EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 24 - 26 April 2023

News 26/04/2023

Seven new medicines recommended for approval

EMA's human medicines committee (CHMP) recommended seven medicines for approval at its April 2023 meeting.

The CHMP recommended granting a marketing authorisation for **Arexvy** (recombinant, adjuvanted), the first vaccine for active immunisation to protect adults aged 60 years and older against lower respiratory tract disease caused by respiratory syncytial virus (RSV). RSV is a common respiratory virus that usually causes mild, cold-like symptoms that can be serious in vulnerable people, including older adults and those with lung or heart disease and diabetes. See more information in the news announcement in the grid below.

The Committee gave a positive opinion for **Camzyos** (mavacamten) for the treatment of symptomatic obstructive hypertrophic cardiomyopathy, a disease in which the heart muscle becomes thickened and can make it harder for the heart to pump blood.

A positive opinion was adopted for **Columvi*** (glofitamab) under conditional marketing authorisation for the treatment of diffuse large B-cell lymphoma, an aggressive type of non-Hodgkin lymphoma, a cancer of the lymphatic system that can arise in lymph nodes or outside of the lymphatic system.

Jaypirca* (pirtobrutinib) received a positive opinion under conditional marketing authorisation from the CHMP for the treatment of relapsed or refractory mantle cell lymphoma which develops when B-cells, a type of white blood cell that makes antibodies, become abnormal.

The CHMP gave a positive opinion for **Lytgobi*** (futibatinib) for the treatment of cholangiocarcinoma or bile duct cancer, a type of cancer that forms in the slender tubes that carry the digestive fluid.

The Committee recommended **Opfolda** (miglustat) for the treatment of glycogen storage disease type II (Pompe disease) in combination with cipaglucosidase alfa. Pompe disea rare genetic disorder in which the body is not able to break down glycogen, leading to

progressive build-up that causes a wide range of symptoms, including an enlarged heart, breathing difficulties and muscle weakness. This medicine was submitted as a hybrid application, which relies in part on pre-clinical and clinical data of an already authorised reference product and in part on results of new studies.

A positive opinion was adopted for **Sugammadex Piramal** (sugammadex), a generic medicine indicated for the treatment of the reversal of neuromuscular blockade induced by rocuronium or vecuronium in adults. Rocuronium and vecuronium are muscle relaxants used during some types of surgeries requiring general anaesthesia. Sugammadex is used to speed up the recovery from the effects of the muscle relaxant.

Recommendations on extensions of therapeutic indication for ten medicines

The Committee recommended 11 extensions of indication for medicines that are already authorised in the European Union (EU): **Adempas**, **Bimzelx** (includes two new indications), **Cosentyx**, **Opdivo**, **Orkambi**, **Revestive***, **Ronapreve**, **Spikevax**, **Vemlidy**, **Yervoy**.

More information on the extensions of indication for the COVID-19 treatment Ronapreve and the COVID-19 vaccine Spikevax is available below.

Withdrawals of applications

The application for marketing authorisation for the advanced therapy medicinal product **Lumevoq*** was withdrawn. The medicine was intended for the treatment of vision loss due to Leber hereditary optic neuropathy. A question-and-answer documents on the withdrawal for Lumevoq is available in the grid below.

The application for marketing authorisation for **Tidhesco*** was withdrawn. This medicine was intended for the treatment of acute myeloid leukaemia. Tidhesco was a duplicate of Tibsovo. Both applications received a positive opinion on 23 February 2023.

Other updates

Concluding the assessment of an application to extend the use of **Epidyolex*** (cannabidiol), the CHMP recommended that the medicine should continue to be administered only in conjunction with clobazam for adjunctive therapy of seizures associated with Lennox-Gastaut syndrome (LGS) or Dravet syndrome (DS) in patients two years of age and older. LSG and DS are severe forms of childhood epilepsy. A question-and-answer document on the update is available in the grid below.

The CHMP endorsed an update to the **Statement on the Interchangeability of Biosimilar medicines** in the EU to stress that healthcare professionals and patients should carefully consider the product information before the decision to interchange a biosimilar treatment. The updated statement and an expanded question-and-answer document including these revisions are available in the grid below.

COVID-19 updates

The Committee recommended granting an extension of indication for **Spikevax bivalent Original/Omicron BA.4-5** to include the use of this COVID-19 vaccine as a booster in children aged six to 11.

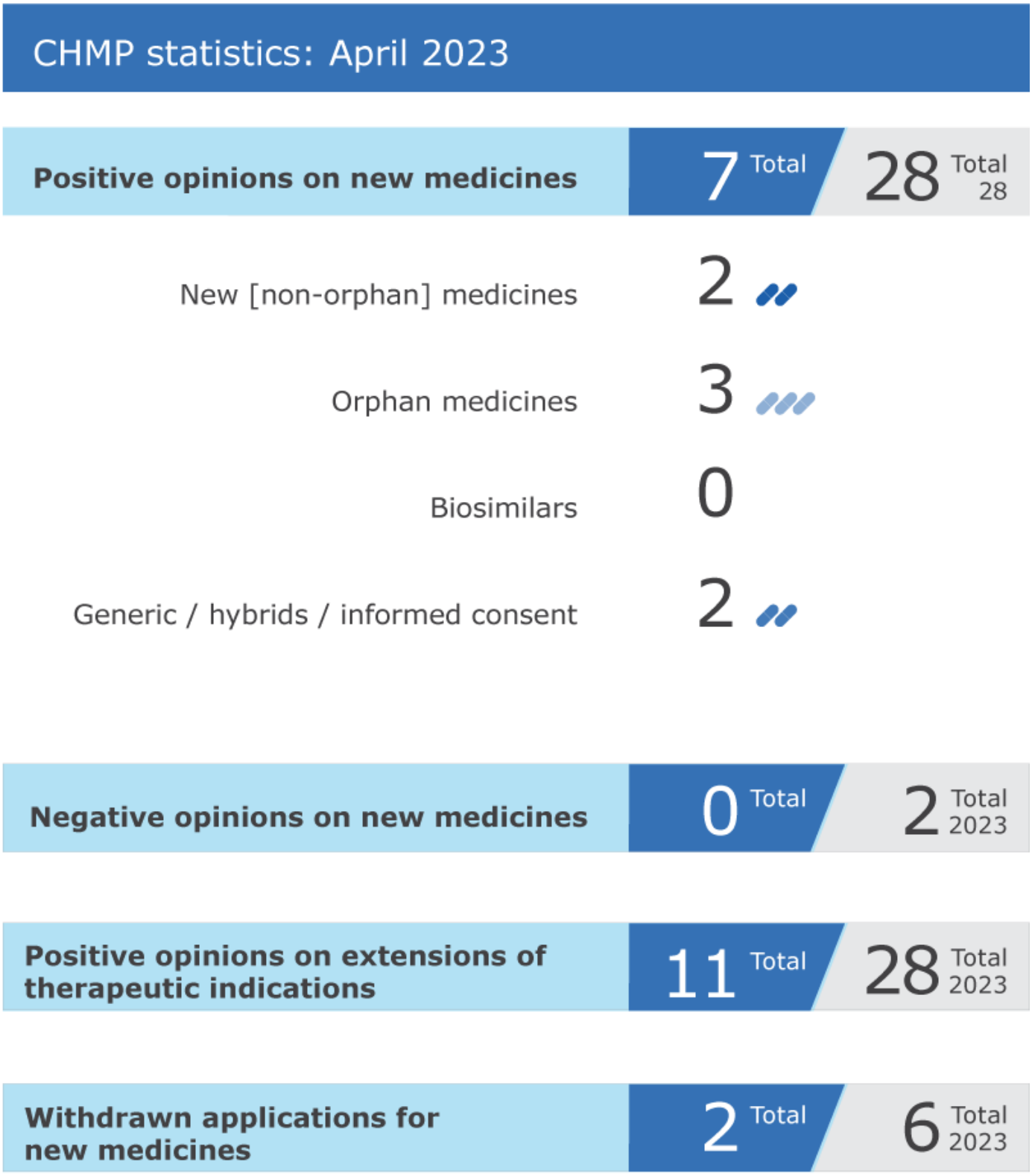
The CHMP also recommended an extension of indication for **Ronapreve** to include treatment of COVID-19 in hospitalised adults and adolescents aged 12 years and older weighing at least 40 kg who are receiving supplemental oxygen and have a negative SARS-CoV-2 antibody test.

Agenda and minutes

The agenda of the April 2023 CHMP meeting is published on EMA's website. Minutes of the March 2023 CHMP meeting will be published in the coming weeks.

CHMP statistics

Key figures from the April 2023 CHMP meeting are represented in the graphic below.



*This product was designated as an orphan medicine during its development. Orphan designations are reviewed by EMA's Committee for Orphan Medicinal Products (COMP) at the time of approval to determine whether the information available to date allows maintaining the medicine's orphan status and granting the medicine ten years of market exclusivity.

Positive recommendations on new medicines

Name of medicine	Arexvy

Common name	Recombinant, adjuvanted
Marketing-authorisation applicant	GlaxoSmithkline Biologicals S.A.
Therapeutic indication	Active immunisation for the prevention of lower respiratory tract disease (LRTD) caused by RSV (new active substance)
More information	Arexvy: Pending EC decision News: First vaccine to protect older adults from respiratory syncytial virus (RSV) infection (26/04/2023)

Name of medicine	Camzyos
INN	mavacamten
Marketing-authorisation applicant	Bristol-Myers Squibb Pharma EEIG
Therapeutic indication	Treatment of symptomatic obstructive hypertrophic cardiomyopathy
More information	Camzyos: Pending EC decision

Name of medicine	Columvi
INN	glofitamab
Marketing-authorisation applicant	Roche Registration GmbH
Therapeutic indication	Treatment of diffuse large B-cell lymphoma (new active substance)
More information	Columvi: Pending EC decision

Name of medicine	Jaypirca
INN	pirtobrutinib
Marketing-authorisation applicant	Eli Lilly Nederland B.V.
Therapeutic indication	

	Treatment of mantle cell lymphoma (MCL) (new active substance)
More information	Jaypirca: Pending EC decision

Name of medicine	Lytgobi
INN	futibatinib
Marketing-authorisation applicant	Taiho Pharma Netherlands B.V.
Therapeutic indication	Treatment of cholangiocarcinoma (new active substance)
More information	Lytgobi: Pending EC decision

Positive recommendation on new hybrid medicine

Name of medicine	Opfolda
INN	miglustat
Marketing-authorisation applicant	Amicus Therapeutics Europe Limited
Therapeutic indication	Treatment of glycogen storage disease type II (Pompe disease) in combination with cipaglucosidase alfa
More information	Opfolda: Pending EC decision

Positive recommendation on new generic medicine

Name of medicine	Sugammadex Piramal
INN	sugammadex
Marketing-authorisation applicant	Piramal Critical Care B.V.
Therapeutic indication	Reversal of neuromuscular blockade induced by rocuronium or vecuronium in adults (generic of Bridion)
More information	Sugammadex Piramal: Pending EC decision

Positive recommendations on extensions of indications

Name of medicine	Adempas
INN	riociguat
Marketing-authorisation holder	Bayer AG
More information	Adempas: Pending EC decision

Name of medicine	Bimzelx
INN	bimekizumab
Marketing-authorisation holder	UCB Pharma S.A.
More information	Bimzelx: Pending EC decision (II/0010)

Name of medicine	Bimzelx
INN	bimekizumab
Marketing-authorisation holder	UCB Pharma S.A.
More information	Bimzelx: Pending EC decision (II/0011)

Name of medicine	Cosentyx
INN	secukinumab
Marketing-authorisation holder	Novartis Europharm Limited
More information	Cosentyx: Pending EC decision

Name of medicine	Opdivo
INN	nivolumab

Marketing-authorisation holder	Bristol-Myers Squibb Pharma EEIG
More information	Opdivo: Pending EC decision

Name of medicine	Orkambi
INN	lumacaftor / ivacaftor
Marketing-authorisation holder	Vertex Pharmaceuticals (Ireland) Limited
More information	Orkambi: Pending EC decision

Name of medicine	Revestive
INN	teduglutide
Marketing-authorisation holder	Takeda Pharmaceuticals International AG Ireland Branch
More information	Revestive: Pending EC decision

Name of medicine	Ronapreve
INN	casirivimab / imdevimab
Marketing-authorisation holder	Roche Registration GmbH
More information	Ronapreve: Pending EC decision

Name of medicine	Spikevax
INN	elasomeran
Marketing-authorisation holder	Moderna Biotech Spain, S.L.
More information	Spikevax: Pending EC decision

Name of medicine	Vemlidy
INN	tenofovir alafenamide
Marketing-authorisation holder	Gilead Sciences Ireland UC
More information	Vemlidy: Pending EC decision

Name of medicine	Yervoy
INN	ipilimumab
Marketing-authorisation holder	Bristol-Myers Squibb Pharma EEIG
More information	Yervoy: Pending EC decision

Withdrawals of initial marketing authorisation applications

Name of medicine	Lumevoq
INN	lenadogene nolparvovec
Marketing-authorisation applicant	GenSight Biologics S.A.
More information	Lumevoq: Withdrawn application

Name of medicine	Tidhesco
INN	ivosidenib
Marketing-authorisation applicant	Les Laboratoires Servier
More information	This application was a duplicate of Tibsovo, for which a positive opinion was adopted on 23 February 2023

Other updates

Scientific advice and protocol assistance adopted during the CHMP meeting 24-26 April 2023 (PDF/241.37 KB) (new)

Adopted

First published: 26/04/2023
EMA/CHMP/SAWP/188869/2023

Statement on the scientific rationale supporting interchangeability of biosimilar medicines in the EU (PDF/167.41 KB) (updated)

First published: 19/09/2022
Last updated: 26/04/2023
EMA/627319/2022

Q&A on the Statement on the scientific rationale supporting interchangeability of biosimilar medicines in the EU (PDF/126.78 KB) (updated)

First published: 27/01/2023
Last updated: 26/04/2023
EMA/93740/2023 Rev. 1

Related content

- Adempas: EPAR
- Bimzelx: EPAR
- Cosentyx: EPAR
- Opdivo: EPAR
- Orkambi: EPAR
- Revestive: EPAR
- Ronapreve: EPAR
- Spikevax (previously COVID-19 Vaccine Moderna): EPAR
- Vemlidy: EPAR
- Yervoy: EPAR
- Ronapreve: Pending EC decision
- Camzyos: Pending EC decision
- Adempas: Pending EC decision
- Bimzelx: Pending EC decision
- Opfolda: Pending EC decision
- Yervoy: Withdrawn application
- Vemlidy: Pending EC decision
- Cosentyx: Pending EC decision
- Opdivo: Withdrawn application
- Arexvy: Pending EC decision

- Opdivo: Withdrawn application
- Lumevoq: Withdrawn application
- Adempas: Withdrawn application
- Bimzelx: Pending EC decision
- Orkambi: Pending EC decision
- Sugammadex Piramal: Pending EC decision
- Spikevax (previously COVID-19 Vaccine Moderna): Pending EC decision
- Yervoy: Pending EC decision
- Lytgobi: Pending EC decision
- Revestive: Pending EC decision
- Jaypirca: Pending EC decision
- Columvi: Pending EC decision
- Opdivo: Pending EC decision
- Opdivo: Withdrawn application
- Opdivo: Withdrawn application
- Tidhesco: Pending EC decision
- Yervoy: Paediatric investigation plan
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- Cosentyx: Paediatric investigation plan
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- Adempas: Paediatric investigation plan
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- Spikevax (previously COVID-19 Vaccine Moderna): Paediatric investigation plan
- Ronapreve: Paediatric investigation plan
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- Revestive: Orphan designation
- Lumevoq: Orphan designation
- Tidhesco: Orphan designation
- Lytgobi: Orphan designation
- Jaypirca: Orphan designation
- Columvi: Orphan designation
- Columvi: Orphan designation

Related content

- First vaccine to protect older adults from respiratory syncytial virus (RSV) infection (26/04/2023)
- COVID-19 vaccines
- Committee for Medicinal Products for Human Use (CHMP): 24-26 April 2023
- CHMP: Agendas, minutes and highlights

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