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 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), Efgratin (pegfilgrastim), Graspa (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.

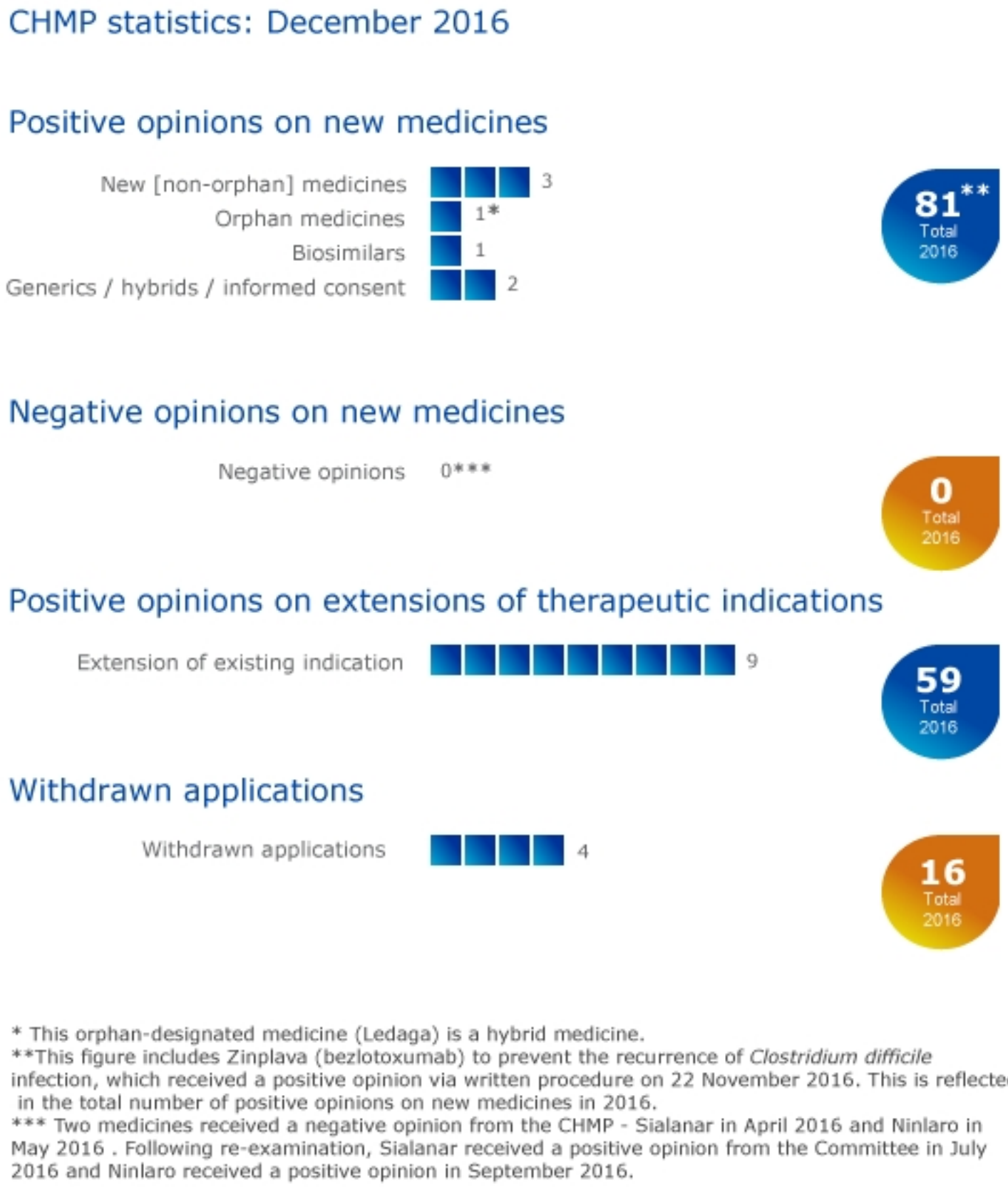
CHMP statistics

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.

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



* 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 arthrit

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 artl

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 neuropathi

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 recommendations on extensions of therapeutic indications

Name of medicine

Ameluz

INN

5-aminolevulinic ac

Market ing-authoris

Biofrontera Biosci

More information

Summary of opinion for Ameluz

Name of medicine

Cinryze

INN

c1-esterase inhibi

Marketing-authoris

Shire Services BV

More information

Summary of

opinion for Cinryze

Name of medicin

Ilaris

INN

canakinumab

Marketing-author

Novartis Europha

More information

Summary of opinion for Ilaris

Name of medici

Jardiance

INN

empagliflozin

Marketing-autho

Boehringer Inge

More informatio

Summary of opinion for Jardiance

Name of medic

Jentadueto

INN

linagliptin / met

Marketing-auth

Boehringer Inge

More informatio

Summary of opinion for Jentadueto

Name of medi

Keytruda

INN

pembrolizumal

Marketing-auth

Merck Sharp &

More informati

Summary of opinion for Keytruda

Name of medi

Tivicay

INN

dolutegravir

Marketing-aut

ViiV Healthca

More informat

Summary of opinion for

Tivicay

Name of med

Trajenta

INN

linagliptin

Marketing-au

Boehringer Ir

More informa

Summary of opinion for Trajenta

Name of me

Votubia

INN

everolimus

Marketing-au

Novartis Eur

More informa

Summary

of opinion for Votubia

Start of referral

Name of me

Micro Thera

More inform

Start of a review concerning

the conduct of studies at Micro Therapeuti

c

Research Labs, India

Public health recommendation

Name of me

Direct-actir

More inform

Direct-acting antivirals

for hepatitis C: EMA confirms recommen

dation to screen for hepatitis B

Outcome of harmonisation procedur

e

Name of m

Lovenox a

INN

enoxaparin

More inform

Questions and answers on Lovenox

and associated names (enoxaparin,

solution for injection)

Withdraw

als of applicati ons

Name of m

Arzerra

INN

ofatumuma

More inforr

Questions and

answers on Arzerra

Name of m

Cavoley

INN

pegfilgrast

More infor

Questions and

answers on Cavoley

Name of n

Efgratin

INN

pegfilgrast

More infor

Questions and

answers on Efgratin

Name of r

Graspa

INN

eryaspase

More infor

Questions and

answers on Graspa

Name of

Kepnetic

INN

aceneura

More info

Questions and

answers on Kepneti c

Other outcomes

Name of

Inovelon

INN

rufinamid

Marketing

Eisai Ltd

More info

Questions and answers on

Inovelon

Name of

Repatha

INN

Marketing

Amgen E

More info

Summary of

opinion for Repath a

Other updates

- Scientific advice

and protocol assista nce

- Sta

rt of commu nity reviews

- Overview of

(invented) names reviewe

d in Novem ber 2016 by

the Name Review Group

(NRG)

European Medicines

Agency, 16.12.2016 (tB).