



For Immediate Release

ViiV Healthcare receives approval for Tivicay™ (dolutegravir) in Canada for the treatment of HIV

Mississauga (Nov. 4, 2013) – ViiV Healthcare has received approval in Canada for Tivicay™ (dolutegravir) 50-mg tablets, an Integrase Strand Transfer Inhibitor indicated for use in combination with other antiretroviral agents for the treatment of human immunodeficiency virus (HIV) infection in adults and children 12 years of age and older and weighing at least 40 kg.¹

“HIV is a complicated and devastating disease,” said Gregory Reinaud, General Manager Canada, ViiV Healthcare. “Through ongoing research, our singular focus is to support people living with HIV by providing new treatment options. The life expectancy of Canadians living with HIV has never been higher, and so the choice of long-term treatment is more sensitive and challenging than ever. Today’s Health Canada approval of Tivicay demonstrates ViiV Healthcare’s absolute commitment to the HIV/AIDS response both globally and here at home.”

Since HIV reporting began in Canada in 1985, a total of 74,174 Canadians have been diagnosed with HIV.² According to a 2010 survey, of those people being treated for HIV, over one-third (36%) in North America did not like how their medicines made them feel.³

The data submitted in support of the use of Tivicay included results from a comprehensive program of non-clinical studies, clinical pharmacology studies, and four pivotal phase III clinical trials that covered the HIV treatment spectrum, and included data in children aged 12 years and older. Canadian trial sites were located in Vancouver, Calgary, Edmonton, Winnipeg, Hamilton, Toronto, Ottawa and Montreal. Tivicay was used without a pharmacokinetic boosting agent. Tivicay can be taken with or without food and at any time of the day.

“In many regimens, the differentiating component is the third agent. Tivicay provides a new opportunity for healthcare professionals to choose the right regimen for their patients, providing a focal point around which to individualize therapy,” said Dr John Pottage, Chief Medical Officer, ViiV Healthcare. “HIV treatment should not be a ‘one-size fits all’ paradigm.”

The indication in children aged 12 years and older is based on an evaluation of safety, pharmacokinetics and efficacy of a once-daily Tivicay-based regimen through 24 weeks in a multi-centre, open-label trial in patients who had not previously been treated with integrase inhibitors.¹

“As HIV has become a chronic disease, and people now are living for a long time with the disease, we know that new medicines will always be needed. At ViiV Healthcare we listen to patients and physicians to truly understand the unmet needs in HIV. Today’s approval of Tivicay is the first medicine from the ViiV Healthcare pipeline, and I look forward to seeing the future developments of our HIV science,” said Pottage.



About Tivicay™ (dolutegravir)

Tivicay is an integrase inhibitor indicated for use in combination with other antiretroviral agents for the treatment of HIV in adults and children aged 12 years and older.¹ Integrase inhibitors block HIV replication by preventing the viral DNA from integrating into the genetic material of human immune cells (T-cells).¹ This step is essential in the HIV replication cycle and is also responsible for establishing chronic infection.¹

It is available as a small, yellow, 50-mg tablet and can be taken with or without food, and at any time of the day.¹

Tivicay is the first new treatment delivered globally and in Canada by ViiV Healthcare.

About ViiV Healthcare

ViiV Healthcare is a global specialist HIV company established in November 2009 by GlaxoSmithKline (LSE: GSK) and Pfizer (NYSE: PFE) dedicated to delivering advances in treatment and care for people living with HIV. Shionogi joined as a 10% shareholder in October 2012. The company's aim is to take a deeper and broader interest in HIV/AIDS than any company has done before and take a new approach to deliver effective and new HIV medicines, as well as support communities affected by HIV. For more information on the company, its management, portfolio, pipeline, and commitment, please visit www.viivhealthcare.ca.

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GlaxoSmithKline cautionary statement regarding forward-looking statements: GSK cautions investors that any forward-looking statements or projections made by GSK, including those made in this announcement, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Factors that may affect GSK's operations are described under Item 3.D "Risk factors" in the company's Annual Report on Form 20-F for 2012.

References

¹ Tivicay Canadian Product Monograph. ViiV Healthcare. 2013.

² Government of Canada – HIV and AIDS in Canada: Surveillance Report to December 2011. <http://www.phac-aspc.gc.ca/aids-sida/publication/survreport/2011/dec/index-eng.php>. Accessed September 2013.

³ ATLAS Global Report, April 2010.