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ASIA EDITION

Europe grants marketing nod to HIV drug Tivicay

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Singapore: European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has recommended granting a marketing authorization for UK-based ViiV Healthcare's 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 authorization 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treatment options are still necessary to fulfil the needs of all patients.Ã?Â The agency is currently consulting on new draft guidance on the development of these medicines, taking into account changes in the therapeutic landscape.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.

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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.

As for all medicines, Tivicay has been recommended for marketing approval together with a risk management plan (RMP) that aims to manage and minimize the side effects of the medicine. One of the main aspects of the RMP for Tivicay covers the risk of infrequent but potentially severe hypersensitivity (allergic) reactions.