Joong Myung Cho â?? Chairman & CEO, CrystalGenomics, South Korea

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Joong Myung Cho of Korean biotech success story CrystalGenomics introduces the companyâ??s unique drug discovery platform, key growth factors, highly promising R&D pipeline, and internationalisation plans.

Dr Cho, could you start by introducing CrystalGenomics to our international readers?

CrystalGenomics is a structural biology biotech company focusing on the discovery and development of novel drug candidates in three core areas: oncology, infectious diseases, and pain and inflammation.

Our competitive drug discovery platform was featured on the cover of *Nature* in September 2003, which was the first time any Korean institution, industry or academia, was featured on the cover of the magazine. It featured our expertise in structural chemoproteomics, which helped us become the first group in the world to decipher the 3-D complex structure of the ViagraÂ® drug target in 2003. This scientific accomplishment validated our scientific capabilities on a global level.

Our integrated drug discovery process consists of three different platform technologies: the Soluble Protein Solution (SPSâ?¢) technology, the Structural Chemo Proteomics (SCPâ?¢) technology, and the Structural-based Drug Factory (SDFâ?¢) technology, which ensures that we are able to do drug

discovery in a rapid, effective and productive manner.

In 2006, we became the first biotech company to IPO on the KOSDAQ exchange under the governmentâ??s special policy to support the IPO of companies with innovative technologies.

We were also the first Korean biotech to have independently developed, commercialized, marketed and exported an innovative drug, which is AcelexÂ®.

What have been some of the key factors contributing to CrystalGenomicsâ?? success?

Biopharmaceuticals is a science-driven industry. Unfortunately, in South Korea generally, the level of basic science has historically been weaker than in Europe or the US, which makes it challenging for really innovative Korean companies to develop. We do have excellent scientists and researchers but the base is smaller. I can attribute our success to four factors.

The first is our management team. We have experience with both R&D and out-licensing novel drugs to multinational pharmacos, US NDA submissions, as well as the establishment and management of a JV company with a US-based VC.

The second is our competitive discovery platform and our scientific talent, with our highly competent research team comprising 15 PhDs. In addition, we are continuously looking for novel targets globally through different publications from top academic and research institutions globally. Exceptionally, we are also the only company in Korea to possess a synchrotron (a type of cyclic particle accelerator) for commercial use. This was an investment of several hundred million USD but it has given us a significant competitive advantage.

The third is our collaborations and strategic alliances with global academic and industry organizations, including pharma MNCs. Open innovation is very important. As a small company, we cannot do everything ourselves. We need to maintain an open mind and build a network of collaborators. For instance, we recently in-licensed an immuno-oncology drug for the Korean market from the largest Chinese pharmaco, Jiangsu Hengrui.

We have also been supported by the Korean government. In 2012, we were selected one of the 43 â??Korean Innovative Pharmaceutical Companiesâ?? (KIPC), an initiative by the Korean government to nurture and support selected pharma and biotech companies to grow their global presence by 2020. Under this program, we received favourable pricing and reimbursement benefits for novel drugs as well as R&D and financial support like research grants, government subsidies and tax breaks.

Can you tell us a little about your commercial product, AcelexÂ®?

AcelexÂ® or polmacoxib is a tissue-selective COX inhibitor that improves upon the conventional nonsteroidal anti-inflammatory drugs (NSAIDs) like ibuprofen and newer selective COX-2 inhibitors. It has a higher efficacy coupled with lower gastrointestinal and cardiovascular risks, and you only need a 2mg dose once a day â?? the lowest daily dose amongst all known NSAIDs.

It was approved by the Ministry of Food and Drug Safety (MFDS) in Korea in February 2015 and launched by Dong-A ST, our partner. It has since become the second-biggest selling COX-2 inhibitor in the country.

We have since partnered with a number of other companies to export this drug to emerging markets: TR-Pharm for Turkey & MENA in January 2016; Aspen Pharma in Brazil (September 2018); and PharmArtis International for Russia (November 2018).

What else are you excited about in CrystalGenomicsâ?? R&D pipeline?

One of our core focus areas is infectious diseases and in particular, antimicrobial resistance, which is a significant global problem. We have CG-549, a novel antibiotic against methicillin-resistant *Staphylococcus aureus* (MRSA), which uses a novel mechanism to block a key enzyme in the bacterial cell membrane formation pathway. CG-549 is a first-in-class fatty-acid biosynthesis inhibitor (Fabl). The standard of care for MRSA currently includes treatments like vancomycin, linezolid and daptomycin, all of which have toxicity and usage limitations. CG-549 has not demonstrated any of the major toxicities of current therapies.

Our second candidate is CG-745, a best-in-class Histone Deacetylase (HDAC) inhibitor with superior pharmacokinetic (PK) and safety profiles compared to other HDAC inhibitors (those approved and those in clinical development) due to the high level of drug exposure even at low doses.

We currently have two Phase II trials in progress in Korea for myelodysplastic syndrome (MDS) and pancreatic cancer. In particular, we have also received U.S. FDA Orphan Drug Designation for CG-745 in MDS, which would give us access to accelerated approval pathways, market exclusivity and premium pricing. Current therapies, unfortunately, have an 80 percent failure rate with the median overall survival being 4.3 months so there is really an urgent medical need here. CG-745 will target MDS patients that have failed to respond to available therapies.

We are also preparing a Global Phase I/II in combination with a PD-1 inhibitor for hepatocellular carcinoma (HCC). CG-745 has demonstrated direct effects on cancer death as well as immune-stimulation effects, making it a superb choice for combination therapy with checkpoint inhibitors, particularly for solid tumours.

Our third candidate is CG-806, an FMS-like tyrosine kinase 3 (FLT3) / Brutonâ??s tyrosine kinase (BTK) inhibitor with the potential to be a first-in-class therapeutic for acute myeloid leukaemia (AML), which represent nearly 60 percent of all leukaemias.

In June 2016, we launched an exclusive global option and license with San Francisco-based Aptose Biosciences, who agreed to co-develop CG-806 for global rights to commercialize it outside of South Korea and China. In June 2018, they also gained the rights to CG-806 for China.

What is your strategy for international collaboration?

Fundamentally, we are committed to global and open innovation. We work with both Korean and international research organizations as well as pharma and biotech companies from different countries, including the US, Europe, and more emerging markets. Emerging markets tend to prefer later-stage or commercial assets while companies in the US or Europe are typically looking for novel candidates in earlier stages. Therefore, we pursue two different strategies for emerging and mature markets.

We have a small presence in the US already with our California office, which currently has four people overseeing clinical management. We plan to expand this and develop it into our R&D centre

in the US in order to capitalize on the talent pool in the US.

For our CG-745, which has received US FDA Orphan Drug Designation in MDS, we are currently looking for a US partner to support clinical trials but we are also able to proceed without a partner as we do not need to hold large-scale clinical trials.

In 2019, we also signed a memorandum of understanding (MoU) for a strategic partnership with Swiss global asset manager, Bellevue Asset Management, which would help us connect to early-stage start-ups or academic projects across academia and industry globally.

Looking forward, what is your dream for CrystalGenomics in a decade?

The goal for the next decade is to become the top innovative biopharma company in Korea focusing solely on novel drug discovery and development in terms of market capitalization. I am not interested in biosimilars or generics. CrystalGenomics will always be a company that does first-in-class or best-in-class innovation. We have recently added manufacturing and commercialization capabilities through multiple acquisitions. For instance, we acquired one of the largest API manufacturers in Korea.

I am very proud of CrystalGenomicsâ?? progress over the past two decades. It has been a long journey but we are one of the few companies developing breakthrough therapies and working on innovative R&D in Korea. This is why we are excited to come to work every day. Our ultimate vision is to become a fully integrated global biopharmaceutical company by extending our footprint in Korea and throughout the world.

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