



**New Agreement to Commercialize and
Develop HIV Integrase Inhibitor
Portfolio with ViiV Healthcare**

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 **SHIONOGI & CO., LTD.**



1. New Alliance Scheme with ViiV Healthcare

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- New Alliance Scheme
- Global HIV Market and Profile of Dolutegravir
- Background and Contract Detail

2. Financial impact for Shionogi

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Finance & Accounting

3. Summary

Isao Teshirogi, Ph.D., President & CEO

4. Q&A



New Alliance Scheme

New Alliance Scheme



- **Restructuring Integrase Alliance between Shionogi and ViiV**
 - **Shionogi-ViiV Healthcare LP (JV)'s rights to the integrase inhibitor franchise products are transferred to ViiV Healthcare**
 - **Shionogi becomes a 10% shareholder in ViiV with Board representation**
 - **Shionogi Limited (UK subsidiary) receives dividends from ViiV**
 - **Shionogi receives royalty^{*1} on net sales of integrase inhibitor portfolio, averaging in high teens**

***1:** Royalty levels are identical for dolutegravir (DTG) and Triii, fixed-dose combination of DTG plus Epzicom. For a defined period post-launch, as the franchise is becoming established, the royalty applies to sales above certain minimum thresholds

Global HIV Market



- **Global sales of anti-HIV drugs will reach to \$20B in 2017 at an annual growth rate of 1-2%. Top 3 companies represent about 70% of the market: Gilead (\$7.6B), ViiV (\$2.4B) and BMS (\$1.8B)**
- **ViiV is the 2nd largest company in the HIV area with a global HIV portfolio that includes Epzicom (\$1B) and Combivir (\$500M)**
- **Current blockbusters include Atripla and Truvada (Gilead), Reyataz (BMS) and Isentress (Merck). Future market changes are expected, however, due to patent expirations and upcoming launches, including DTG**

Profile of Dolutegravir (DTG)



- **Strong anti-HIV activity**
- **Unlikely to produce drug resistant virus**
- **Low cross-resistance**
- **Good pharmacokinetics**
- **Can administer with most of anti-HIV drugs without dose adjustment**

**Completion of the initial clinical registration package
from 4 phase III studies
(Press release on October 4, 2012)**

Background to the New Scheme (1)



- **September 2001:**

Shionogi and GSK established a joint venture of Shionogi-GSK Healthcare LP involving compounds in multiple therapeutic areas

- **Shionogi held a call option for acquiring the entirety of the joint venture**

- **August 2002:**

Shionogi and GSK started collaborative research programs on HIV integrase inhibitor

- **October 2009:**

GSK and Pfizer established ViiV (GSK/Pfizer; 85/15) by contributing their anti-HIV drug related assets. GSK transferred the equity of Shionogi-GSK Healthcare LP to ViiV, creating Shionogi-ViiV Healthcare LP

Background to the New Scheme (2)



- **The new agreement reflects the evolution of the business environment and of Shionogi itself**
 - **Progression of integrase inhibitors in the original JV took longer than originally expected, requiring extensive efforts under the collaborative research program to produce DTG and related compounds**
 - **Shionogi now has its own US sales infrastructure, Shionogi Inc., following the Sciele Pharma acquisition**
 - **SI's business model and therapeutic focus areas do not include anti-HIV drugs**
 - **The JV now has only HIV integrase inhibitors as its assets**

Difference between the Two Schemes (1)



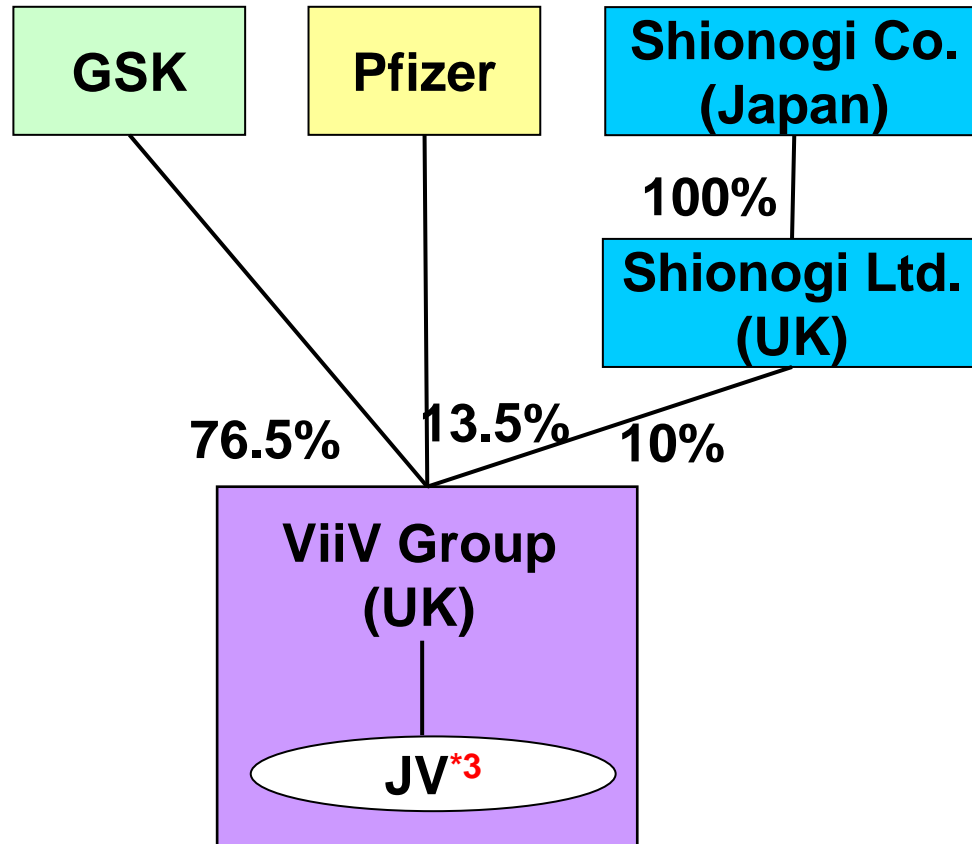
	Former contract	New scheme
Royalty and financial condition	<ul style="list-style-type: none"> ■ Royalty rate depends on sales amount and territories • JV territory (US and potentially EU5); JV sells products, and the profit is shared on a 50/50 basis, in principle. An originator receives the royalty depending on the sales amount • Shionogi territory (Japan and Taiwan); were under discussion in former contract • ViiV territory (ROW); ViiV sells products in principle, and pays royalty ■ In case of combination products such as Trii, JV profit share and royalty is calculated by the proportion of DTG in the combination ■ Shionogi holds call option for acquiring the JV. The option could be conducted anytime after 10 years since the JV established, or after 12 years since the first product was launched or sales exceed a certain amount 	<ul style="list-style-type: none"> ■ Shionogi receives royalty averaging high teens ■ Shionogi becomes a 10% shareholder of ViiV and receives dividends ■ Royalty is the same for DTG and Trii ■ Shionogi has no call option

Difference between the Two Schemes (2)



	Former contract	New scheme
R&D and SG&A expenses	<ul style="list-style-type: none"> Both Shionogi and ViiV pay on a 50/50 basis 	<ul style="list-style-type: none"> ViiV pays all of expenses in the future
Commercial scheme	<ul style="list-style-type: none"> US; JV establishes its subsidiary EU5; Option to establish a subsidiary for commercialization by JV. If not conducting the option, ViiV sells and royalty scheme applies Japan and Taiwan; approach was under discussion ROW; ViiV sells products 	<ul style="list-style-type: none"> ViiV sells products globally

Background and Contract Detail



*3: Shionogi held 50% rights in the former contract

- Shionogi Ltd (SL) becomes a 10% shareholder in ViiV and receives dividends
- Shionogi receives royalties on net sales of all integrase inhibitor franchise products
- ViiV is functionally and financially responsible for the global development and commercialization of integrase inhibitor franchise products



Financial Impact for Shionogi

Financial Impact for Shionogi (1)



- **FY2012**
 - **Difference between book value of equity interest in JV and value of equity share in ViiV will be allocated as extraordinary income**
 - **Income and losses may be allocated on the re-evaluation of other assets such as goodwill**
 - **JV development costs will not be incurred after the new agreement**
- **FY2013**
 - **Royalty income after the launch of DTG**
 - **Development costs, SG&A expenses will be reduced**
 - **A proportional share of dividends from ViiV**
 - **Amortization of goodwill and other intangible assets may be reduced**

Financial Impact for Shionogi (2)

Changing the Treatment of “Goodwill”



- **Goodwill from acquiring Sciele Pharma (now Shionogi Inc.) has been amortized by the whole Shionogi group so far, based on the intent to globally commercialize products from our R&D pipeline**
- **DTG will not be commercialized by Shionogi in the US based on this new alliance scheme. Shionogi Inc. is focused only on the US market, and it will require some time before we are ready to commercialize our internal pipeline products in the US**

Financial Impact for Shionogi (3)

Changing the Treatment of “Goodwill”



- Based on the background mentioned above, the grouping for the amortization of goodwill will be changed from the whole Shionogi group to our US business only.
- After changing the grouping, re-evaluation of goodwill will be conducted based on the earnings anticipated from the US business in the future
- On this occasion, re-evaluation of the sales rights of current US business will be conducted for re-allocation of the investment in the US business

*** Above re-evaluation of the goodwill and sales rights should be conducted after the results of review process regarding the earnings of the US business in the future and need a certain period for calculation**

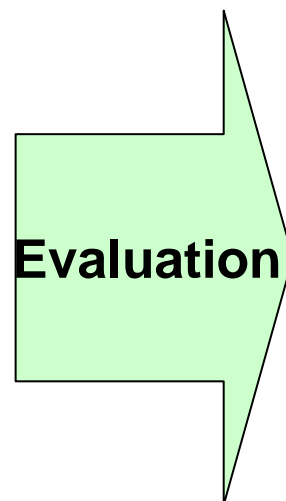
Financial Impact for Shionogi (4)



- Appraised value of ViiV shares will be booked on the balance sheet
- Other assets such as goodwill and sales rights will also be re-evaluated

Consolidated balance sheet

Investment Securities (equity interest of JV) Book Value	Liabilities
Goodwill Sales Rights	
Other Assets	Net Assets



Consolidated balance sheet

Investment Securities (Shares of ViiV) Appraised Value	Liabilities
Goodwill Sales Rights	
Other Assets	Net Assets



Summary



- **Shionogi continues to contribute to maximize DTG's potential, and thus the value of the royalty stream, through our Board representation and continued involvement in formulating development and commercialization plans**
- **Shionogi (SL) has rights to a proportional share of any ordinary dividends paid as a 10% shareholder in ViiV, not only from the integrase inhibitor franchise. SL can invest in the development of our pipeline products in Europe**
- **Shionogi can focus its resources, and accelerate the progress, of its other future growth drivers, such as ospemifene, S-297995, S-555739, and the cancer peptide vaccines**

Forward-Looking Statements



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