EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 12-15 December 2022

News 16/12/2022

Five new medicines recommended for approval

EMA's human medicines committee (CHMP) recommended five medicines for approval at its December 2022 meeting.

The CHMP recommended granting a conditional marketing authorisation for the advanced therapy medicinal product (ATMP) **Hemgenix*** (etranacogene dezaparvovec), the first gene therapy for the treatment of severe and moderately severe Haemophilia B. Haemophilia B is an inherited disorder characterised by an increased bleeding tendency due to a partial or complete deficiency in the activity of factor IX, a protein needed to produce blood clots to stop bleeding. Hemgenix was supported through EMA's PRIority MEdicines (PRIME) scheme, which provides early and enhanced scientific and regulatory support to medicines that have a particular potential to address patients' unmet medical needs. See more information in the news announcement in the grid below.

The committee adopted a positive opinion for **Imjudo*** (tremelimumab), to be used in combination with Imfinzi (durvalumab) for the treatment of adults with hepatocellular carcinoma, a type of liver cancer.

The committee adopted a positive opinion for **Tremelimumab AstraZeneca** (tremelimumab), for the treatment of metastatic non-small-cell lung cancer in combination with Imfinzi (durvalumab) and platinum-based chemotherapy.

The CHMP adopted a positive opinion for **Pombiliti*** (cipaglucosidase alfa) for the treatment of glycogen storage disease type II, also known as Pompe disease. This is a rare, often fatal genetic disorder that causes muscle weakness and disables the heart due to glycogen that builds up in the body cells and nerves.

A generic medicine, **Dimethyl fumarate Accord** (dimethyl fumarate), received a positive opinion for the treatment of multiple sclerosis, a chronic disease affecting the central nervous system. Dimethyl fumarate Accord is indicated for the treatment of adult and paediatric patients aged 13 years and older.

Negative opinion for one new medicine

The CHMP recommended the refusal of a marketing authorisation for **Omblastys** for the treatment of neuroblastoma, a rare type of cancer. For more information on this negative opinion, see the question-and-answer documents in the grid below.

Recommendations on extensions of therapeutic indication for 11 medicines

The committee recommended 12 extensions of indication for medicines that are already authorised in the
EU: **Adcirca**, **Dupixent**, **Edistride**, **Enhertu**, **Fintepla**, **Forxiga**, **Hemlibra**, **Imfinzi** (includes two new indications), **Kerendia**, **Spikevax** and **Triumeq**.

Withdrawals of applications

The application for marketing authorisation for **Imbarkyd*** was withdrawn. This medicine was intended for the treatment of chronic kidney disease caused by Alport syndrome in adults and children 12 years and above.

The application for extension of therapeutic indication for **Olumiant** for the treatment of COVID-19 was withdrawn.

Question-and-answer documents on the withdrawals are available in the grid below.

Conclusions of referrals

The CHMP completed reviews under Article 29(4), following disagreements among EU Member States regarding two medicines authorisations.

The committee concluded that the benefits of **Gelisia** outweigh its risks, and the marketing authorisation should be granted in the Netherlands and in the following EU Member States: France, Germany, Italy, Romania and Spain. Gelisia is an eye gel that is used to reduce pressure inside the eye in adults who have ocular hypertension (when the pressure in the eye is higher than normal) or open-angle glaucoma (a disease where the pressure in the eye rises because fluid cannot drain out of the eye).

The committee concluded that the benefits of **Rambis** outweigh its risks, and the marketing authorisation should be granted in Poland and in the other EU Member States where the company has applied for a marketing authorisation (Czechia and Slovakia). Rambis is a medicine for patients with certain long-term heart conditions and high blood pressure in whom these conditions are well controlled by a combination of two medicines called ramipril and bisoprolol.

For more information about these referrals, see the question-and-answer documents in the grid below.

COVID-19 update

The committee recommended to extend the use of original **Spikevax** vaccine and Spikevax bivalent Original/Omicron BA.1 as a booster dose in children aged 6 to 11 years.

The committee recommended converting the conditional marketing authorisation of the COVID-19 vaccine **Jcovden** to a standard marketing authorisation.

An overview of all the COVID-19 vaccines authorised in the EU is available on EMA's website.

Agenda and minutes

The agenda of the December 2022 CHMP meeting is published on EMA's website. Minutes of the November 2022 CHMP meeting will be published in the coming weeks.

CHMP statistics

Key figures from the December 2022 CHMP meeting are represented in the graphic below.

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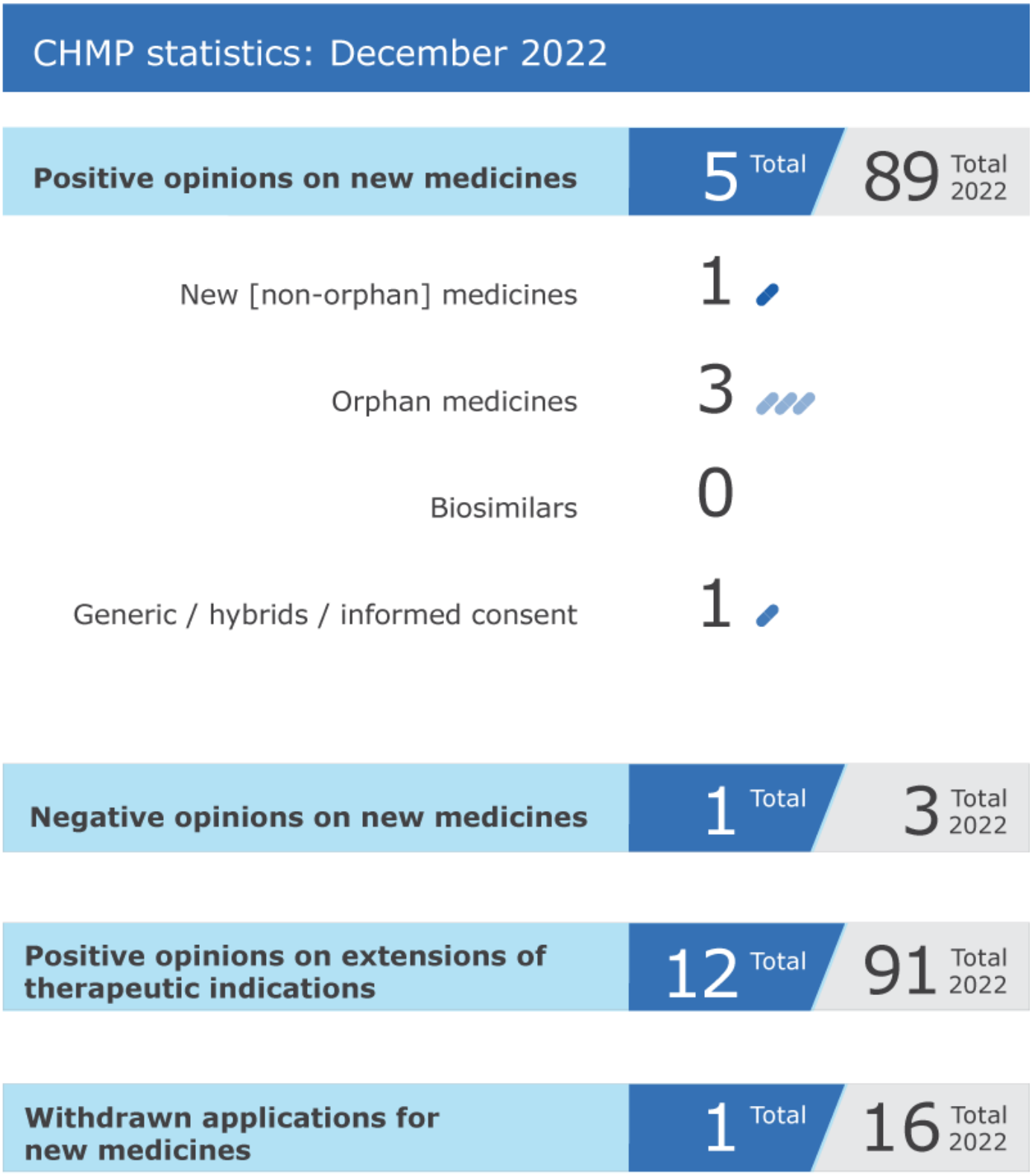
*This product was designated as an orphan medicine during its development. Orphan designations are reviewed by EMA's Committee for Orphan Medicinal Products (COMP) at the time of approval to determine whether the information available to date allows maintaining the medicine's orphan status and granting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



Positive recommendation on new medicines

Name of medicine
Hemgenix
International non-proprietary name (INN)
etranacogene dezaparvovec
Marketing-authorisation applicant

CSL Behring GmbH

Therapeutic indication

Treatment of severe and moderately severe Haemophilia B

More information

Hemgenix: Pending EC decision

News announcement: First gene therapy to treat haemophilia B

Name of medicine

Imjudo

INN

tremelimumab

Marketing-authorisation applicant

AstraZeneca AB

Therapeutic indication

Treatment of hepatocellular carcinoma

More information

Imjudo: Pending EC decision

Name of medicine

Pombiliti

INN

cipaglucosidase alfa

Marketing-authorisation applicant

Amicus Therapeutics Europe Limited

Therapeutic indication

Treatment of glycogen storage disease type II (Pompe disease)

More information

Pombiliti: Pending EC decision

Name of medicine
Tremelimumab AstraZeneca
INN
tremelimumab
Marketing-authorisation applicant
AstraZeneca AB
Therapeutic indication
Treatment of metastatic non-small-cell lung cancer
More information
Tremelimumab AstraZeneca: Pending EC decision

Positive recommendation on new generic medicine

Name of medicine
Dimethyl fumarate Accord
INN
dimethyl fumarate
Marketing-authorisation holder
Accord Healthcare S.L.U.
Therapeutic indication
Treatment of multiple sclerosis
More information
Dimethyl fumarate Accord: Pending EC decision

Negative recommendation on new medicine

Name of medicine
Omblastys
INN
iodine (131I) omburtamab

Marketing-authorisation holder

Y-Mabs Therapeutics A/S

Therapeutic indication

Treatment of neuroblastoma

More information

Omblastys: Pending EC decision

Positive recommendations on extensions of indications

Name of medicine

Adcirca

INN

tadalafil

Marketing-authorisation holder

Eli Lilly Nederland B.V.

More information

Adcirca: Pending EC decision

Name of medicine

Dupixent

INN

dupilumab

Marketing-authorisation holder

sanofi-aventis groupe

More information

Dupixent: Pending EC decision

Name of medicine

Edistride

INN

dapagliflozin

Marketing-authorisation holder

AstraZeneca AB

More information

Edistride: Pending EC decision

Name of medicine

Enhertu

INN

trastuzumab deruxtecan

Marketing-authorisation holder

Daiichi Sankyo Europe GmbH

More information

Enhertu: Pending EC decision

Name of medicine

Fintepla

INN

fenfluramine

Marketing-authorisation holder

Zogenix ROI Limited

More information

Fintepla: Pending EC decision

Name of medicine

Forxiga

INN

dapagliflozin

Marketing-authorisation holder

AstraZeneca AB

More information

Forxiga: Pending EC decision

Name of medicine

Hemlibra

INN

emicizumab

Marketing-authorisation holder

Roche Registration Limited

More information

Hemlibra: Pending EC decision

Name of medicine

Imfinzi

INN

durvalumab

Marketing-authorisation holder

AstraZeneca AB

More information

Imfinzi: Pending EC decision (II-41)

Name of medicine

Imfinzi

INN

durvalumab

Marketing-authorisation holder

AstraZeneca AB

More information

Imfinzi: Pending EC decision (II-45)

Name of medicine

Kerendia

INN

finerenone

Marketing-authorisation holder

Bayer AG

More information

Kerendia: Pending EC decision

Name of medicine

Spikevax

INN/common name

elasomeran / imelasomeran and elasomeran / davesomeran and elasomeran / COVID-19 mRNA vaccine (nucleoside-modified)

Marketing-authorisation holder

Moderna Biotech Spain, S.L.

More information

Spikevax: Pending EC decision

Name of medicine

Triumeq

INN

dolutegravir sodium / lamivudine / abacavir (as sulfate)

Marketing-authorisation holder

ViiV Healthcare B.V.

More information

Triumeq: Pending EC decision

Withdrawal of initial marketing authorisation application

Name of medicine

Imbarkyd

INN

bardoxolone methyl

Marketing-authorisation applicant

Reata Ireland Limited

More information

Imbarkyd: Withdrawn application

Withdrawal of post-authorisation marketing authorisation application

Name of medicine

Olumiant

INN

baricitinib

Marketing-authorisation holder

Eli Lilly Nederland B.V.

More information

Olumiant: Withdrawn application

Outcomes of arbitration procedures

Name of medicine

Gelisia

INN

timolol maleate

Marketing-authorisation holder

Sifi S.p.A.

More information

EMA recommends authorisation of Gelisia (timolol, eye gel) in the EU

Name of medicine

Rambis

INN

ramipril, bisoprolol fumarate

Marketing-authorisation holder

Adamed Pharma S.A.

More information

EMA recommends authorisation of Rambis (ramipril / bisoprolol) in the EU

Other updates

Scientific advice and protocol assistance Adopted during the CHMP meeting 12-15 December 2022 (PDF/241.98 KB) (new)

Adopted

First published: 16/12/2022
EMA/CHMP/SAWP/939122/2022

Overview of (invented) names reviewed in November 2022 by the Name Review Group (NRG) Adopted at the CHMP meeting of 12-15 December 2022 (PDF/176.68 KB) (new)

First published: 16/12/2022
EMA/934083/2022

Related content

- Adcirca (previously Tadalafil Lilly): EPAR
- Dupixent: EPAR
- Edistride: EPAR
- Enhertu: EPAR
- Fintepla: EPAR

- Forxiga: EPAR
- Hemlibra: EPAR
- Imfinzi: EPAR
- Kerendia: EPAR
- Olumiant: EPAR
- Spikevax (previously COVID-19 Vaccine Moderna): EPAR
- Triumeq: EPAR
- Fintepla: Pending EC decision
- Pombiliti: Pending EC decision
- Forxiga: Pending EC decision
- Imjudo: Pending EC decision
- Hemgenix: Pending EC decision
- Triumeq: Pending EC decision
- Omblastys: Pending EC decision
- Imfinzi: Pending EC decision
- Dimethyl fumarate Accord: Pending EC decision
- Imfinzi: Pending EC decision
- Enhertu: Pending EC decision
- Hemlibra: Pending EC decision
- Dupixent: Pending EC decision
- Imbarkyd: Withdrawn application
- Tremelimumab AstraZeneca: Pending EC decision
- Adcirca (previously Tadalafil Lilly): Pending EC decision
- Kerendia: Pending EC decision
- Imfinzi: Pending EC decision
- Edistride: Pending EC decision
- Spikevax (previously COVID-19 Vaccine Moderna): Pending EC decision
- Enhertu: Pending EC decision
- Olumiant: Withdrawn application
- Dupixent: Pending EC decision
- Adcirca (previously Tadalafil Lilly): Paediatric investigation plan
- Forxiga: Paediatric investigation plan
- Forxiga: Paediatric investigation plan
- Forxiga: Paediatric investigation plan
- Forxiga: Paediatric investigation plan
- Forxiga: Paediatric investigation plan
- Forxiga: Paediatric investigation plan
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- Dupixent: Paediatric investigation plan
- Kerendia: Paediatric investigation plan
- Imfinzi: Paediatric investigation plan
- Enhertu: Paediatric investigation plan
- Fintepla: Orphan designation
- Omblastys: Orphan designation
- Hemgenix: Orphan designation
- Pombiliti: Orphan designation
- Imbarkyd: Orphan designation
- Imjudo: Orphan designation
- Janus Kinase inhibitors (JAKi): Article 20 procedures
- SGLT2 inhibitors: Article 20 procedures
- SGLT2 inhibitors (previously canagliflozin): Article 20 procedures
- Gelisia and associated names: Article 29(4) referrals
- Rambis and associated names : Article 29(4) referrals

Related content

- First gene therapy to treat haemophilia B (16/12/2022)
- Committee for Medicinal Products for Human Use (CHMP): 12-15 December 2022
- CHMP: Agendas, minutes and highlights

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