2026 | 2 | |
| MBG453 (sabatolimab) | Myelodysplastic syndrome | 2022/2023 | 3 | – FDA Fast Track designation<br>– EU Orphan Drug designation |
| | Unfit acute myeloid leukemia | 2024 | 2 | |
| MIJ821 | Depression | ≥2026 | 2 | |
| NIS793 | 1L Pancreatic cancer | 2025 | 3 | – FDA Orphan Drug designation |

| Compound/ product | Potential indication/ Disease area | First planned submissions | Current Phase | News update |
|---|---|---|---|---|
| QBW251 (icenticaftor) | Chronic obstructive pulmonary disease | 2025 | 2 | |
| QGE031 (ligelizumab) | Chronic spontaneous urticaria | TBD | 3 | – FDA Breakthrough Therapy designation<br>– Ligelizumab demonstrated superiority compared with placebo PEARL 1 and PEARL 2 trials, but not versus omalizumab further evaluating PEARL data |
| | Chronic inducible urticaria | 2025 | 3 | – Ph3 initiated |
| | Food allergy | 2025 | 3 | – Ph3 initiated |
| SAF312 (libvatrep) | Chronic ocular surface pain | ≥2026 | 2 | |
| SKO136 (ensovibep) | Corona virus infection | 2022 | 2 | – Positive topline data from Ph2 |
| TQJ230 (pelacarsen) | Secondary prevention of cardiovascular events in patients with elevated levels of lipoprotein(a) | 2025 | 3 | – Enrollment ongoing<br>– FDA Fast Track designation<br>– China Breakthrough Therapy designation |
| UNR844 | Presbyopia | 2024 | 2 | |
| VAY736 (ianalumab) | Auto-immune hepatitis | ≥2026 | 2 | |
| | Sjögren's syndrome | ≥2026 | 2 | – FDA Fast Track designation |
| VDT482 (tislelizumab) | NSCLC | 2022 | 3 | |
| | 1L Nasopharyngeal carcinoma | 2022 | 3 | |
| | 1L Gastric cancer | 2023 | 3 | |
| | 1L ESCC | 2023 | 3 | |
| | Localized ESCC | 2023 | 3 | |
| | 1L Hepatocellular carcinoma | 2023 | 3 | |
| | 1L Small cell lung cancer | 2024 | 3 | |
| | 1L Bladder urothelial cell carcinoma | 2024 | 3 | |
| VPM087 (gevokizumab) | Colorectal cancer, 1st line | ≥2026 | 1 | |
| *Xolair* | Food allergy | 2023 | 3 | |
| YTB323 | 2L Diffuse large B-cell lymphoma | 2024 | 3 | – Ph3 to be initiated in 2022 |

## Selected Sandoz approvals and pipeline projects

| Project/ Compound | Potential indication/ Disease area | News update |
|---|---|---|
| GP2411 (denosumab) | Osteoporosis (same as originator) | – In Ph3 |
| SOK583 (aflibercept) | 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 |
| Trastuzumab | HER2-positive cancer tumors | – Collaboration EirGenix |
| Bevacizumab | Solid tumors | – Bio-Thera Solutions |