

EMA

Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 12-15 December 2016

- Seven medicines recommended for authorisation, 81 overall in 2016

London, GB (December 16, 2016) - The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) recommended seven new medicines for marketing authorisation at its December 2016 meeting. This brings the total number of medicines recommended for approval by the CHMP in 2016 to 811.

The CHMP recommended granting a marketing authorisation to Olumiant (baricitinib) for the treatment of moderate to severe active rheumatoid arthritis. For more information, please see the press release in the grid below.

The CHMP recommended granting a conditional marketing authorisation for Alecensa (alectinib) for the treatment of anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC) previously treated with crizotinib.

Lifmior (etanercept) received a positive recommendation from the Committee for the treatment of rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, axial spondyloarthritis, plaque psoriasis and paediatric plaque psoriasis.

A biosimilar medicine, Truxima (rituximab), received a positive opinion from the CHMP for the treatment of non-Hodgkin's lymphoma, chronic lymphocytic leukaemia, rheumatoid arthritis, granulomatosis with polyangiitis and microscopic polyangiitis.

One hybrid medicine, Ledaga (chormethine), received a positive opinion for the treatment of mycosis fungoides-type cutaneous T-cell lymphoma. Hybrid applications rely in part on the results of pre-clinical tests and clinical trials for a reference product and in part on new data. Ledaga has an orphan designation.

A generic medicine, Pregabalin Zentiva k.s (pregabalin), received a positive opinion from the Committee for the treatment of epilepsy, neuropathic pain and generalised anxiety disorder.

The CHMP also granted a positive opinion for the informed consent application for Vihuma (simoctocog alfa) for the prevention and treatment of bleeding in patients with haemophilia A (congenital factor VIII deficiency). In an informed consent application, reference is made to an authorised medicine and the marketing authorisation holder of the reference medicine has given consent to the use of their dossier in the application procedure.

Positive opinion on Zinplava adopted by written procedure

In addition to the positive opinions for the seven new medicines adopted at the December 2016 meeting, the CHMP recommended granting a marketing authorisation for Zinplava (bezlotoxumab) to prevent the recurrence of Clostridium difficile infection via written procedure on 22 November 2016.

Nine recommendations on extensions of therapeutic

indications

The Committee recommended extensions of indications for Ameluz, Cinryze, Ilaris, Jardiance, Jentadueto, Keytruda, Tivacy, Trajenta and Votubia.

Start of referral: Micro Therapeutics Research Labs, India

The CHMP started a review of medicines for which studies have been conducted by Micro Therapeutic Research Labs at two sites in India. This follows a good clinical practice inspection which raised concerns about the study data used to support marketing authorisation applications of some medicines in the European Union. For more information, please see the start of referral document in the grid below.

Outcome of review of direct-acting antivirals

The CHMP confirmed the recommendation of the Pharmacovigilance Risk Assessment Committee (PRAC) to screen all patients for hepatitis B before starting treatment with direct-acting antivirals for hepatitis C; patients infected with both hepatitis B

and C viruses must be monitored and managed according to current clinical guidelines. These measures aim to minimise the risk of hepatitis B re-activation with direct-acting antivirals. For more information, please see the public health communication in the grid below.

Withdrawals of applications

Applications for marketing authorisations for Cavoley (pegfilgrastim), Efgratin (pegfilgrastim), Graspas (eryaspase) and Kepnetic (aceneuramic acid) have been withdrawn. Questions-and-answers documents on these withdrawals are available in the grid below.

A request to extend the indication of Arzerra (ofatumumab) to be used in a new combination with bendamustine for the treatment of relapsed chronic lymphocytic leukaemia has been withdrawn. A questions-and-answers document on this withdrawal is available below.

Agenda and minutes

The agenda of the December 2016 CHMP meeting is published on EMA's website. Minutes of the November 2016 CHMP meeting will be published next week.

CHMP statistics

Key figures from the December 2016 CHMP meeting are represented in the graphic below.

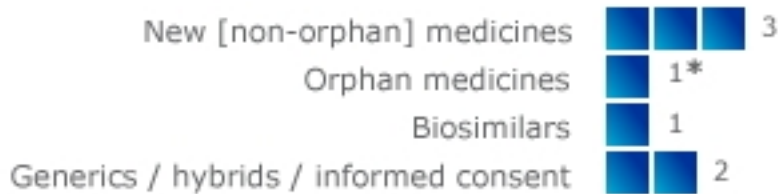
More information on this, and all other outcomes of the CHMP's December

2016 meeting, is available in the grid below.

1 EMA will publish its human medicines highlights for 2016 in early 2017.

CHMP statistics: December 2016

Positive opinions on new medicines



81**
Total
2016

Negative opinions on new medicines

Negative opinions 0***

0
Total
2016

Positive opinions on extensions of therapeutic indications

Extension of existing indication  9

59
Total
2016

Withdrawn applications

Withdrawn applications  4

16
Total
2016

* This orphan-designated medicine (Ledaga) is a hybrid medicine.

**This figure includes Zinplava (bezlotoxumab) to prevent the recurrence of *Clostridium difficile* infection, which received a positive opinion via written procedure on 22 November 2016. This is reflected in the total number of positive opinions on new medicines in 2016.

*** Two medicines received a negative opinion from the CHMP - Sialanar in April 2016 and Ninlaro in May 2016 . Following re-examination, Sialanar received a positive opinion from the Committee in July 2016 and Ninlaro received a positive opinion in September 2016.

Positive recommendations on new

medicines

Name of medicine

Alecensa

International non-proprietary name

alectinib

Marketing-authorisation applicant

Roche Registration Limited

Therapeutic indication

Treatment of anaplastic lymphoma

More information

[Summary of opinion for
Alecensa](#)

Name of medicine

Lifmior

INN

etanercept

Marketing-authorisation applica

Pfizer Limited

Therapeutic indication

Treatment of rheumatoid arthritis

More information

Summary of opinion for Lifmior

Name of medicine

Olumiant

INN

baricitinib

Marketing-authorisation appl

Eli Lilly Nederland B.V.

Therapeutic indication

Treatment of rheumatoid art

More information

[Summary of opinion for Olumiant](#)

Press [release: New oral treatment](#)

for rheumatoid arthritis

**Positive
recommendation on
new informed-consent
application**

Name of medicine

Vihuma

INN

simoctocog alfa

Marketing-authorisation ap

Octapharma AB

Therapeutic indication

Treatment and prophylaxis

More information

[Summary of opinion for
Vihuma](#)

Positive recommendation on new generic medicine

Name of medicine

Pregabalin Zentiva k.s.

INN

pregabalin

Marketing-authoris ation

Zentiva k.s.

Therapeutic indication

Treatment of neuropathic

More information

Summary of opinion for Pregabalin Zentiva k.s.

Positive recommendation on new hybrid medicine

Name of medicine

Ledaga

INN

chlormethine

Marketing-authorisatio

Actelion Registration L

Therapeutic indication

Treatment of mycosis

More information

[Summary of opinion
for Ledaga](#)

Positive recommendation on new biosimilar medicine

Name of medicine

Truxima

INN

rituximab

Marketing-authorisat

Celltrion Healthcare

Therapeutic indicatio

Treatment of Non-Ho

More information

Summary of opinion for Truxima

Positive recommendation s on extensions of therapeutic indications

Name of medicine

Ameluz

INN

5-aminolevulinic ac

Marketing-authoris

Biofrontera Bioscie

More information

[Summary of
opinion for
Ameluz](#)

Name of medicine

Cinryze

INN

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Shire Services BV

More information

Summary of

opinion for Cinryze

Name of medicine

Ilaris

INN

canakinumab

Marketing-author

Novartis Europha

More information

Summary of opinion for llaris

Name of medicinal product

Jardiance

INN

empagliflozin

Marketing-author

Boehringer Inge

More information

Summary of opinion for Jardiance

Name of medic

Jentadueto

INN

linagliptin / met

Marketing-auth

Boehringer Inge

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Summary of opinion for Jentadueto

Name of medic

Keytruda

INN

pembrolizumab

Marketing-auth

Merck Sharp &

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Summary of opinion for Keytruda

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INN

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Marketing-aut

ViiV Healthcare

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Summary of
opinion for

Tivicay

Name of med

Trajenta

INN

linagliptin

Marketing-au

Boehringer In

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Summary of opinion for Trajenta

Name of med

Votubia

INN

everolimus

Marketing-au

Novartis Euro

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of opinion for Votubia

Start of referral

Name of me

Micro Thera

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enoxaparin

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Arzerra

INN

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Name of m

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