Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 12-15 November 2018

- EMA's human medicines committee (CHMP) recommended four medicines for approval, including a medicine for use in countries outside the European Union, at its November 2018 meeting.

London, UK (November 16, 2018) - The CHMP adopted a positive opinion for Fexinidazole Winthrop (fexinidazole), the first oral-only medicine (tablets) for the treatment of human African trypanosomiasis, commonly known as sleeping sickness, due to Trypanosoma brucei gambiense. This is the tenth medicine recommended by EMA under Article 58, a mechanism that allows the CHMP to assess and give opinions on medicines for use outside the European Union. For more information, please see the press release in the grid below.

Erleada (apalutamide) received a positive opinion for the treatment of non-metastatic castration resistant prostate cancer.

The CHMP recommended granting a marketing authorisation for Macimorelin Aeterna Zentaris (macimorelin), for the diagnosis of growth hormone deficiency in adults.

The generic medicine Silodosin Recordati (silodosin) received a positive opinion from the CHMP for the treatment of the signs and symptoms of benign prostatic hyperplasia.

Four recommendations on extensions of therapeutic indication

The Committee recommended extensions of indication for Kisqali, Mabthera, Orkambi and Ravicti.

Positive recommendations on extension of therapeutic indication following re-examination

The Committee recommended an extension of therapeutic indication for Blincyto (blinatumomab) in patients with residual cancer cells in the body after previous treatment, after re-examining its negative opinion for this medicine adopted in July 2018.

The CHMP also adopted a positive opinion for the use of Opdivo (nivolumab) and Yervoy (ipilimumab) in combination to treat renal cell

carcinoma (kidney cancer), after re-examining its negative opinion adopted in July 2018.

For more information on these positive opinions following re-examination please see the question-and-answer documents in the grid below.

Outcome of review on quinolone and fluoroquinolone antibiotics

The CHMP recommended suspending some quinolone and fluoroquinolone antibiotics and introducing changes including restrictions on the use of all others following a review of disabling and potentially permanent side effects reported with these medicines. The review incorporated the views of patients, healthcare professionals and academics presented at EMA’s public hearing on these medicines in June 2018. For more information, please see the public health recommendation in the grid below.

Withdrawal of extension of indication application

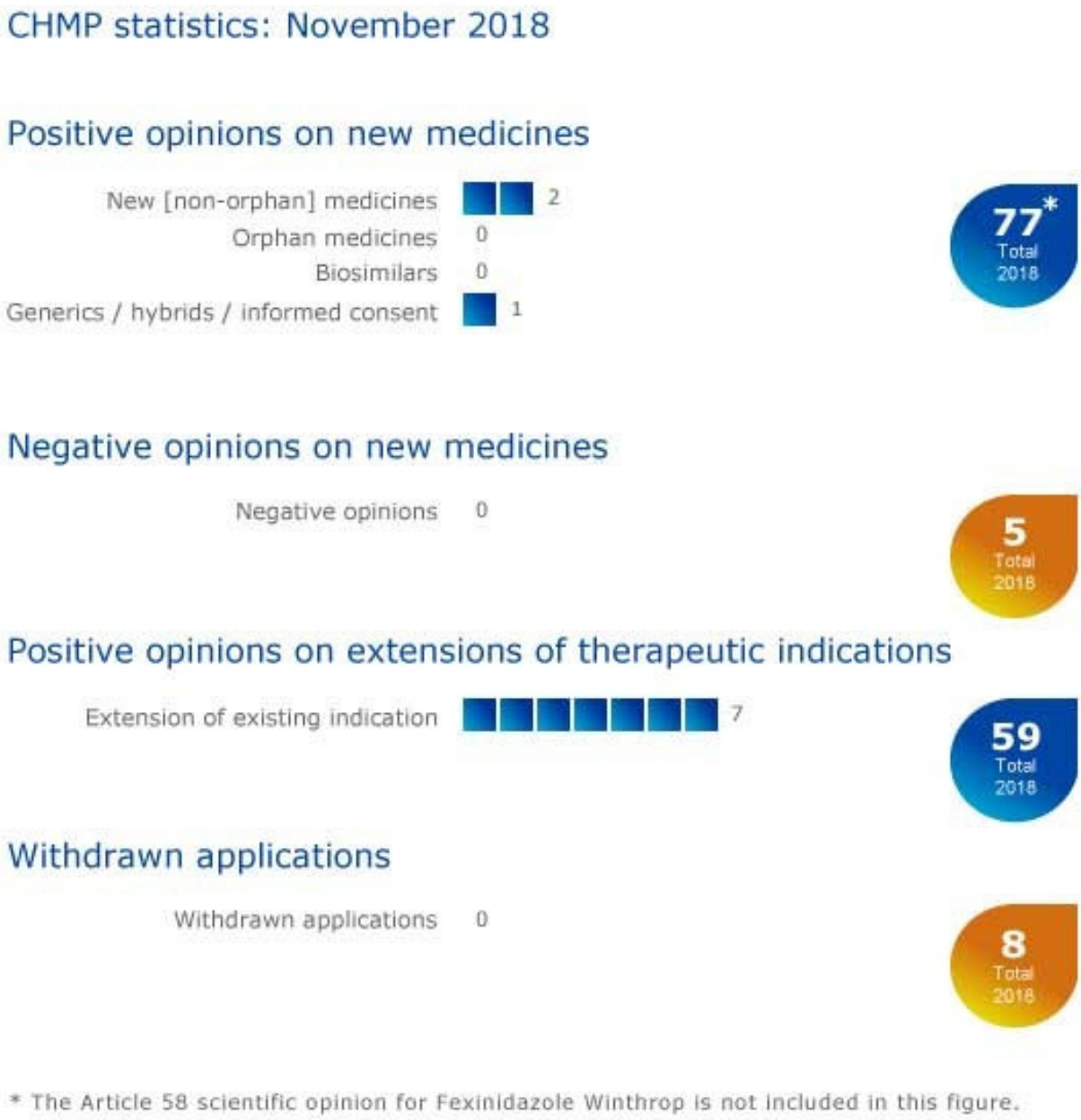
The application to extend the use of Tecentriq (atezolizumab) to treat kidney cancer was withdrawn. A question-and-answer document on this withdrawal is available in the grid below.

Agenda and minutes

The agenda of the November 2018 meeting is published on EMA's website. Minutes of the October 2018 CHMP meeting will be published in the coming weeks.

CHMP statistics

Key figures from the November 2018 CHMP meeting are represented in the graphic below.



Positive recommendations on new medicines

Name of medicine	Erleada
INN	apalutamide
Marketing-authorisation applicant	Janssen-Cilag International N.V.
Therapeutic indication	Treatment of non-metastatic castration resistant prostate cancer

Name of medicine	Macimorelin Aeterna Zentaris
INN	macimorelin
Marketing-authorisation applicant	Aeterna Zentaris GmbH
Therapeutic indication	Diagnosis of growth hormone deficiency in adults

List item

CHMP summary of positive opinion for Macimorelin Aeterna Zentaris (PDF/62.48 KB)

Adopted

First published: 16/11/2018
EMA/CHMP/777751/2018

Positive recommendation on new generic medicine

Name of medicine	Silodosin Recordati
INN	silodosin
Marketing-authorisation applicant	Recordati Ireland Ltd
Therapeutic indication	Treatment of the signs and symptoms of benign prostatic hyperplasia

List item

CHMP summary of positive opinion for Silodosin Recordati (PDF/73.33 KB)

Adopted

First published: 16/11/2018
EMA/766073/2018

Positive recommendation on medicine for use outside the European Union

Name of medicine	Fexinidazole Winthrop
INN	fexinidazole
Opinion holder	sanofi-aventis groupe
Therapeutic indication	Treatment of human African trypanosomiasis (HAT) due to

Name of medicine	Fexinidazole Winthrop
	Trypanosoma brucei gambiense
More information	Press release: CHMP recommends first oral-only treatment for sleeping sickness

List item

CHMP summary of opinion for Fexinidazole Winthrop (PDF/73.53 KB)

Adopted

First published: 16/11/2018
EMA/791484/2018

Positive recommendations on extensions of indications

Name of medicine	Kisqali
INN	ribociclib
Marketing-authorisation applicant	Novartis Europharm Limited

List item

CHMP post-authorisation summary of positive opinion for Kisqali (II-04) (PDF/64.74 KB)

Adopted

First published: 16/11/2018
EMA/CHMP/795769/2018

Name of medicine	Mabthera
INN	rituximab
Marketing-authorisation applicant	Roche Registration GmbH

List item

CHMP post-authorisation summary of positive opinion for MabThera (II-149) (PDF/71.67 KB)

Adopted

First published: 16/11/2018
EMA/CHMP/790642/2018

Name of medicine	Orkambi
INN	lumacaftor / ivacaftor
Marketing-authorisation applicant	Vertex Pharmaceuticals (Europe) Ltd

List item

CHMP post-authorisation summary of positive opinion for Orkambi (X-34-G) (PDF/67.93 KB)

Adopted

First published: 16/11/2018
EMA/774653/2018

Name of medicine	Ravicti
INN	glycerol phenylbutyrate
Marketing-authorisation applicant	Horizon Pharma Ireland Limited

Positive recommendations on extensions of indications following re-examination

Name of medicine	Blincyto
INN	blinatumomab
Marketing-authorisation applicant	Amgen Europe B.V.

List item

CHMP post-authorisation summary of positive opinion for Blincyto (II-0011) (PDF/69.16 KB)

Adopted

First published: 16/11/2018
EMA/CHMP/799482/2018

List item

Questions and answers on the positive opinion on the change to the marketing authorisation for Blincyto (blinatumomab) (PDF/76.47 KB)

Adopted

First published: 16/11/2018
EMA/800602/2018

Name of medicine	Opdivo
INN	nivolumab
Marketing-authorisation applicant	Bristol-Myers Squibb Pharma EEIG

List item

CHMP post-authorisation summary of positive opinion for Opdivo (WS-1278) (PDF/72.85 KB)

Adopted

First published: 16/11/2018
EMA/CHMP/788598/2018

Name of medicine	Yervoy
INN	ipilimumab
Marketing-authorisation applicant	Bristol-Myers Squibb Pharma EEIG

List item

CHMP post-authorisation summary of positive opinion for Yervoy (WS-1278) (PDF/71.11 KB)

Adopted

First published: 16/11/2018
EMA/795695/2018

Public-health recommendation

Name of medicine	Quinolone- and fluoroquinolone-containing medicinal products
INN	nalidixic acid, pipemidic acid, cinoxacin, enoxacin, pefloxacin, lomefloxacin, ciprofloxacin, levofloxacin, ofloxacin, moxifloxacin, norfloxacin, prulifloxacin, rufloxacin, flumequin

List item

Quinolone and fluoroquinolone Article-31 referral - Disabling and potentially permanent side effects lead to suspension or restrictions of quinolone and fluoroquinolone antibiotics (PDF/81.98 KB)

First published: 16/11/2018
EMA/795349/2018

Outcomes of arbitration procedures

Name of medicine	Diclofenac sodium spray gel 4%
INN	diclofenac

List item

Diclofenac Article 29(4) referral – EMA recommends authorisation of Diclofenac Sodium Spray Gel 4% (diclofenac) in the EU (PDF/77.59 KB)

First published: 16/11/2018
EMA/631720/2018

Name of medicine	Diotop capsules
INN	diclofenac / omeprazole

List item

Diotop Article 29(4) referral – EMA recommends authorisation of Diotop (diclofenac / omeprazole capsules) in the EU (PDF/76.5 KB)

First published: 16/11/2018
EMA/790726/2018

Withdrawal of extension of indication application

Name of medicine	Tecentriq
INN	atezolizumab
Marketing-authorisation applicant	Roche Registration GmbH

List item

Questions and answers on the withdrawal of application for a change to the marketing authorisation for Tecentriq (atezolizumab) (PDF/112.51 KB)

First published: 16/11/2018

EMA/798527/2018

Other updates

List item

Start of community reviews - CHMP meeting of 12-15 November 2018 (PDF/66.92 KB)

First published: 16/11/2018
EMA/712987/2018

List item

Scientific advice and protocol assistance adopted during the CHMP meeting 12-15 November 2018 (PDF/123.54 KB)

Adopted

First published: 16/11/2018
EMA/CHMP/SAWP/800757/2018

Related content

Blincyto: EPAR

Kisqali: EPAR

MabThera: EPAR

Opdivo: EPAR

Orkambi: EPAR

Ravicti: EPAR

Tecentriq: EPAR

Yervoy: EPAR

Opdivo: Pending EC decision

Kisqali: Pending EC decision

Opdivo: Withdrawn application

Macimorelin Aeterna Zentaris: Pending EC decision

MabThera: Pending EC decision

Orkambi: Pending EC decision

Tecentriq: Withdrawn application

Opdivo: Withdrawn application

Yervoy: Pending EC decision

Blincyto: Pending EC decision

Silodosin Recordati: Pending EC decision

Opdivo: Withdrawn application

Erleada: Pending EC decision

Yervoy: Paediatric investigation plan

Yervoy: Paediatric investigation plan

MabThera: Paediatric investigation plan

MabThera: Paediatric investigation plan

Blincyto: Paediatric investigation plan

Opdivo: Paediatric investigation plan

Opdivo: Paediatric investigation plan

Orkambi: Paediatric investigation plan

Blincyto: Orphan designation

Ravicti: Orphan designation

Ravicti: Orphan designation

Ravicti: Orphan designation

Ravicti: Orphan designation

Ravicti: Orphan designation

Ravicti: Orphan designation

Diclofenac Sodium Spray Gel 4%: Article 29(4) referrals

Diotop capsules: Article 29(4) referrals

Quinolone- and fluoroquinolone-containing medicinal products: Article 31 referrals

Medicines for use outside the EU

Fexinidazole Winthrop H-W-2320

Related content

CHMP recommends first oral-only treatment for sleeping sickness

Committee for Medicinal Products for Human Use (CHMP): 12-15 November 2018

CHMP: Agendas, minutes and highlights

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European Medicines Agency, 16.11.2018 (tB).