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The Korea National Enterprise for Clinical Trials (KoNECT) was established in 2007 by the Korean government to meet the increasing demand for local clinical trials and strengthen the countryâ??s clinical research network. Deborah Chee, president of KoNECT, explains the organizationâ??s ambition to become a world leader in clinical trials.

When you became president of KoNECT, what were the initial objectives you set for yourself?

KoNECTâ??s main focus is on the use of clinical trials as the tool to care for patients more effectively. KoNECT views clinical trials from the industry perspective; the organization used to be one of the governmentâ??s biggest R&D projects from 2008 until March 2014. I was hired to provide some industrial perspectives and experience, as those in the pharmaceutical industry understand the need of global partners and customers. From that background, my personal objective to join KoNECT was to contribute to the clinical trial industry for Korea. This country has shown impressive growth in clinical trials in terms of volume and quality. My objective is to maintain that trend and to achieve an even bigger footprint than before. Koreaâ??s current global ranking for clinical trials is tenth; I would like to raise that to fifth in terms of output.

What characteristics of clinical trials are outstanding here?

Korea started its clinical trials program like many other countries; our previous focus was in late phase clinical trials, and our strengths were addresses by the sponsors as having comparable quality to developed countries but with very fast patient recruitment. However now we position ourselves not only for conventional traditional clinical trials but also technology. The attrition rate is increasing every day; investigators are looking for better ways to do clinical trials with new biomarkers. Korea has very good academic institutions and large hospitals where investigators work on their own research. I think Korea has one of the best environments to do translational research and early phase clinical trials that use cutting-edge clinical trial technologies. The country is also very

good at connecting patients to new technology.

What are some of the elements that have lead to Korea having such a favorable environment?

We have a very strong foundation for growth. With 50 million citizens all covered by a single public healthcare system, Korea has a much bigger pool than other countries in term of people exposed to clinical trials. The size of our economy and the characteristics of Koreaâ??s population as the fastest-growing ageing society worldwide provide us great potential. Our disease patterns are similar to that of western countries; for the elderly, the government focuses primarily on cancer and neurodegenerative diseases. Korea has causes of death similar to that of Western countries, and healthcare expenditure is almost 100 billion won.

Our clinical trial regulatory framework has improved greatly since 2000. In 2001, our clinical trial authorization scheme was separated from the NDA system. Prior to this, the government legislated Korean Good Clinical Practice (GCP) as early as 1995. We adopted the International Conference on Harmonization (ICH) GCP in 2002 by revising Korean GCP almost identically to ICHGCP. We have the reduced review time for clinical trial protocol to 30 working days, which is very attractive for our sponsors. Korea has a parallel IRB process, and the period from submission to study initiation in hospitals takes about two to three months.

Moreover, Korea has world-class clinical trial centers. The first such center has been designated and supported by the Korean government since 2004. As of today, there are 15 supported regional clinical trial centers across the nation with financial support from the government and with matching funds from hospitals. Each center belongs to a medical center or university hospitals. In 2012 the government launched new Global Centers of Excellence for Clinical Trials. We have identified four centers so far and we just released our fifth. These Global Centers of Excellence should further the clinical trial capability in Korea, especially focusing on specialized areas like complex clinical trials, studies in special populations, for example elderly or pediatric, and patient-oriented Phase I clinical trials. The most important studies, including Phase I, used to be conducted in the US and Europe because their difficulty level and high ethical requirements. However, Korea is contracting more global Phase I studies for indications like Oncology. The Ministry of Food and Drug Safety (MFDS) designates institutions for clinical trials and accredits their sites. So far about 160 sites have been accredited by MFDS, who has strict criteria for the designation that actually guarantees the quality of clinical trials and the fast patient recruitment.

Additionally, Korea has been identified for its fast recruitment centers for late-phase trials. Korea has always been first or second for speed and quality, mostly in Phase IIb and III studies that recruit more patients. Now Korea is being included in early phase trials. Such examples include Pfizerâ??s and Novartisâ?? Oncology programs. After joining Phase I-III trials, it took only four years for a US FDA approval. The Korean investigator for Phase I studies was invited to the plenary sessions of ASCO. One of the unique aspects of Korean sites was their multi-ethnicity; trials can recruit Chinese, Japanese, Korean and Caucasian patients for Phase I trials. In 2007, the Ministries of Health of Japan, Korea and China held a tripartite meeting to collaborate in studying the ethnic differences between these countries to accumulate experience in ethnic differences and to work with the mutual acceptance of clinical data. That eventually lead Japan to accept the foreign data in their approvals, which is a huge change. Japan has approved over ten products using foreign data, and Korea is one of the most popular countries for pan-Asian studies.

Lastly, KoNECT has been reported to be one of the best government initiatives for clinical trial infrastructure. In 2011, the OECD clinical trial forum report mentioned that KoNECT was the first example of the best initiative of its kind. Other magazines have cited KoNECT for its best practices. Now other countries are following our cases and some of them want to import our system to their

countries. KoNECT is now discussing that collaboration for the transfer of our system with a few countries. We have visitors from South America, China and the Middle East to learn about what we did and what we will do.

What examples exist of big investments that multinationals have made here?

We have Korean affiliates of almost every global CRO as well as most multinational pharmaceutical companies. KoNECTâ??s big clinical trial centers actually have partnerships or the Korean sites selected as their preferred site.

How influential is your training academy in terms of being a comprehensive training base in Korea?

KoNECTâ??s academy is considered the main source of education and training for clinical trial professionals and is the main focus of KoNECT. We run courses for CRAs and CSAs across the country almost weekly. KoNECT is officially the central organization for training and education and we soon expect a collaboration agreement with MFDS regarding training. Since 2007, KoNECT has educated over 42,000 people. KoNECT also signed a MOU with the Drug Information Association (DIA) in September 2014 to collaborate on education with the organization. We will share their training expertise and programs for Koreans and exchange information on market.

What are the strengths of Korean clinical trials?

Oncology is Koreaâ??s strength today. Our experience ranges across all phases and all indications for Oncology studies. Our global sponsors are very interested in our regional indications like hepatocellular carcinoma, gastric and gall balder cancer because Koreans have a high prevalence and incidence rate. Korean investigators are regarded as the key opinion leaders in protocol development for these kinds of studies. Korea also has a higher incidence in lung and colorectal cancer, which are popular indications for global markets.

What are your expectations for Korean clinical trials over the next five years?

We aim to continue to have strong oversight for patient safety and research ethics while we work to attract more trials. High tech studies and early phase trials will be a strong focus. I want Korea to become a hub for Asian clinical trials and for macro-Asian strategy for companies. KoNECT and the Ministry of Health and Welfare are planning the â??Korea Innovation Center for Global Clinical Trialsâ?•, which will provide a one-stop service for global sponsors or partners to enter the Korean market by providing the consultation for clinical trial site selection. KoNECT can also provide some incentives for Asian regional offices to be based in Korea with virtual infrastructure and other services. We think this can be realized in 2015.

KoNECT encourages multinational partners to work with us for their Asian clinical development. We want to be the best strategic partner whenever they plan to do any Asian studies. We consider big multinationals as conventional customers; KoNECT is now looking for new customers who do not know Korea or its market but want to establish a presence and Asian strategy here. For Korea, clinical trial infrastructure development is not just about fostering clinical trials but also fostering our new drug development capability. Korea represents itself as a NDD country and clinical trial capability is a very important part of that. I want to work directly with Korean companies in the future to help them in this regard.

By 2020, we really want to lead NDD. Koreaâ??s strength is its cultural working relationship between investigators and the industry. We highly regard the group in a family of collective ideas. In recent years, the most talented Koreans have pursued careers in the medical or pharmaceutical sectors,

which the Korean government has lauded and encouraged. While the major industry to lead revenue in Korea is IT electronics, our government is now rapidly moving its focus to biopharmaceuticals. In five years, you can expect to see biopharma as the leading industry in Korea. Internally, we want to take the role of the center for collaboration among experts groups in clinical trials and externally we want to promote Korea clinical trial infrastructure and capability and to be the gateway to Korea and the Korean pharmaceutical industry.

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