

Compassionate Use Program (CUP)

Approved by The Norwegian Medicines Agency

Active substance	Indication	Date of approval	Responsible for the CUP
CUP available for patients			
Pevonedistat (TAK-924/MLN4924) 10 mg/ml concentrate for solution for iv infusion	Higher risk myelodysplastic syndromes (HR-MDS), or low blast acute myelogenous leukemia (LB-AML)	25 th Aug, 2020	Takeda Contact person: Cathrine Roppen Telephone: +47 959 99 253 E-mail: cathrine.roppen@takeda.com
Risdiplam (RO7034067) 60mg, mixture	Spinal muscular atrophy (SMA)	8 th May, 2020	Roche Norge AS Contact person: Merethe Brevik-Andersen, Cand.pharm., PhD Telephone: +47 99 64 05 15 E-mail: merethe.brevik-andersen@roche.com www.roche.no
Nimorazole tablets, 500 mg	Squamous cell Cancer of the Head and Neck (SCCHN)	1 st December, 2016	Azanta Danmark A/S Contact person: Janne Hartmann Telephone: +45 7025 9545 E-mail: jah@azanta.com
Zanamivir 10mg/ml Infusion bag.	Hospitalised patients severely ill with influenza infection	25 th February, 2011	GlaxoSmithKline Research & Development Limited, United Kingdom Telephone nr.: +44 0800 2468 3579 free phone or +44(0)2089904855 E-mail: GSKClinicalSupportHD@gsk.com
CUP no longer available for new patients			
Polatuzumabvedotin, 140mg concentrate for infusjon	Relapsed or refractory Diffuse Large B-Cell Lymphoma (r/r DLBCL)	1 st February, 2019	Roche Norge AS
Entrectinib capsules, 100mg, 200mg	Solid Tumors harboring a NTRK Gene Fusion or Patients with Non-Small Cell Lung Cancer (NSCLC) harboring a ROS1 Gene Fusion (AG40852)	7 th March, 2019	Roche Norge AS

Quizartinib tablets, 20mg and 30mg	Relapsed or Refractory Acute Myeloid Leukemia (AML) with FLT3-ITD Mutations	12 th March, 2019	Daiichi Sankyo Inc.
Lorlatinib tablets, 5mg, 25mg, and 100mg acetate solvate tablets or as 25mg or 50mg free base tablets	Advanced non-small cell lung cancer (NSCLC) with an ALK or ROS1 gene rearrangement	5 th September, 2018	Pfizer Norge AS
Brigatinib tablets, 90 mg and 180 mg	ALK positive Non-Small Cell Lung Cancer	20 th April, 2018	Takeda Pharmaceuticals AS,
Emicizumab, 150 mg/1 ml	Hemophilia A and FVIII Inhibitors	1 st November, 2017	Roche Norge AS
Ocrelizumab, 300 mg intravenous infusion	Primary Progressive Multiple Sclerosis (PPMS)	7 th June, 2017	Roche Norge AS
Pembrolizumab, intravenous infusjon 2 mg/kg	Metastatic Melanoma	9 th September, 2014	MSD Norge AS
Ibrutinib capsules, 140mg	Relapsed or Refractory Chronic Lymphocytic Leukaemia/Small Lymphocytic Lymphoma with Deletion 17p	6 th May, 2014	Janssen-Cilag AB
Cobimetinib (GDC-0973) 20 mg	advanced/metastatic BRAF ^{V600} mutation-positive melanoma	25 th June, 2015	Roche Norge AS
Combination regimen of trametinib and dabrafenib. Dabrafenib 150 mg Trametinib 2 mg	BRAF activating mutation-positive metastatic melanoma	22 nd August, 2015	GlaxoSmithKline (GSK) AS, Oslo
Daclatasvir, 60 mg	Chronic hepatitis C	23 rd June, 2014	Bristol-Mayers Squibb AS
Boceprevir	Hepatitis C	5 th May, 2011	MSD
Abiratrone	Metastatic Advanced Prostate Cancer	19 th November, 2011	Jansen Cilag

Crizotinib (PF-02341066)	Cancer (Positive ALK-fusion)	13 th October, 2011	Pfizer
Aflibercept	Metastatic Colorectal Cancer (mCRC)	28th September, 2011	Sanofi