



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

HCPWP feedback from CHMP

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An agency of the European Union





Summary

- CHMP opinions on medicines
 - New medicines June - September 2016
- HCP input provided in the context of CHMP activities



Positive recommendations on new medicines

- **12 positive recommendations on new medicines**

- 3 conditional marketing authorisation



- 3 orphan



- 10 pending EC decision

- **3 subject to additional monitoring**



- 1 with Educational material/programme for HCP



- **7 initiated / monitored (supervision) HCP**

- 9 subject to Restricted prescription

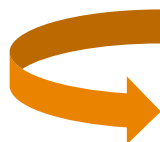




Positive recommendations on new medicines

Transplantation

Name	Active S	Indication
Zalmoxis	allogeneic T cells genetically modified with a retroviral vector encoding for a truncated form of the human low affinity nerve growth factor receptor (Δ LNFR) and the herpes simplex I virus thymidine kinase (HSV-TK Mut2)	Treatment in haploidentical haematopoietic stem cell transplantation



Educational material for healthcare professionals with detailed information on the risks, including graft-versus-host disease, and how to use the medicine correctly.

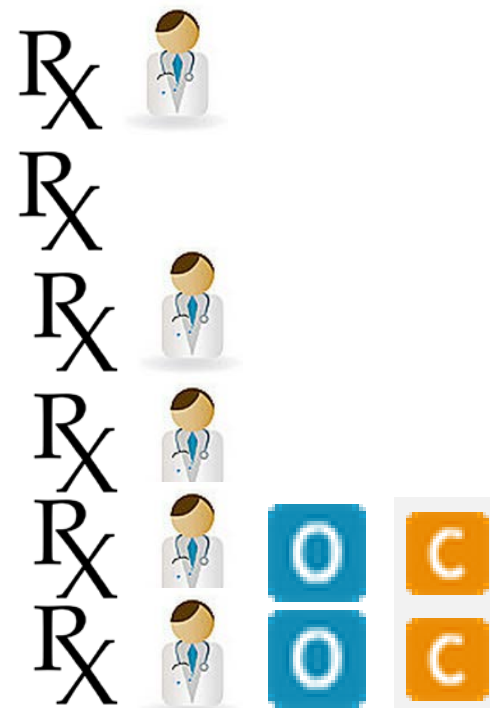
Registry of patients treated with Zalmoxis and monitorization of progress after treatment to study long-term safety and effectiveness of the medicine.



Positive recommendations on new medicines

Cancer

Name	Active S	Indication
Cabometyx	cabozantinib	Treatment of advanced renal cell carcinoma
Onivyde	irinotecan	Treatment of metastatic adenocarcinoma of the pancreas
Kisplyx	lenvatinib	In combination with everolimus for the treatment of unresectable advanced or metastatic renal cell carcinoma
Ibrance	palbociclib	Treatment of locally advanced or metastatic breast cancer
Lartruvo	olaratumab	Treatment of soft tissue sarcoma
Ninlaro	ixazomib	Treatment of multiple myeloma





Positive recommendations on new medicines

Neurodegenerative disorders

Name	Active S	Indication
Sialanar	glycopyrronium bromide	Symptomatic treatment of severe sialorrhoea (chronic pathological drooling) in children and adolescents aged 3 years and older with chronic neurological disorders



Diabetes

Name	Active S	Indication
Glyxambi	empagliflozin / linagliptin	Treatment of type 2 diabetes mellitus



Positive recommendations on new medicines

Name	Active S	Indication
Cinqaero	reslizumab	Treatment of severe eosinophilic asthma
Truberzi	eluxadoline	Treatment of irritable bowel syndrome with diarrhoea
Parsabiv	etelcalcetide	Treatment of secondary hyperparathyroidism.





Interaction between CHMP and HCP

Participation in Scientific Advisory Groups and ad-hoc Experts Groups

- **Contributing for decision on recommendations (Ninlaro and Sialanar)**