Daehwa Pharmaceutical – Lee Han-Koo, President – South Korea

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Lee Han-Koo, president of Daehwa Pharmaceutical, explains his strategy to corner the transdermal drug delivery system (TDDS) market through innovative patch products as well as a special focus on oral anticancer medication.

Could you briefly introduce our readers to Daehwa?

Daehwa was founded in January 1984 and listed on the KOSDAQ since 2002. Today, we are running three factories for production and three laboratories for R&D, as well as one overseas Representative office in Vietnam. Daehwa also has four subsidiary companies.

For production, the first and second factories are located at Hoengseong-Gun in Gangwon-Do. The first factory is specialized for the manufacturing of oral formulation products, and the second factory is specialized to manufacture TDDS products. Our thirds factory is located at Hyangnam-Eup in Gyeonggi-Do and is specialized in the synthesis of active pharmaceutical ingredients (APIs) and manufacturing health supplementary products.

For the R&D, Daehwa's main R&D center is located in the Pangyo Biotechnology Area, and each factory site runs laboratories separately. With these three laboratories, we are researching and developing new drugs, drug delivery systems, and natural medicines among other things.

Furthermore, we have four subsidiary companies as follows: C-Tri Pharmaceutical Co. as pharmaceutical manufacturer (Mainly Peptide products) / DH Horim Co. as pharmaceutical wholesaler / Redox Bio Co. as synthesis (Mainly Hyaluronic acid) / Specialized Med Co. as medical information system contents service.

What have been biggest challenges over the last few years for you?

Our biggest recent challenge has been Daehwa's main interest, namely anticancer medicine. More specifically, we have a drug called DHP107 which is a newly formulated drug that has historically functioned as an injectable. Daewha has been studying and developing this injection drug to work as an oral drug since 2003. We were supposed to finish Phase III clinical trials by the end of December 2014, but because of a lack of patients, we expect to finish it in January 2015.

What was the reason for converting this drug from an injectable to an oral medication? What unmet need does it fulfill?

Currently, patients who need to take injectable this drug have to spend about half a day waiting in the hospital to get the injection, which can take up to two hours to finish. However, if patients are able to take the same drug orally, patients only need to drop by a hospital to get a prescription, and could rest on where it is most comfortable for them, usually at home.

Considering this point, we started to develop DHP 107, but the API of this drug as an injectable does not dissolve in water. We have tried other solutions that dissolve in alcohol. But the human body is primarily comprised by water. Therefore it was our goal to make this product dissolve in water, as many other companies have also tried but failed. However, Daehwa was able to make DHP107 absorbable by edible oil; but not enough quantity for a first-time treatment. Intestinal tissues tend to split when they absorb more than they can handle. The body absorption rate of DHP107, for which we are currently working, is about 30 to 40 percent. We dissolve the product with edible oil that does not contain any toxic substances. It allows the drug to be absorbed to the necessary amount. When we successfully convert DHP107 to oral drug status, it will make life much easier for patients.

Concomitantly, there is no such thing as a single injection for oncology. One drug has to be used in conjunction with other anticancer drugs, such as enhancers that need to be interactive with each other. DHP107 avoids this situation altogether.

Where are you planning to market this drug?

Firstly, we will market the drug in Korea and then we will move to other countries. At the moment we have 15 patents in 17 countries and we are negotiating with 15 different companies. Daehwa had 217 patients in clinical trials in November 2014, and our goal is to finish this in just a couple of months. The company will arrange the data, which we will submit for approval. It might be possible to get the patent for DHP107 by 2015; otherwise we can expect to receive it in 2016.

In our discussions with the Korean government and associations, we've heard many dreams about Korea creating 20 new drugs by 2020. Could DHP107 be one of those real game changing drugs in the Korean pharmaceutical industry?

I wouldn't call it 'game changer', because it is not an innovative new chemical entity. However, Daehwa's product has the necessary strength that I mentioned, and it will be used effectively by patients.

Daehwa controls about 70 percent of the TDDS market in Korea. How are you using that to your advantage in terms of developing other drugs?

In the United States, this form of drug delivery is referred to as the "patch". In Korea, we define this into three categories: Patch, Plaster, and Cataplasma. Daehwa is trying to make these three categories as the best in the world. Plaster and Cataplasma are locally workable in the body by being attached, but Patch is systemically workable in the body using metabolism.

For Cataplasma, we have actually changed the product slightly. Previously the product suffered from a couple of issues such as detachment and had to be rolled up because of clothes. Korean people used to apply the drug part and adhesive part separately. But now we make it as one.

Anyway, in terms of quality, we want to take a leading role in the world for TDDS.

For new TDDS projects, Daehwa is especially interested in injections without needles. There are cases when patients need a small quantity of drugs continually, and taking these drugs as patches rather than injections is immensely preferable.

What interests do you receive from customers or pharmaceutical companies that want to partner with Daehwa around the world?

We are trying to put patches on the market through preparation of cGMP. Daehwa has already finished building the necessary facilities, and we have conducted biological tests with companies from a diverse set of countries, ranging from Taiwan to the United States. Apart from that, we have trading relationships with more than 30 countries in the world, including regions like Southeast

Asia, South America and Africa. Daehwa is also covering mature markets in Europe like France, in addition to developing markets. Our customers in Poland will deal with the East-European bloc. There are about 0.3 billion people living within 200 kilometers of the Polish border including Russia, and this represents significant market potential for Daehwa.

Our biggest goal in terms of countries is China. We have signed contracts with three companies, and have sent the relevant dossiers and other data, which the Chinese FDA is currently in the process of reviewing.

Daehwa currently exports to 22 countries worldwide. How much more do you expect to expand your international presence around the world given the additional firepower that your cGMP facilities provide?

Of course we will expand to satisfy all people's needs. However, the methods of expanding could be diversified. For example, we have recently signed a technical contract with Iran. We send the products first and will build a plant later. We also will have made our spot in Chengdu. Furthermore, following the market situation and requests, we will expand our business territory to the whole of the world to serve all people for a healthier and happier life.

If we come back in 2020, what would you like to have achieved by then? Will you already be the number one TDDS player in the market?

I expect to see Daehwa in the top 20 by then with about five incrementally modified drugs and one innovative NCE drug. We will try to be number one worldwide in terms of patch products.

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