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SCIENCE MEDICINES HEALTH

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Press Office

Press release

European Medicines Agency recommends approval of new HIV medicine

Tivicay shown to be effective in patients with resistant HIV virus

The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has recommended granting a marketing authorisation for Tivicay in combination with other antiretroviral medicines for the treatment of adults and adolescents over 12 years of age infected with human immunodeficiency virus (HIV).

Tivicay can be used in adult patients with and without resistance to the integrase class and in adolescents infected with HIV-1 without resistance to the integrase class.

There are approximately 35 million people living with HIV globally. Over the past few years, the authorisation and subsequent use of new, potent antiretroviral agents has changed the landscape of HIV treatment. With these new medicines, most patients are now able to achieve sustained viral suppression.

However, new treatment options are still necessary to fulfil the needs of all patients.

The Agency is currently consulting on new draft guidance on the development of these medicines, taking into account changes in the therapeutic landscape.

Tivicay contains the new active substance dolutegravir, an integrase inhibitor. The medicine blocks an enzyme called integrase, which is involved in the reproduction of HIV, and therefore slows down the spread of infection.

Tivicay has demonstrated its efficacy in large scale studies covering previously untreated patients as well as patients with advanced treatment histories and resistant to multiple classes of HIV medicines. Tivicay also demonstrated a high barrier to resistance meaning that it is less prone to resistance development.

In the absence of integrase class resistance, the dosing regimen is one tablet a day. In the presence of such resistance, Tivicay should be administered twice a day with food.

As for all medicines, Tivicay has been recommended for marketing approval together with a risk management plan (RMP) which aims to manage and minimise the side effects of the medicine. One of

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8427 **Facsimile** +44 (0)20 7418 8409
E-mail press@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

the main aspects of the RMP for Tivicay covers the risk of infrequent but potentially severe hypersensitivity (allergic) reactions.

The applicant for Tivicay, ViiV Healthcare, received scientific advice from the CHMP during the development of the medicine.

The CHMP opinion on Tivicay will now be sent to the European Commission for adoption of a marketing-authorisation decision.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. The draft guideline on the clinical development of medicinal products for the treatment of HIV infection is available on the Agency's website. Comments can be submitted until end of March 2014.
3. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

Contact our press officer

Monika Benstetter

Tel. +44 (0)20 7418 8427

E-mail: press@ema.europa.eu