Jeong Woo Cho – CEO & President, SK Biopharmaceuticals & SK Life Science, South Korea

We need to conduct drug development in a smarter way utilizing bioinformatics and data mining tools

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SK Group, the second largest conglomerate in South Korea and renowned as a

leader in energy, telecommunications, and the semiconductor business, entered drug development in 1993. In an exclusive interview, Jeong Woo Cho PhD, CEO & president of SK Biopharmaceuticals and SK Life Science, provides an overview of the current status of their drug development and commercialization efforts. Dr Cho also offers an insight into SK's innovative AI platform, which can increase the efficiency of drug research and discovery and concludes with his assessment of the potential for the Korean pharmaceutical industry.

SK Group has a long history in the energy and telecommunications sector. How has it adapted to becoming a global player in the capital and risk intensive pharmaceutical sector?

SK Group has a long history with excellent capabilities and a strong experience in M&A, acquiring our first oil refinery business around 40 years ago, and starting from scratch as the first Korean telecommunications business, building the market and establishing itself as the market leader. Then, through the acquisition of SK Hynix, SK has become a globally competitive company in the semiconductor industry. SK set up a new goal to be a leading player in the pharmaceutical industry, beginning the project in 1993. We were able to utilise the knowledge gained from

entering new industries and securing a leadership position in other sectors, to accelerate our efforts in this new endeavour. Our first step was setting up labs for drug discovery in the United States, then transferring the skills and knowledge back to Korea. Since 1993, we have developed the organisation step by step. It was certainly a long game project. Although we suffered several setbacks, particularly in the beginning, we never gave up, continuing to invest capital, time and effort throughout, to achieve our goals.

As of today, SK Biopharmaceuticals has generated 16 investigational new drugs (INDs), which have been filed with the U.S. Food and Drug Administration (FDA).

As for new drug applications (NDA), we have two that are being reviewed by the FDA. In 2017, our partner Jazz Pharmaceuticals filed an NDA for solriamfetol, which we discovered and licenced-out to Jazz after completing the phase 1 clinical trial. Last November, we independently filed another NDA with the U.S. FDA for cenobamate. Our short-term goal is to receive FDA approval for both compounds – solriamfetol and cenobamate. The Prescription Drug User Fee Act (PDUFA) goal date for solriamfetol is March 20, 2019.

During late 2016, we began building a sales and marketing organisation for the US market. We have a very experienced commercial team with a very strong track record. We are ready to hit the start button to launch cenobamate, upon approval by the FDA.

We are also running bridging studies in Japan, with a plan to expand sales and marketing in China, Korea, and Japan within the next 4-5 years. By that time, we will have developed the competencies and processes necessary to succeed in multiple markets, and we will be prepared to launch our second and third products as we have very strong drug candidates in our pipeline.

We want to emerge as a global player in the pharmaceutical industry through both organic growth and M&A strategy, as SK has done, to further expand our portfolio of potential treatments.

The vision of SK Biopharmaceuticals is to become a fully integrated pharma company and tap into the US market. To achieve this, you are focusing on CNS, which is a higher risk development area. What was the background to this decision?

When SK first entered the pharmaceutical industry, SK was engaging in R&D in three therapeutic areas: CNS, oncology, and metabolic disease. Although CNS is a challenging therapeutic area, we realise it is an area with a high unmet need for new treatment options. That is why despite many challenges, we decided to focus our efforts in CNS. Our oncology pipeline was put on hold as we

made slow progress in this therapeutic area. We resumed our oncology research three years ago, focusing on the development of drugs for the treatment of primary and metastatic brain tumours, based on our experience in creating substances to penetrate the blood-brain barrier.

In recent years, SK Biopharmaceuticals has increased its focus in epilepsy and has successfully discovered and developed from inception through submission of an NDA, our investigational antiepileptic drug cenobamate without partnering or out-licensing. Doing this independently represents a first for a Korean pharmaceutical company. Through this experience, we have developed strong relationships with key opinion leaders in the field, which has enhanced our understanding of epilepsy and informed our commercial strategy.

In addition to cenobamate and solriamfetol, we have six more drug candidates being studied as potential treatments for CNS disorders including schizophrenia, ADHD, and Parkinson’s disease. Unfortunately, while there are many treatment options for Parkinson’s disease and schizophrenia, there is still no cure. We will continue to invest in the development of new treatments for the patients who suffer from these intractable diseases

What is the benefit of becoming fully integrated and keeping all of your capabilities in-house?

Whenever a company licenses out, while offloading some risk, it inevitably comes at a financial loss. Licensing out after phase III completion and co-marketing with a partner can generate a loss of almost 50 percent of the profits. Hence, full integration has always been our goal and has remained so for the last 25 years. As mentioned earlier, we aim to become the first Korean company to independently discover and develop the drug, moving into sales and marketing in the USA, making us pioneers in that regard.

Last year you launched a drug development platform based on artificial intelligence (AI). Could you provide us with an insight into this project and its implications for your future drug development?

Drug development takes time – 10-15 years and billions of dollars. Even so, most projects fail. Therefore, we need to conduct drug development in a smarter way utilizing bioinformatics and data mining tools.

We have excellent assistance through our collaboration with other members of the SK Group, in particular with SK C&C. They have been building a software database with a keen focus on AI. SK Biopharmaceuticals had a wide range of research data accumulated over the past 25 years. Thus, it was decided that a tool should be developed to mine and interpret that data in order to potentially improve efficiency in drug development using AI.

Interestingly, two years ago, I proposed building an AI tool which reads scientific papers for researchers to increase efficiency, enabling researchers to focus on research and experiments, rather than devoting the whole day to reading. Physically, a researcher cannot read more than ten papers per day. Consequently, I wanted to build a tool to read papers and list those that match the research concept, thus providing the scientific material which aids the development process.

We are in the early stages of development with our AI Drug Design platform, but early results seem positive. Nevertheless, the tool must be subjected to further rigid checks to confirm and optimise its operations. We are using our proprietary data to assess its utility and remain hopeful of its broader potential to help us efficiently search for, predict and design new compounds.

Korea will be a test market for the software. We will share this platform with Korean academia and Korean companies, and we will encourage our collaborators in academia to share their scientific data using our platform to create a more robust data set.

What are your expectations of Korea’s future position in the global market for pharmaceuticals?

There are many gifted Korean scientists out there. In many industries, semiconductors for example, Korea is a global leader. However, pharmaceutical industries in the U.S. or Europe are fully matured, making it challenging for Korean companies to take leadership in the global market. Notwithstanding this, many Korean companies are equipped with capabilities, so while it may take time, we will be able to gain a dominant presence in the global market in the future. I hope that through a successful product launch and strong sales uptake in the US market, SK Biopharmaceuticals can set a strong example of what a Korean company can achieve in this sector. Quite simply, we want to be a leader, not only in Korea but in the global market.

What I believe makes the Korean capabilities the right ones for this enterprise is most definitely the R&D environment. In addition, we hope to raise the interest in the younger generations to enter the pharmaceutical sector, and if Korean companies can collaborate and support the growth of R&D,

Korea can excel within the global pharmaceutical sector. It is time to work together to build a better industry and environment in Korea.

What do you wish to leave behind as your legacy for SK, and for South Korea?

My short-term goal is to make sure that we obtain FDA approval for cenobamate and successfully commercialize it in the U.S. and in other global markets for adult patients with epilepsy who need a new treatment option.

I also want to drive company growth both organically and by emulating the SK Group strategy of looking closely at M&A and deal-making to further expand our portfolio of treatments. With this approach, I hope we can achieve our vision to become a competitive global fully integrated pharmaceutical company.

As a group, SK is placing great importance on ‘Sharing’ and ‘Collaboration’. I would also like to share our experiences in independently developing new drugs and marketing them globally with other Korean small-to-medium sized businesses and start-ups, and in the end, make a meaningful contribution to the Korean healthcare industry.

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