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Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 11-14 November 2024

15 November 2024

Leqembi (lecanemab) recommended for treatment of early Alzheimer’s disease

News Human Medicines

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Eight new medicines recommended for approval

EMA's human medicines committee (CHMP) recommended eight medicines for approval at its November 2024 meeting.

The committee recommended granting a conditional marketing authorisation for **Augtyro** (repotrectinib), a medicine intended for the treatment of adults and adolescents with advanced solid tumours, and adults with locally advanced or metastatic non-small cell lung cancer.

The CHMP recommended granting a marketing authorisation under exceptional circumstances for **Gohibic** (vilobelimab), for the treatment of adult patients with SARS-CoV2-induced acute respiratory distress syndrome who are receiving systemic corticosteroids as part of standard of care and receiving invasive mechanical ventilation with or without extracorporeal membrane oxygenation. EMA's Emergency Task force was consulted during the assessment of this medicine.

Lazcluze (lazertinib) received a positive opinion for the first-line treatment of adult patients with advanced non-small cell lung cancer in combination with amivantamab.

The committee adopted positive opinions for four biosimilar medicines:

- **Baiama** (aflibercept) and its duplicate **Ahzantive**, for the treatment of neovascular age-related macular degeneration, and visual impairment due to macular oedema secondary to retinal vein occlusion, diabetic macular oedema or myopic choroidal neovascularisation.
- **Obodence** (denosumab), for the treatment of osteoporosis and bone loss.
- **Xbryk** (denosumab), for the prevention of skeletal-

related events in adults with advanced malignancies involving bone, and the treatment of giant cell tumour of bone that is unresectable or where surgical resection is likely to result in severe morbidity.

Recommendations on extensions of therapeutic indication for 11 medicines

The committee recommended extensions of indication for 11 medicines that are already authorised in the EU: **CellCept**, **Evkeeza**, **Jakavi**, **Kevzara**, **Keytruda**, **Opdivo**, **Palforzia**, **Rybrevant**, **Sarclisa**, **Tagrisso** and **Yervoy**.

Negative opinions for two medicines

The CHMP recommended the refusal of marketing authorisations for **Cinainu** (allium/citrus/paullinia/cacao), a medicine intended for the treatment of moderate-to-severe alopecia areata, a disease causing hair loss of the scalp or other parts of the body, and **Kizfizo*** (temozolomide), for the treatment of neuroblastoma, a rare cancer that forms from immature nerve cells.

For more information on these negative opinions, see the question-and-answer documents in the grid below.

Outcomes of re-examination

Following a re-examination, the CHMP has recommended granting a marketing authorisation for **Leqembi** (lecanemab), for the treatment of mild cognitive impairment (memory and thinking problems) or mild dementia due to Alzheimer's disease (early Alzheimer's disease) in patients who have only one or no copy of *ApoE4*, a certain form of the gene for the protein apolipoprotein E. During the re-examination, the company that applied for authorisation provided additional analyses of the data to support the proposed use in a subgroup of patients. The committee concluded that in the restricted population of patients who have only one or no copy of *ApoE4,* the benefits of Leqembi outweigh the risks. For more information, see the public health communication in the grid below.

After re-examining its initial opinion, the CHMP

recommended updating the advice aimed at minimising the risks of interaction between the weight loss medicine **Mysimba** (naltrexone/bupropion) and opioid-containing medicines, including painkillers such as morphine and codeine, other opioids used during surgery, and certain medicines for cough, cold or diarrhoea. Opioid medicines may not work effectively in patients taking Mysimba, because one of the active substances in Mysimba, naltrexone, blocks the effects of opioids. There is also a risk of rare but serious and potentially life-threatening reactions, such as seizures and serotonin syndrome (a potentially life-threatening condition that results from having too much serotonin in the body), in people taking Mysimba together with medicines for treating depression and opioids. For more information, see the public health communication in the grid below.

Withdrawal of applications

An application for an initial marketing authorisation was withdrawn. **Izelvay** (avacincaptad pegol) was intended for the treatment of geographic atrophy caused by age-related macular degeneration, a disease that affects the central part of the retina at the back of the eye.

An application to extend the therapeutic indication of **Inaqovi** (cedazuridine/decitabine) was also withdrawn. It concerned the use in the treatment of acute myeloid leukaemia, to include myelodysplastic syndromes, conditions where the bone marrow does not make enough healthy blood cells or platelets, and chronic myelomonocytic leukaemia, another type of cancer of the white blood cells.

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

Agenda and minutes

The agenda of the November 2024 CHMP meeting is published on EMA's website. Minutes of the meeting will be published in the coming weeks.

CHMP statistics

Key figures from the November 2024 CHMP meeting are represented in the graphic below.

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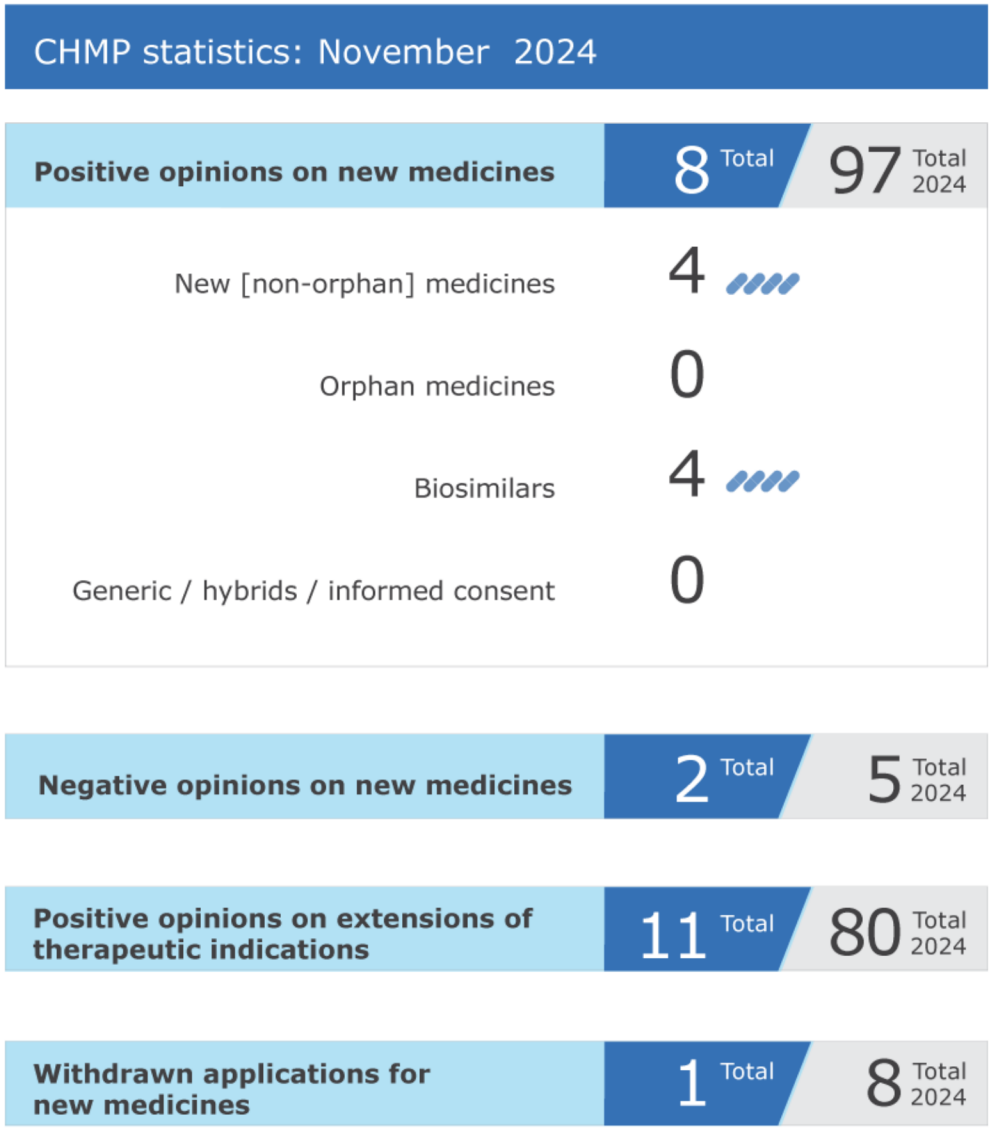
*This product was designated as an orphan medicine during its development. Orphan designations are reviewed by EMA's Committee for Orphan Medicinal Products (COMP) at the time of approval to determine whether the information available to date allows maintaining the medicine's orphan status and granting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



Positive recommendations on new medicines

Augtyro

International non-proprietary name (INN)

repotrectinib

Marketing authorisation applicant

Bristol-Myers Squibb Pharma EEIG

Therapeutic indication

Treatment of ROS1-positive locally advanced or metastatic non-small cell lung cancer (NSCLC) and for solid tumours

More information

Augtyro: pending EC decision

Gohibic

INN

vilobelimab

Marketing authorisation applicant

InflaRx GmbH

Therapeutic indication

Treatment of adult patients with SARS-CoV2-induced acute respiratory distress syndrome who are receiving systemic corticosteroids as part of standard of care and receiving invasive mechanical ventilation with or without extracorporeal membrane oxygenation

More information

Gohibic: pending EC decision

Lazcluze

INN

lazertinib

Marketing authorisation applicant

Janssen Cilag International

Therapeutic indication

Treatment of adult patients with advanced non-small cell lung cancer (NSCLC)

More information

Lazcluze: pending EC decision

Positive recommendations on new biosimilar medicines

Ahzantive

INN

aflibercept

Marketing authorisation applicant

Klinge Biopharma GmbH

Therapeutic indication

Treatment of age-related macular degeneration (AMD) and visual impairment

More information

Ahzantive: pending EC decision

Baiama

INN

aflibercept

Marketing authorisation applicant

Formycon AG

Therapeutic indication

Treatment of age-related macular degeneration (AMD) and visual impairment

More information

Baiama: pending EC decision

Obodence

INN

denosumab

Marketing authorisation applicant

Samsung Bioepis NL B.V.

Therapeutic indication

Treatment of osteoporosis and bone loss

More information

Obodence : pending EC decision

Xbryk

INN

denosumab

Marketing authorisation applicant

Samsung Bioepis NL B.V.

Therapeutic indication

Prevention of skeletal related events with advanced malignancies and treatment of giant cell tumour of bone

More information

Xbryk: pending EC decision

Positive recommendations on extensions of therapeutic indications

CellCept

INN

mycophenolate mofetil

Marketing authorisation holder

Roche Registration GmbH

More information

CellCept: pending EC decision

Evkeeza

INN

evinacumab

Marketing authorisation holder

Ultragenyx Germany GmbH

More information

Evkeeza: pending EC decision

Jakavi

INN

ruxolitinib

Marketing authorisation holder

Novartis Europharm Limited

More information

Jakavi: pending EC decision

Kevzara

INN

sarilumab

Marketing authorisation holder

Sanofi Winthrop Industrie

More information

Kevzara: pending EC decision

Keytruda

INN

pembrolizumab

Marketing authorisation holder

Merck Sharp & Dohme B.V.

More information

Keytruda: pending EC decision

Opdivo

INN

nivolumab

Marketing authorisation holder

Bristol-Myers Squibb Pharma EEIG

More information

Opdivo: pending EC decision

Palforzia

INN

defatted powder of Arachis hypogaea L., semen (peanuts)

Marketing authorisation holder

Stallergenes

More information

Palforzia: pending EC decision

Rybrevant

INN

amivantamab

Marketing authorisation holder

Janssen-Cilag International N.V.

More information

Rybrevant: pending EC decision

Sarclisa

INN

isatuximab

Marketing authorisation holder

Sanofi Winthrop Industrie

More information

Sarclisa: pending EC decision

Tagrisso

INN

osimertinib

Marketing authorisation holder

AstraZeneca AB

More information

Tagrisso: pending EC decision

Yervoy

INN

ipilimumab

Marketing authorisation holder

Bristol-Myers Squibb Pharma EEIG

More information

Yervoy: pending EC decision

Negative recommendations on new medicines

Cinainu

INN

liquid ethanolic extract 30 per cent (W/W) of allium cepa fresh bulb and citrus limon fresh fruit / dry aqueous extract of paullinia cupana seed / dry hydroethanolic extract of theobroma cacao seed

Marketing authorisation applicant

Legacy Healthcare (France) S.A.S.

Therapeutic indication

Treatment of alopecia areata in children and adolescents

More information

Cinainu: pending EC decision

Kizfizo

INN

temozolomide

Marketing authorisation applicant

Orphelia Pharma

Therapeutic indication

Treatment of neuroblastoma

More information

Kizfizo: pending EC decision

Withdrawal of initial marketing authorisation application

Izelvay

INN

avacincaptad pegol

Marketing authorisation applicant

Astellas Pharma Europe B.V.

More information

Izelvay: withdrawn application

Withdrawal of application to change the marketing authorisation

Inaqovi

INN

decitabine / cedazuridine

Marketing authorisation applicant

Otsuka Pharmaceutical Netherlands B.V.

More information

Inaqovi: withdrawn application (II-0002)

Outcome of re-examinations

Leqembi

INN

lecanemab

Marketing authorisation applicant

Eisai GmbH

More information

Leqembi: pending EC decision

News: Leqembi recommended for treatment of early Alzheimer's disease

Mysimba

INN

naltrexone hydrochloride / bupropion hydrochloride

Marketing authorisation holder

Orexigen Therapeutics Ireland Limited

More information

Updated advice to minimise risks of interaction between weight loss medicine Mysimba and opioids

Other updates

Scientific advice and protocol assistance adopted during the CHMP meeting 14-17 October 2024

Adopted

Reference Number: EMA/CHMP/SAWP/531144/2024

English (EN) (237.48 KB - PDF)

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Emergency Task Force (ETF)

Committee for Medicinal Products for Human Use (CHMP)

Committee for Medicinal Products for Human Use (CHMP): 11-14 November 2024

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