



29 May 2019
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Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 27 – 29 May 2019

Pre-authorisation: scientific advice and protocol assistance EMA centralised procedures

	1995 - 2018	2019	Overall total
Scientific Advice	3866	149	4015
Follow-up to Scientific Advice	1150	53	1203
Protocol Assistance	932	46	978
Follow-up to Protocol Assistance	477	21	498
EMA/EUnetHTA parallel consultation advice	139	11	150
Qualification of novel methodologies	126	4	130
	6689	284	6973

Outcome of the May 2019 CHMP meeting in relation to scientific advice procedures

Final scientific advice procedures

Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Chemical	Treatment of dementia		x					x	
Biological	Treatment of glycogen storage disease		x			x			
Advanced Therapy	Treatment of mantle cell lymphoma		x			x		x	
Advanced Therapy	Treatment of-synovial sarcoma				x			x	
Biological	Treatment of paroxysmal nocturnal haemoglobinuria				x		x	x	

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Chemical	Treatment of Niemann-Pick disease				x		x	x	x
Chemical	Prevention of invasive aspergillosis		x				x	x	
Biological	Treatment of idiopathic pulmonary fibrosis		x				x	x	x
Biological	Treatment of fibrodysplasia ossificans progressiva		x			x			
Chemical	Treatment of uraemic pruritus		x				x	x	
Chemical	Treatment of Alzheimer's disease	x						x	
Biological	Treatment of Alzheimer's disease	x						x	
Chemical	Treatment of vitiligo	x				x	x	x	
Biological	Treatment of lupus nephritis	x						x	
Advanced Therapy	Treatment of acute-on-chronic liver failure	x					x	x	
Advanced Therapy	Treatment of acute-on-chronic liver failure	x				x			
Biological	Application during assisted reproductive technologies				x			x	
Chemical	Entire development program for Idasanutlin (AML, PV, iNHL)	x				x			
Chemical	Treatment of chronic rhinosinusitis	x						x	
Biological	Treatment of renal cell carcinoma	x						x	
Biological	Treatment of uremic syndrome	x					x	x	
Chemical	Treatment of mantle cell lymphoma	x						x	
Biological	Treatment of neovascular macular degeneration, macular edema, diabetic macular edema, and diabetic retinopathy.				x		x		
Chemical	Treatment of menopause				x		x	x	
Biological	Treatment of breast cancer				x			x	
Biological	Treatment of rheumatoid arthritis, juvenile idiopathic arthritis, idiopathic polyarthritis, giant cell arteritis				x		x	x	
Chemical	Treatment of vulvovaginal candidiasis	x					x		
Biological	Treatment of Staphylococcus aureus endocarditis and bacteraemia	x					x		
Chemical	Treatment of myasthenia gravis	x					x	x	
Biological	Treatment of glomerulosclerosis				x		x		
Biological	Treatment of diabetic macular edema	x					x	x	x
Chemical	Reduction/prevention of myocardial necrosis.	x					x	x	
Biological	Treatment and control of prostate cancer	x						x	
Advanced Therapy	Treatment of solid tumors	x					x	x	
Chemical	Treatment of cystic fibrosis	x					x	x	

Chemical	Treatment of diabetic macular edema	x				x	x	x	
Chemical	Treatment of HIV-1 infection	x					x	x	
Chemical	Treatment of transthyretin-mediated amyloidosis	x					x	x	
Biological	Treatment of myasthenia gravis	x					x	x	
Biological	Treatment of aplastic anaemia	x				x			
Advanced Therapy	Treatment of mtDNA mutation syndromes	x				x	x	x	
Chemical/Innovative product or therapy	Treatment of geographic atrophy secondary to AMD.	x					x	x	
Chemical	Treatment of hypoparathyroidism	x					x		
Chemical	Weight management	x					x		
Biological	Treatment of cervical cancer	x					x	x	
Chemical	Treatment of pulmonary arterial hypertension	x				x	x	x	
Biological	Reduction in the duration of neutropenia and the incidence of febrile neutropenia	x				x	x	x	
Chemical	Treatment of diabetic retinopathy	x					x	x	
Biological	Treatment of diabetic macular oedema and medulloblastoma	x				x	x	x	
Chemical	Treatment of knee osteoarthritis	x					x	x	
Biological	Treatment of diabetic macular edema	x				x	x	x	
Biological	Treatment of neovascular age-related macular degeneration	x				x	x	x	
Chemical	Treatment of diabetic kidney disease				x				x
Biomarker	Magnetic Resonance Imaging Proton Density Fat Fraction (MRI-PDFF)	x							x
Biomarker	Iron Corrected T1 (cT1)	x							x
Biological	Treatment of tuberculosis					x	x	x	x

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 34 Scientific Advice letters, 7 Protocol Assistance letters, 7 Follow-up Scientific Advice, 4 Follow-up Protocol Assistance, 2 Qualifications of novel methodologies and 2 EMA/EUnetHTA parallel consultation advices, were adopted at the 27 - 29 May 2019 CHMP meeting.

New requests for scientific advice procedures

The Committee accepted 72 new Requests for which the procedure started at the SAWP meeting held on 13 – 16 May 2019. The new requests are divided as follows: 42 Initial Scientific Advice, 13 Follow-up Scientific Advice, 8 Initial Protocol Assistance, 5 Follow-up Protocol Assistance, 1 Qualification of novel methodologies and 2 EMA/EUnetHTA parallel consultation advices.