PRESS RELEASE

March 24, 2014

**Tivicay® Tablets 50mg, HIV Integrase Inhibitor obtains approval in Japan**

New Treatment Option for Treatment-naïve Patients and Patients –Requiring an Alternative to Current Treatment Regime

ViiV Healthcare K. K. (Head Office: Tokyo; President: Hirohisa Iriyama) is pleased to announce today that it obtained approval by the Ministry of Health, Labour and Welfare (MHLW) on March 24, 2014 for the marketing of HIV Integrase Inhibitor Tivicay® Tablets 50mg (nonproprietary name: dolutegravir sodium) with an indication for the treatment of HIV infection.

At the same time, ViiV and Shionogi & Co., Ltd. (Head Office: Osaka; President & CEO: Isao Teshirogi, Ph.D.), in accordance with the Co-promotion Agreement in Japan concluded as of December 16, 2013 for this product, are starting today to jointly provide medical information on Tivicay® Tablets 50mg to medical institutions. The distribution and sales operations will be conducted by GlaxoSmithKline K. K. (Head Office: Tokyo; President: Philippe Fauchet), in the same way as for existing products of ViiV in Japan.

Tivicay® Tablets 50mg is a novel HIV integrase inhibitor discovered through collaborative research and development by Shionogi, GlaxoSmithKline (GSK, Head Office: London; Chief Executive Officer: Andrew Witty) and ViiV Healthcare Ltd (Head Office: London; Chief Executive Officer: Dr. Dominique Limet). ViiV Healthcare Ltd holds the global development and sales rights of Tivicay® Tablets 50mg, which was approved in the U.S. in August 2013 and in Europe in January 2014, with an indication for the treatment of HIV infection. In Japan, it was designated by the MHLW as an orphan drug on September 13, 2013, with an expected indication for the treatment of HIV infection, followed by filing of the marketing application by ViiV on December 5, 2013 for the treatment of HIV infection.

**Product Characteristics of Tivicay® Tablets 50mg**

- Tivicay® Tablets 50mg, an integrase inhibitor, prevents replication of HIV by potently inhibiting the activity of integrase, which incorporates HIV DNA into the chromosomes of human immune cells.
- Clinical studies outside Japan demonstrated favorable virological effect and tolerability of this product in patients previously treated or untreated with anti-HIV agents. There is evidence that it is less likely to cause drug-resistant viruses to develop.
Tivicay® Tablets 50mg can be orally administered once daily without regard to meals, while eliminating the necessity of adding pharmacokinetic booster; thus, improved adherence can be anticipated.

1 For patients resistant to HIV integrase inhibitors, 50 mg of dolutegravir should be orally administered twice daily.

“ViiV is pleased to obtain the approval, which enables us to deliver Tivicay® Tablets 50mg as a new treatment option to Japanese patients living with HIV as a company dedicated to HIV medications,” said Hirohisa Iriyama, President of ViiV, regarding the approval. “Despite significant improvement of HIV medications, there remain unmet medical needs with existing drugs. We believe that Tivicay® Tablets 50mg will offer a significant treatment option as a new integrase inhibitor to overcome the therapeutic challenges.”

Isao Teshirogi, President & CEO of Shionogi, said, “Shionogi took part in researching and developing of Tivicay® Tablets 50mg jointly with GlaxoSmithKline and ViiV Healthcare over the years. It enables once-daily administration in low dosages and is less likely to cause drug-resistant viruses to develop, making it an innovative novel drug that can significantly contribute to treating HIV-positive patients who need to take medicines over the long term. With our experience and achievements in the promotion of proper use of anti-infective agents, Shionogi is determined to make efforts to fulfill the unmet medical needs of Japanese patients through the synergistic effect from collaboration with ViiV, a specialist HIV company.”

ViiV and Shionogi aim to contribute further to HIV treatment by providing Tivicay® Tablets 50mg to healthcare professionals and HIV patients in Japan as soon as possible through the co-promotion of this product.

About Tivicay® Tablets 50mg

<table>
<thead>
<tr>
<th>Product name</th>
<th>Tivicay® Tablets 50mg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nonproprietary name</td>
<td>Dolutegravir sodium</td>
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<tr>
<td>Approval date</td>
<td>March 24, 2014</td>
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<tr>
<td>Indication</td>
<td>HIV infectious disease</td>
</tr>
</tbody>
</table>

Dosage and administration

- Usually in adults, dolutegravir is orally given as described below. The drug may be given without regard to meals. It should be given with other anti-HIV drugs.
  1. Treatment-naïve patients and patients who experienced treatment with other anti-HIV drugs than integrase inhibitors: Dolutegravir is orally given at a dose of 50 mg once daily.
  2. Patients with integrase inhibitor resistance: Dolutegravir is orally given at a dose of 50 mg twice daily.
- In treatment-naïve patients who are aged 12 years or older weighing 40 kg or more, and pediatric patients who experienced treatment with other anti-HIV drugs than integrase inhibitors, dolutegravir may be orally given at a dose of 50 mg once daily.
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. ViiV Healthcare K. K. is the Japanese subsidiary of ViiV Healthcare in the UK. For more information on the company, please visit [http://glaxosmithkline.co.jp/viiv/](http://glaxosmithkline.co.jp/viiv/).

About Shionogi & Co., Ltd
Headquartered in Osaka, Japan, Shionogi & Co., Ltd. is a major research-driven pharmaceutical company dedicated to placing the highest value on patients. Shionogi's Research and Development currently targets three therapeutic areas: Infectious Diseases, Pain, and Metabolic Syndrome. The Company is the originator of innovative medicines which have been successfully delivered to millions of patients worldwide. In addition, Shionogi is engaged in new research areas such as allergy and cancer. Contributing to the health of patients around the world through development in these therapeutic areas is Shionogi's primary goal. For more details, please visit [www.shionogi.co.jp](http://www.shionogi.co.jp).

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<thead>
<tr>
<th>Marketing authorization holder</th>
<th>ViiV Healthcare K.K.</th>
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<tbody>
<tr>
<td>Distributor</td>
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