Seok Joo Lee – CEO, ISU Abxis, South Korea

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ISU Abxis, a subsidiary of the ISU conglomerate, is a biotech company with a focus on orphan drugs and rare disease. CEO Seok Joo Lee explains the rationale behind his decision to transform ISU Abxis' international strategy from targeting developing markets to aiming for developed Western markets, such as the USA. He also offers an insight into the complexity of finding the appropriate expertise when developing orphan drugs for rare diseases.

What was the motivation behind the ISU conglomerate's decision to move, from its original focus on the chemical industry, into biotechnology?

ISU founded its chemical line 50 years ago and is a leading company in Linear Alkylbenzene, a component used in the production of detergents. ISU is the sole producer in Korea and amongst the top 4 producers globally. With continuous interests and concern for biotechnology, ISU chemical is expanding into three kinds of business: red bio – biopharmaceutical, green bio-agriculture, and white bio-industrial. We occupy one of those three main divisions.

In 2000, the group pondered the idea of where it had to expand in order to maintain its growth. ISU Chemical had a division of fine chemicals for pharmaceuticals. Consequently, the most feasible new area for expansion was determined to be biopharmaceuticals. Thus, ISU Abxis was established in 2001. ISU was a very early mover in Korea, focusing on antibodies and enzymes. Throughout this pursuit, ISU Abxis has been forced to overcome several challenging set-backs: in 20 years only

three items have proved successful. Nonetheless, we have learnt and developed significantly through these testing experiences.

The company’s development is based on the willingness of our parent organisation, the ISU group. ISU Chemical has a 32% stake in ISU Abxis and maintains a willingness to provide financial support. Additionally, ISU Chemical has part of a stake in a number of biotech companies: one has a PEGylating technology and others assist in target searching and drug candidate discovery. Through the ISU group, we have a strategic network where we can rely on these partners through ISU Chemical to utilise their technology should it be beneficial to our project development.

You became the CEO of ISU Abxis in November 2016. How has ISU Abxis’ direction and focus changed under your leadership?

I had previously worked for ISU Holdings and other subsidiaries such as chemical, construction, venture capital and a kind of an IT component manufacturing. My main roles at those companies were as a CFO and developing strategies for each department. I am now developing a future strategy for ISU Abxis.

ISU Abxis’ original strategy was to first target emerging markets based on the rapid commercialization of products, with a view to expanding into more developed markets like Europe and the USA at a later date. One of my first initiatives after becoming the CEO was to amend our strategy to target the European and the US markets first, and then the rest of the world.

At this moment our package needs more clinical datasets for major markets. Therefore, ISU Abxis is now beginning to develop at the global standard, operating according to, or even exceeding the regulatory standards of the US FDA and the EMA. Consequently, I am planning to redevelop this package, collecting data from additional clinical trials. At the same time, we are currently seeking for a business partner to break into the US and European markets and have several ongoing projects in the process. My hope is that in the near future we will work with global big pharma for our common interest.

The order of our approach is slightly reversed compared to conventional development: we have already marketed our products and are now commencing the trials. We remain very confident of being able to penetrate these Western markets in the near future, given that our products have displayed safety and efficacy in the five years post-launch.

ISU Abxis distinguishes itself from many Korean Biotech firms in that it has already launched products. What is your current product reach?

We received our first approval from the MFDS for *Clotinab*® in 2006*,* the first antibody therapeutic in Korea. ISU Abxis has also developed two more products which are now marketed: *Abcertin*® for Gaucher disease in 2012 and *Fabagal*® in 2014, treating Fabry disease. These three products were developed too early, so are officially classified as orphan drugs.

ISU Abxis' sales revenue has exceeded USD 17 million, with around 65 percent of revenues generated locally within the Korean market. As the global orphan drug market is estimated to reach USD 262 billion by 2024 and is growing annually by 11.3 percent CAGR, there is significant potential to expand our growth. We have penetrated the Korean market already, and have received approval in 12 overseas emerging markets, including Turkey, Iran, Mexico and Kazakhstan. We are awaiting product approvals in ten more markets, for example, Russia, Argentina, and Algeria. We are yet to receive any approval from the largest markets, namely the US and the EU.

From 2010 we invested more into new research for new drugs and biosimilars and have two projects for new drugs. Our major target new drug is ISU104. This is an anti-cancer drug, targeting ErbB3. We hope that this product will be a first in class product. This candidate is currently undergoing phase I studies. We have already received very promising safety data demonstrating effectiveness. Last year we presented preclinical data at AACR Annual Meeting and hopefully will plan to present interim phase I clinical data at ASCO this year.

The second candidate, ISU304, treats haemophilia B. We believe that it may ease of patient administration using more convenient subcutaneous infusion. Individuals with haemophilia B would welcome this type of injection that eliminates intravenous therapy. This candidate is in co-development with a US company, Catalyst Biosciences. ISU Abxis is responsible for advancing ISU304 up to the global stage I trials. Upon completion of phase I, the responsibility then lies with our US partner.

Given that you concentrate on orphan drugs and rare diseases, how does ISU Abxis overcome the limited scientific literature regarding rare diseases in order to develop its products?

Indeed, only five percent of rare diseases have available treatments. While there is a lot of potential to develop first in class products within blue ocean markets, one of the major issues is

that there is a lack of scientific literature and research, making collaboration with the right key opinion leaders imperative.

Moreover, rare diseases have a limited number of key opinion leaders, perhaps only 3-5 in each country who are specialised in that particular field. We are within the top tier for the rare disease market and have been involved in this market for a long time, allowing us to develop a strong network, which is, of course, most prevalent in Korea. Some countries have already set up their own networks to connect study groups and key opinion leaders involved in the field of rare diseases. ISU Abxis can utilise their infrastructure to extract a lot of necessary information.

In addition to key opinion leaders, co-operation with government authorities in relation to pricing is also critical for ensuring patient access to rare disease drugs. Orphan drugs are an issue of high priority in reimbursement policy. I think the role of ISU Abxis in this regard is to provide products with similar efficacy at low cost to help the government and patients. Internationally, this is not done directly by ISU Abxis, but through our overseas partners.

Korea represents only 1.5% of the global pharma industry, with no Korean pharma company in the global top 50. India and Japan, on the other hand, have broken through. What does Korea have to do to propel itself to the next level?

Korea is already leading in the fields of semiconductors and information technology – Korea has the fastest internet speed in the world, perhaps even up to ten times faster than the USA. After that, the next generation of technology is biotechnology. Korea has no natural resources, only human capital. This is the only way we can maintain a competitive advantage.

Market cap for the biotech companies is growing. One of the main reasons for this growing excitement around biotech is that the government has set up a final plan to direct the industry. When Korean people and the government decided to do something and put their minds to it, they can achieve it. The Korean people believe that the next generation is biotechnology and that Korea can lead. This is why large investments are flowing into biotech companies and this rise is continuing.

As mentioned, Korea is currently only 1.5% of global pharma. It is a small portion. Notwithstanding that, Korean biotechnology is gaining recognized within the global community – especially in the biosimilar market. Korean pharma even continues to expand its investment every year for the development of new drugs and continue R&D projects at a global level. ISU Abxis included, Korean pharma will, in the future come out to be listed within the global top 50 pharmaceutical companies.

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