Young-Whan Park â?? President, National OncoVenture, South Korea

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07.12.2018

Tags:

Korea, Cancer, National OncoVenture, Research

Young-Whan Park, president of National OncoVenture, discusses their programme to support oncology drug development in South Korea, with a view to discovering and producing a globally competitive, Korean-made oncology medicine. Dr Park also provides his assessment of Koreaâ??s challenge in commercialising its academic research.

Can you provide our international audience with an introduction to the mission of National OncoVenture, and the activities that you undertake?

National OncoVenture (NOV) is a government-funded Korean drug development programme. We concentrate on pre-clinical development up until phase II. Since we are focused solely on oncology, we have developed a specialist expertise. While we only employ 17 people, we are able to run 12 projects simultaneously since we develop drugs through virtual drug development. 70 percent of our pipelines are in the clinical stage.

NOV not only supports research financially but also co-develops the chosen oncology drug candidate in collaboration with the originator. This differentiates us from other government R&D support initiatives which are fund supporting programs. During the process, we establish a joint development committee (JDC) for each of these programmes. The JDC is normally attended by the heads of research from the programme originators. The committee meets monthly and its members are divided equally between representatives of NOV and the originator. The JDC decide everything, from how to evaluate the results of an experiment to decisions on progression to the next phase.

As we are involved in the whole drug development process, we ensure that NOVâ??s key leaders are recruited from big pharma with extensive experience in drug development, for example, our biological drug development head previously led the Green Cross Research Institute and chemical drug development head was previously head of the Research Institute of ChongKeunDang Pharma.

Our programme is split into two phases. The first phase ran from 2011-2016, and the second phase began in 2017and will run until2021. The first phase was mainly based on chemical candidates. The second phase also includes biological candidates, such as antibodies, gene and cellular therapies. In the first phase we had only two biologic programmes, but now have six in the second phase. In addition, we have added the companion diagnostic (CDx) program in the second phase so that it could help select right cancer patients for the specific drug and eventually increase the success rate of the drug development.

What are the criteria for determining which candidates are selected for the programme?

We have strict evaluation and selection procedures to determine our choice of candidates. Selection is very stringent. Each candidate must have the prospect of being globally competitive. Although some of them are first in class, most of them are best in class but have globally competitive aspects, such as better efficacy, patient selectivity or safety.

Over the past six years we have received around 170 applications, but, following our thorough evaluation procedure, we have selected 21 for the programme. Currently, NOV is conducting 12 programs for further development. We must select only those that have the potential to be globally successful oncology products.

We have no preference over chemical or biological candidates. The importance is global competitiveness. Currently, we are observing a growing trend in Korea of pharmaceutical companies prioritising biological products. This is the global pharmaceutical trend as well, and this explains why the number of biological candidates in our pipeline has increased: biologics pipelines have grown much larger, so we select more.

What is the current climate for developing oncology drugs in Korea?

Some of the Korean pharmaceutical companies have invested heavily in oncology. However, others have completely ignored it. Across the whole industry, oncology drug development in Korea, as a proportion of total drug development is still relatively low, at around 20 percent. The global average is around 40 percent. Moreover, the Korean oncology drug prescriptions are heavily dependent on drugs from large global pharmaceutical companies, at around 90 percent. Thus, to maintain high access and limit costs of oncology therapies, we still need to assist in the development of local Korean biotech companies.

What is the cause of the underdevelopment of oncology products in Korea?

In my opinion, oncology drug development is more difficult than other disease areas, particularly when conducting clinical trials. Consider a diabetes drug. One diabetes candidate can go to one trial. However, with an oncology drug, one candidate can go to multiple trials as there are a number of different cancer types, so researchers must design trials for all the different variations. Consequently, it must be decided even before the trials which type of cancer is suitable for this candidate, which is very difficult as the pre-clinical models are unreliable as predictors of the human response to cancer. As this demands significant time and funding, developers may be incentivised to take an easier path and develop drugs in other therapeutic areas.

Nonetheless, CNS drugs are also difficult to produce, yet Korean pharmaceutical companies are investing in those areas. Therefore, there is no simple reason to explain the lower levels of oncology candidate development in Korea.

In terms of translational research, there is a traditional disjoint in some Asian countries where academic research suffers from an inability to align with industry to commercialise. What is your assessment of this problem in Korea?

This is very true. Basic research is strong with many good publications. However, throughout my 20-year career in the industry, I have noticed that there is a big difference between conducting research and developing the product. While Korean government drug R&D support has existed for around 35 years, the real drug development has been only the last 10-15 years. I think the real development part must be conducted by those with experience in the industry. However, it used to be the case that this was conducted in Korea by academics. While I would stop short of claiming that they are incapable of fulfilling the role, they are certainly less experienced.

Korean professors are very keen to collaborate with the commercial sector. The major problem is that Korean pharmaceutical companies are relatively small when compared with the US. Their R&D budgets are smaller too. Academics with good candidates will try to license out to companies who will give the best offering. In this regard, the Korean pharmaceuticals simply cannot compete with the multinationals.

Hence, a specific programme is required to address this, such as Stanfordâ??s SPARK programme. It is a bridge from academia to the industry by providing frequent mentorship by industry experts as well as research fund for early-stage R&D. This type of programme has been heavily missed in Korea. NOVâ??s programme only covers the pre-clinical candidate up until phase II, so does not address the synergies between basic research and a pre-clinical candidate. However, few other government-funded drug R&D supported programs, such as the Korean Drug Development Fund (KDDF) cover those areas. These programs were initiated a few years ago and started to generate successful outcomes. Both KDDF and NOV are run by drug development experts with heavy experience in the pharmaceutical/biotech industry. These are the two representative programmes which have significantly improved Korean drug development. Perhaps in ten 10-20 years, with the groundwork being laid by these schemes, and the investment from the government, we will overcome this issue.

What is your vision for Korea as an innovator of new oncology products in the future?

I am very optimistic. In our activities conducting licensing activities in the USA and Europe or China, we have received a lot of interest in our pipelines. Currently, we are seeing an explosion of the new start-up biotechnology companies with innovative ideas and pipelines. I expect a real global oncology drug to emerge from Korea within the next ten years and for Korea to become a leading player in the global market. Korea achieved this in the past in the information technology sector. Now biotechnology with the support of information technology, which Korea is already first in the world, can become a leading area in the era of Fourth Industrial Revolution.

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