KDB Daewoo Securities

Healthcare
(Overweight/Maintain)

Healthcare Weekly Briefing

Sector Briefing
October 8, 2015

Daewoo Securities Co., Ltd.

[Healthcare]

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1. Major issues

Dong-A ST's Suganon Tab obtained domestic approval (October 4th)

On October 2nd, Dong-A ST gained approval from the Ministry of Food and Drug Safety for Suganon Tab, an in-house developed diabetes treatment.

Suganon Tab is a supplementary drug to help type 2 diabetes patients control blood glucose levels. Patients take one tablet a day, regardless of food intake. Suganon Tab stimulates insulin by inhibiting DPP-4 (a protein that decomposes the insulin-stimulating incretin hormones), thus facilitating the process of glucose removal.

Suganon Tab is now the ninth DPP-4 inhibitor to obtain domestic approval. The drug's release is anticipated for 1H16, after the registration process.

We are optimistic about the commercial success of Suganon Tab, considering that: 1) only a small dose is needed for the drug to have an effect; 2) patients experiencing kidney failure can take the drug without adjusting the dose; and 3) the drug has limited metabolic interactions with other drugs.

Dong-A ST has also filed for approval for Suganon Complex, another drug using the same ingredient; as such, the Suganon pipeline is likely to improve, contributing to revenue growth.

Full-swing sales of Suganon Tab should boost revenue at the company's hospital business.

The company has secured overseas partners for the drug in major emerging nations, and thus, if the drug is commercially successful, it will likely provide a boost to the company's fundamentals over the medium to long term.

Table 1. Overview of Suganon Tab

	Details
Product	Suganon Tab 5mg (evogliptin tartaric acid)
Effects	Helps type 2 diabetes patients control blood glucose levels
Usage	Patients take one tablet a day regardless of food intake
Mechanism	Stimulates insulin by inhibiting DPP-4, a protein that decomposes the insulin-stimulating incretin hormones
Clinical data	Five phase 1 trials, one phase 2 trial, and two phase 3 trials

Source: Ministry of Food and Drug Safety, KDB Daewoo Securities Research

Table 2. Overview of phase 3 clinical trials for Suganon Tab

	Details
Major phase 3 clinical trial (1)	- A phase 3 randomized, placebo-controlled, double-blind clinical trial - 160 subjects (80 evogliptin takers; 80 placebo subjects) - Tested the safety and effectiveness of evogliptin for type 2 diabetes patients who cannot adjust blood glucose levels through diet and exercise alone
Major phase 3 clinical trial (2)	- A phase 3 randomized, double-blind, active-controlled (sitagliptin 100mg) clinical trial - 222 subjects (112 evogliptin takers; 110 sitagliptin takers) - Tested the safety and effectiveness of evogliptin for type 2 diabetes patients who cannot adjust blood glucose levels through metformin intake
Major phase 3 clinical trials (1 & 2)	- Evogliptin 5mn showed a stronger effect on type 2 patients than placebo - Evogliptin 5mn showed a stronger effect on type 2 patients than sitagliptin 100mg

Source: Ministry of Food and Drug Safety, KDB Daewoo Securities Research

Table 3. DPP-4 inhibitor products in Korea

Product	Januvia	Galvus	Onglyza	Trajenta	Zemiglo	Nesina	Tenelia	Gadlet	Suganon
Manu-facturer	MSD	Novartis	BMS	Boehringer Ingelheim	LG Life Sciences	Takeda Korea	Handok	JW Pharma-ceutical	Dong-A ST
Seller	MSD Korea, Daewoong	Novartis Korea, Hanmi	AstraZeneca Korea, Il dong	Boehringer Ingelheim, Lilly Korea, Yuhan	LG Life Sciences, Sanofi Aventis Korea	Takeda Korea, Cheil	Handok	JW Pharma-ceutical	Dong-A ST
Ingredients	Sitagliptin	Vildagliptin	Saxagliptin	Linagliptin	Gemigliptin	Alogliptin	Teneligliptin	Anagliptin	Evogliptin
Dose(s)	25mg, 50mg, 100mg	50mg	2.5mg, 5mg	5mg	50mg	12.5mg, 25mg	20mg	100mg	5mg

Source: KDB Daewoo Securities Research

Table 4. Approved drugs developed by domestic pharma and biotech firms

	Drug	Company	Active ingredient	Indication	Approval date
1	Sunpla	SK Chemicals	Heptaplatin	Gastric cancer	7/15/1999
2	Easyef	Daewoong	Human epidermal growth factor	Diabetic foot ulcers	5/30/2001
3	Milican	Dong Wha	Holmium nitrate-66	Liver cancer	7/6/2001
4	Q-Roxin	JW Pharmaceutical	Balofloxacin	Antibiotic	12/17/2001
5	Factive	LG Life Sciences	Methanesulfonate	Antibiotic	12/27/2002
6	Apitoxin	Guju Pharm	Dried apitoxin	Arthritis	5/3/2003
7	Pseudovaccin	CJ HealthCare	Dried purified vaccine	Pseudomonas aeruginosa vaccine	5/28/2003
8	Camtobell	Chong Kun Dang	Belotecan	Cancer	10/22/2003
9	Revanex	Yuhan	Revaprazan	Ulcers	9/15/2005
10	Zydena	Dong-A ST	Udenafiil	Erectile dysfunction	11/29/2005
11	Revovir	Bukwang	Clevudine	Hepatitis B	11/13/2006
12	Pelubi	Daewon	Pelubiprofen	Osteoarthritis	4/20/2007
13	Mvix	SK Chemicals	Mirodenafil hydrochloride	Erectile dysfunction	7/18/2007
14	Noltec	Ilyang	Ilaprazole	Ulcers	10/28/2008
15	Kanarb	Boryung	Fimasartan potassium trihydrate	Hypertension	9/9/2010
16	Pyramax	Shin Poong	Pyronaridine phosphate, artesunate	Malaria	8/17/2011
17	Zepeed	JW Pharmaceutical	Avanafil	Erectile dysfunction	8/17/2011
18	Supect	Ilyang	Radotinib hydrochloride	Leukemia	1/5/2012
19	Zemiglo	LGLS	Gemigliptin	Diabetes	6/27/2012
20	Duvie	Chong Kun Dang	Lobeglitazone sulfate	Diabetes	7/4/2013
21	Riavax	GemVax & KAEL	Tertomotide hydrochloride	Pancreatic cancer	9/15/2014
22	Acelex	Crystal Genomics	Polmacoxib	Osteoarthritis	2/5/2015
23	Zabolante	Dong Wha	Zabofloxacin D-asparticacid	Antibiotic	3/20/2015
24	Sivextro oral	Dong-A ST	Tedizolid phosphate	Antibiotic	4/17/2015
25	Sivextro IV	Dong-A ST	Tedizolid phosphate	Antibiotic	4/17/2015
26	**Suganon**	**Dong-A ST**	**Evogliptin**	**Diabetes**	**10/2/2015**

Source: MFDS, KDB Daewoo Securities Research

Figure 1. Global partners for evogliptin

Company	Details
LUYE PHARMA 绿叶制药	Licensed out to Luye Pharma Group for Chinese market in 2012
ALKEM	Licensed out to Alkem Laboratories of India for the Indian and Nepali markets in 2012
Eurofarma Ampliando horizontes	Licensed out to Eurofarma of Brazil for the Brazilian market in 2014 and for the 17 Latin American countries in 2015
ГЕРОФАРМ	Licensed out to Geropharm of Russia for the Russia, Ukraine, and Kazakhstan markets in 2015

Source: Dong-A ST, KDB Daewoo Securities Research

Reaching of agreement on the Trans-Pacific Partnership (October 5th)

The Trans-Pacific Partnership (TPP) is likely to encourage the development of innovative medicines and the expansion of generics, creating a favorable environment for domestic makers of new drugs and incrementally modified drugs (IMD).

The TPP trade deal proposes shortening the exclusivity period for biotech drugs. The deal will likely introduce a data protection period of five years (the US currently allows 12 years of data exclusivity), combined with other government measures to ensure adequate market protection.

The shorter data protection period is unlikely to affect the commercial potential of biotech drugs whose remaining patent terms are longer than the data protection period. And we do not believe this issue will affect domestic healthcare firms, as no domestic firm sells biotech drugs in the US.

Table 5. TPP press conference excerpt related to exclusivity of biologics

Transcript
QUESTION: Krista Hughes from Reuters. I just wanted to follow up on the comment about the biologics. Mr. Froman, you said there was a minimum standard. What is the minimum standard that you agreed? And perhaps Minister Robb also has a perspective on that. AMBASSADOR FROMAN: Yes. So Krista, I think as we have talked about, and I think as Minister Robb was quoted in the press today, I think very articulately, there was a recognition of the importance of innovation, of the importance of having effective market protection for encouraging innovation, and a recognition that there may be multiple ways of achieving that. **So for some of us in our systems, we have – we use data protection as the method for creating effective market protection, and we have in our – the United States of course 12 years, in some of the other countries eight or 10 years. What we're doing in TPP is recognizing that we're all trying to achieve that effective market protection and deliver a comparable outcome through various mechanisms, including at least 5 years of data protection plus other government measures that can achieve a comparable outcome.** And I think that was a long and hard discussion among all the parties around the table, reflecting different levels of development – different levels of development of the pharmaceutical and biotech industry. And the outcome, I believe, both encourages and incentivizes those – the innovation around important, lifesaving medicines and treatments and ensures access to affordable medicines more broadly around the world. […] Krista, can I just add – just want to make the point that what we're talking about is ensuring that there's that effective market protection. And again, we do it in the United States through 12 years of data protection. But even countries that have a lower level – a lower period of data protection through their regulatory measures, their administrative measures, their requirements for perhaps additional clinical trials or their inspection of manufacturing plans or the various steps that they go through – as Minister Robb said earlier today, it may take seven or eight years beyond the five years of data protection for the various biosimilars to be approved. And so our goal is whether you're doing it one way or the other, one stream or another, is to have a comparable outcome in terms of incentivizing innovation and at the same time ensuring access to affordable medicines.

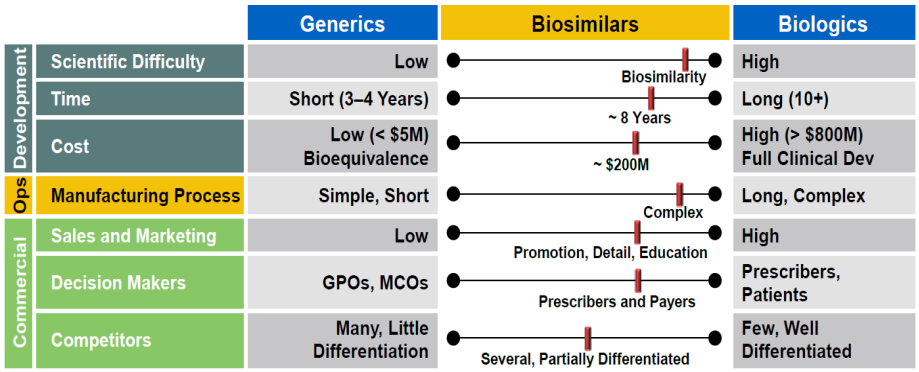
Source: United States Trade Representative, KDB Daewoo Securities Research

Amgen's presentation at the Barclays Biosimilars Symposium (October 7th)

During its presentation at Barclays' biosimilars conference on October 7th, Amgen asserted that, as the biosimilar standard is very similar to that of original drugs in the US, there should be no significant clinical difference between biosimilars and original drugs.

The company also said that its new biosimilar business will largely resemble its existing biologics business.

Figure 2. Biosimilars business is similar to biologics business: Success requires in-depth technical capabilities and strong commercial branding ability



Notes: GPO = group purchasing organization; MCO = managed care organization
Source: Amgen, KDB Daewoo Securities Research

US prescriptions for Dong-A ST's Sivextro

US Sivextro prescriptions for the week ending September 25th came in at US$178,862 (+11.8% WoW).

Actual revenue from Sivextro reached US$2.4mn in 3Q14 and US$3.6mn in 4Q14. And 1Q15 revenue is believed to have outstripped the 4Q14 figure.

Solid July and August figures suggest that the generic versions of Zyvox have barely affected Sivextro prescriptions. (Pfizer's patent for Zyvox expired in May this year.) Record-high prescriptions in August seem to have been driven by increased hospital coverage. Prescriptions for 3Q15 will also likely hit a historic high.

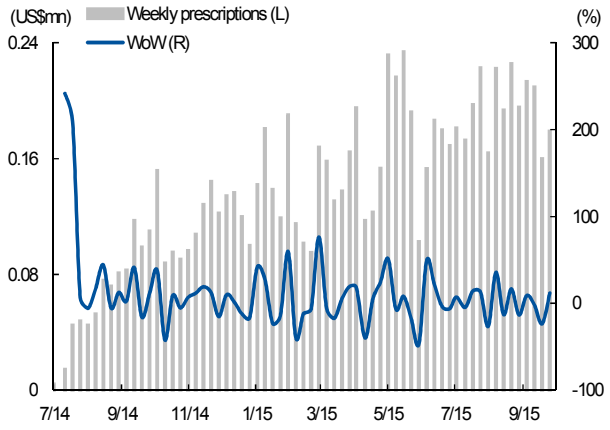
Sivextro was approved and launched in June 2014. US Sivextro prescriptions are expected to continue to trend up QoQ, in line with rising usage in US hospitals.

Merck became the US marketing partner for Sivextro following its acquisition of Cubist Pharmaceuticals (the original partner) in December 2014. The M&A deal was completed in 1Q. Considering Merck's extensive global marketing network, the commercial potential of Sivextro appears huge.

We believe the availability of Zyvox generics will have only a limited impact on Sivextro prescriptions, given that Sivextro is an original drug that is prescribed in general hospitals.

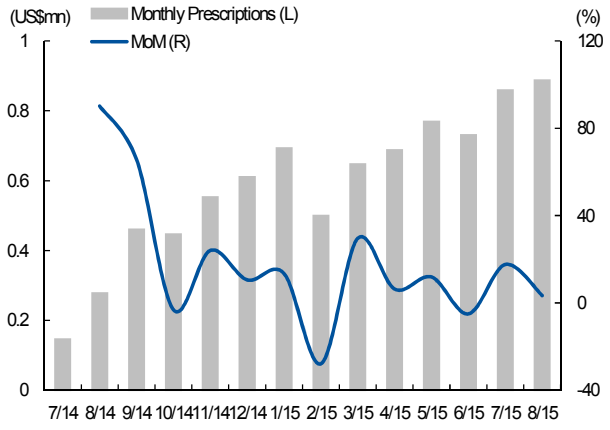
Sivextro was launched in the UK in June. In 2H, we expect the drug to be introduced in more European countries and prescriptions in the region to increase further. This will result in increased running royalties for Dong-A ST.

Figure 3. Weekly US Sivextro prescriptions



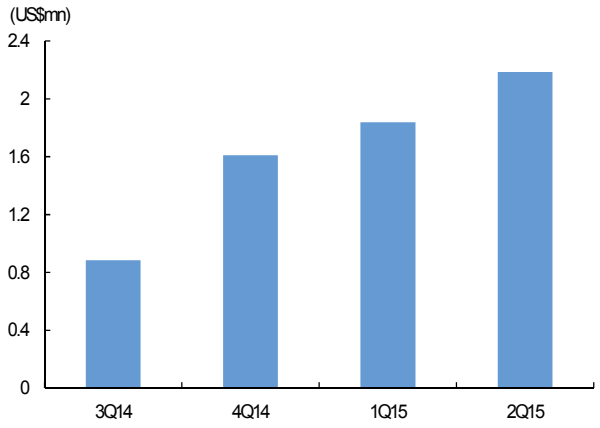
Source: Bloomberg, KDB Daewoo Securities Research

Figure 4. Monthly US Sivextro prescriptions



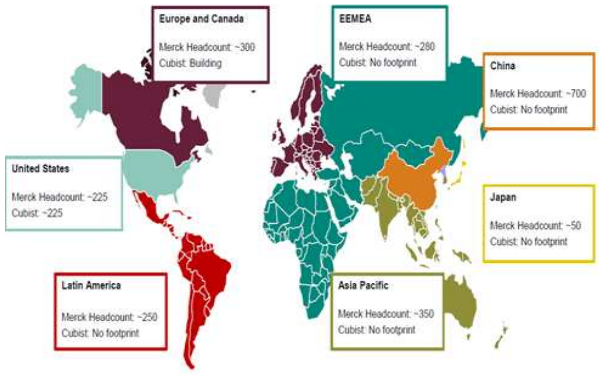
Source: Bloomberg, KDB Daewoo Securities Research

Figure 5. Quarterly US Sivextro prescriptions



Source: Bloomberg, KDB Daewoo Securities Research

Figure 6. Global reach of Merck and Cubist



Source: Merck, KDB Daewoo Securities Research

Figure 7. Sivextro: First MRSA antibiotic proven to be effective with less than one week of treatment

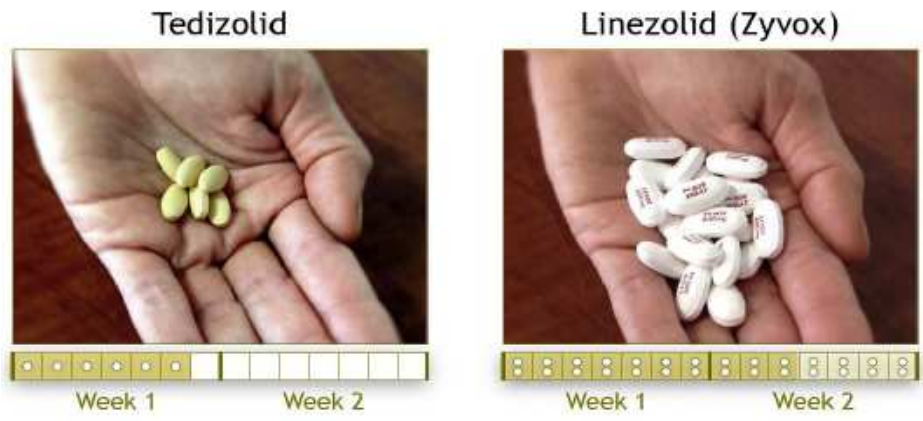
Attribute	Zyvox®	Vancomycin	SIVEXTRO
IV/Oral	✓	✗	✓
Active in Lung Infections	✓	✓	✓
Once Daily Treatment	✗	✗	✓
Less than 1 week of Therapy*	✗	✗	✓

Pfizer Generic CUBIST

* First MRSA antibiotic proven successful in Phase 3 with 6 days of therapy

Source: Dong-A ST, KDB Daewoo Securities Research

Figure 8. Dosage comparison: Sivextro vs. Zyvox



Source: Dong-A ST, KDB Daewoo Securities Research

Figure 9. Global partners for Sivextro

US: Merck launched SIVEXTRO after winning FDA approval in June 2014

EU : Merck received approval from EMA in March 2015 and launched Sivextro in UK in June 2015

Korea : Dong-A ST received approval from MFDS in April 2015

RoW : Bayer holds the right to develop and sell Sivextro outside of Korea, US and EU (currently phase 3 in China and Japan)

Source: Dong-A ST, KDB Daewoo Securities Research

II. Published reports

LG Life Sciences, "Benefiting from product mix improvements" (October 5th)

III. Upcoming events and issues

Johnson & Johnson to release 3Q earnings (October 13th)

Updates on Remicade revenue and competition with Celltrion's Remsima in Europe

September outpatient prescription data (October 15th)

Domestic ethical (ETC) drug market update

Record date for SK Chemicals' new shares issuance (October 16th)

DIO's NDR in Asia (sponsored by KDB Daewoo Securities)

IV. Company visits

PharmaResearch Products (October 5th)

PharmaResearch Products added Rejuran (a tissue regeneration filler) and Rejuvenex (a tissue regeneration activator) to its product lineup. Going forward, it plans to sell eye drops and intra-articular injections.

The firm started to export Rejuran to Japan at end-2014, positioning the product in the premium market segment.

It is also seeking to partner with a Chinese company to market the product in China, where demand for new pharmaceutical ingredients is high.

* Rejuran's performance will be a key determinant of the firm's medium- to long-term earnings. And entry into the Chinese market has the potential to boost the firm's fundamentals markedly.

Whanin Pharmaceutical (October 6th)

Whanin Pharmaceutical is the domestic distributor and seller of Allergan's Botox as well as fillers. The company is expected to record profits from sales of such products starting next year.

The company is seeing solid growth in sales of other ETC drugs, including psychiatric and neurologic drugs. Concerning such drugs, the mental health promotion bill, which is now pending in the National Assembly, deserves attention.

The company plans to introduce functional cosmetics in 1H16.

Whanin Pharmaceutical holds a 9.3% stake in Vivozon (unlisted), which is developing a non-narcotic analgesic drug (currently in phase 2 clinical trials in the US).

* If the mental health promotion bill is passed by the National Assembly, prescriptions of psychiatric and neurologic drugs should increase in Korea. In addition, progress in Vivizon's development of a non-narcotic analgesic drug should help improve Whanin's EV.

Hanmi Pharmaceutical (October 7th)

Hanmi's 3Q earnings are expected to reflect a large proportion of sales of a generic version of Cialis. In addition, an out-licensing deal for an EGFR inhibitor (lung cancer treatment) generated an upfront payment that will be shared with Hanmi Science. (Proportions have not yet been decided.)

Hanmi Pharmaceutical is seeking overseas partners for its IMD Rosuzet (a conjugate of rosuvastatin and ezetimibe, hyperlipidemia treatments) as well as out-licensing for a new persistent diabetes medicine called the Quantum Project.

* The company is looking for overseas partners for a number of in-house developed drugs in the pipeline. In particular, an out-licensing deal for the Quantum Project would significantly boost the company's medium- to long-term earnings.

LegoChem Biosciences (October 8th)

LegoChem Biosciences announced that it will merge with Khanmed. The deal should help the company to generate stable cash flow.

The company is seeking overseas partners for its antibody-drug conjugate (ADC).

LegoChem developed an antibiotic (a beta lactamase inhibitor targeting gram negative bacilli). The company is scheduled to carry out toxicity tests for its BLI and conjugates soon.

* The merger with Khanmed should stabilize the company's earnings. And if it is successful in finding partners for its ADC and antibiotic drugs, the company's medium- to long-term fundamentals should improve sharply.

APPENDIX 1

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