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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 (chlormethine), 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 (nimoctocog 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 medicinesfor 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), Efgrastim (pegfilgrastim), Graspa (eryaspase) and Kepmetic (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

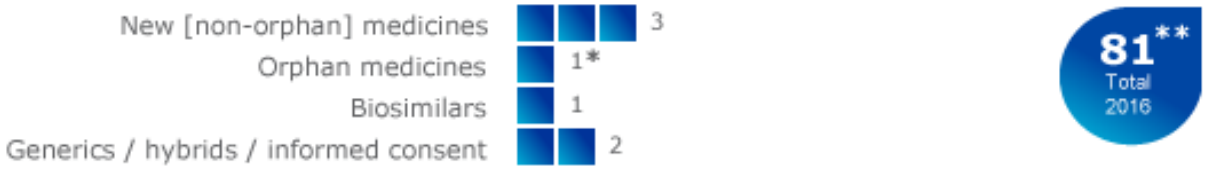
Key figures from the December 2016 CHMP meeting are represented in the graphic below.

More information on this, and all other outcomes of the CHMP's December 2016 meeting, is available in the grid below.

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

CHMP statistics: December 2016

Positive opinions on new medicines



Negative opinions on new medicines

Positive opinions on extensions of therapeutic indications

Withdrawn applications

* 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

Aiscenza

Name of medicine	**Alecensa**
International non-proprietary name (INN)	alectinib
Marketing-authorisation applicant	Roche Registration Limited
Therapeutic indication	Treatment of anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC) previously treated with crizotinib
More information	Summary of opinion for Alecensa

Name of medicine	**Litmior**
INN	etanercept
Marketing-authorisation applicant	Pfizer Limited
Therapeutic indication	Treatment of rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, axial spondyloarthritis, plaque psoriasis and paediatric plaque psoriasis
More information	Summary of opinion for Litmior

Name of medicine	**Olumiant**
INN	baricitinib
Marketing-authorisation applicant	Eli Lilly Nederland B.V.
Therapeutic indication	Treatment of rheumatoid arthritis
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 applicant	Octapharma AB
Therapeutic indication	Treatment and prophylaxis of bleeding in patients with haemophilia A (congenital factor VIII deficiency)
More information	Summary of opinion for Vihuma

Positive recommendation on new generic medicine

Name of medicine	**Pregabalin Zentiva k.s.**
INN	pregabalin
Marketing-authorisation applicant	Zentiva k.s.
Therapeutic indication	Treatment of neuropathic pain, epilepsy and generalised anxiety disorder
More information	Summary of opinion for Pregabalin Zentiva k.s.

Positive recommendation on new hybrid medicine

Name of medicine	**Ledaga**

Name of medicine

Ledaga

INN

chlormethine

Marketing-authorisation applicant

Actelion Registration Ltd

Therapeutic indication

Treatment of mycosis fungoides-type cutaneous T-cell lymphoma (MF-type CTCL)

More information

Summary of opinion for Ledaga

Positive recommendation on new biosimilar medicine

Name of medicine

Truxima

INN

rituximab

Marketing-authorisation applican t

Celltrion Healthcare Hungary Kft.

Therapeutic indication

Treatment of Non-Hodgkin's lymphoma, chronic lymphocytic leukaemia, rheumatoid arthritis and granulomatosis with polyangiitis and microscopic polyangiitis

More information

Summary of opinion for Truxima

Positive recommendations on extensions of therapeutic indications

Name of medicine

Ameluz

INN

5-aminolevulinic acid

Market ing-authorisation holder

Biofrontera Bioscience GmbH

More information

Name of medicine

Ameluz

Summary of opinion for Ameluz

Name of medicine

Cinryze

INN

c1-esterase inhibitor, human

Marketing-authorisation holder

Shire Services BVBA

More information

Summary of opinion for Cinryze

Name of medicine

Ilaris

INN

canakinumab

Marketing-authorisation holder

Novartis Europharm Ltd

More information

Summary of opinion for Ilaris

Name of medicine

Jardiance

INN

empagliflozin

Marketing-authorisation holder

Boehringer Ingelheim International GmbH

More information

Summary of opinion for Jardiance

Name of medicine

Jentadueto

Name of medicine	**Jentadueto**
INN	linagliptin / metformin
Marketing-authorisation holder	Boehringer Ingelheim International GmbH
More information	Summary of opinion for Jentadueto
Name of medicine	**Keytruda**
INN	pembrolizumab
Marketing-authorisation holder	Merck Sharp & Dohme Limited
More information	Summary of opinion for Keytruda
Name of medicine	**Tivicay**
INN	dolutegravir
Marketing-authorisation holder	ViiV Healthcare UK Limited
More information	Summary of opinion for Tivicay
Name of medicine	**Trajenta**
INN	linagliptin
Marketing-authorisation holder	Boehringer Ingelheim International GmbH
More information	

Name of medicine

Trajenta

Summary of opinion for Trajenta

Name of medicine

Votubia

INN

everolimus

Marketing-authorisation holder

Novartis Europharm Ltd

More information

Summary of opinion for Votubia

Start of referral

Name of medicine

Micro Therapeutics Research Labs, India

More information

Start of a review concerning the conduct of studies at Micro Therapeutic Research Labs, India

Public health recommendation

Name of medicine

Direct-acting antivirals indicated for the treatment of hepatitis C (interferon free)

More information

Direct-acting antivirals for hepatitis C: EMA confirms recommendation to screen for hepatitis B

Outcome of harmonisation procedure

Name of medicine

Lovenox and associated names

INN

enoxaparin

Name of medicine

Lovenox and associated names

More information

Questions and answers on Lovenox and associated names (enoxaparin, solution for injection)

Withdrawals of applications

Name of medicine

Arzerra

INN

ofatumumab

More information

Questions and answers on Arzerra

Name of medicine

Caveley

INN

peglilgrastim

More information

Questions and answers on Caveley

Name of medicine

Elgratin

INN

peglilgrastim

More information

Questions and answers on Elgratin

Name of medicine

Graspa

INN

eryaspase

Name of medicine

Grasps

More information

Questions and answers on Grasps

Name of medicine

Kepmetic

INN

acenesuramic acid

More information

Questions and answers on Kepmetic

Other outcomes

Name of medicine

Inovelon

INN

rufinamide

Marketing-authorisation holder

Eisai Ltd

More information

Questions and answers on Inovelon

Name of medicine

Repatha

INN

evolocumab

Marketing-authorisation holder

Amgen Europe B.V.

More information

Summary of opinion for Repatha

Other updates

- Scientific advice and protocol assistance
- Start of community reviews
- Overview of (invented) names reviewed in November 2016 by the Name Review Group (NRG)

European Medicines Agency, 16.12.2016 (kb).