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From Science To Commercialization: How Genexine Is Making The Shift

Inflection Point To Look Beyond Korea

by Jung Won Shin

Genexine CEO Neil Warma talks to *Scrip* in this audio interview about a wide range of topics, including key strategy changes, ambitions to become a leading global biopharma, as well as challenges he has faced since joining the Korean biotech.

Genexine Inc., established more than 20 years ago, has now reached a juncture where it needs significant changes in strategy to move forward towards its ambition of become a leading global biopharma operation over the next several years.

With this in mind, the South Korean biotech appointed global pharma veteran Neil Warma as its new president and CEO last year, with a focus on advancing key products to market and expanding its pipeline, as well as actively pursuing international drug development.

Warma brings over 25 years of experience as a global entrepreneur, company builder and successful CEO at a wide range of global biopharmas firms, including *Novartis AG*, *I-Mab Biopharma Co., Ltd* and *Opexa Therapeutics, Inc.*

Since he joined Genexine, the CEO has placed a focus on prioritizing the existing pipeline into top lead products, including the first-in-class, proprietary DNA vaccine GX-188E, getting these late-stage products to market and at the same time looking to build a new and exciting R&D portfolio for the future.

“You know, in 20 years of developing products, we don't yet have a product on the market so there's a little bit of pressure to get our late-stage pipeline candidates out the door, get them to

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Source: Genexine Inc.

the patient. So for us, we've been really pushing on that," Warma said in this exclusive audio interview with *Scrip*.

"We've been very focused on science and a little bit less focused on development and commercialization. So, trying to make that shift, the philosophical shift, from science to development, commercialization and bringing people along. I think people understand and they're enthusiastic, but there's that challenge and kind of, 'how do we do that?' So it's bringing the team along. It is also supporting the team with people who have that expertise."

Despite the challenging stock market conditions, the company recently completed a large rights offering worth about KRW85bn ($69m) on the Kosdaq market, amid good support from shareholders. It aims to use the proceeds largely to progress clinical trials of key programs.

'Very Excited' About DNA Vaccine

Among the four key pipeline assets, which are either in pivotal Phase III or submission stages, the company highlighted GX-188E, its therapeutic DNA vaccine for cervical cancer. As it focused its pipeline, it was important to lay out timelines and meet the deliverables, Warma said, noting one deliverable last year for the candidate was the completion of a Phase II study.

"We had a really, really important Korean-based study in late-stage cervical cancer with our DNA vaccine. So for me, it was important when I joined the company to envision when we would get those data and when we would be able to communicate them externally." The company presented top-line data at the European Society for Medical Oncology meeting in September and also updated the market with a completed Phase II study.

"The data itself was very exciting. Our overall survival rate and response rate was significantly better than standard of care that we see in the market already. So, we've got some numbers that are very exciting for us moving forward in cervical cancer. The next step for us this year is to initiate the next clinical study."

At present, the company is evaluating a number of different options in the indication. Later this year, it expects to start a Phase III trial and in addition recently received a fast-track designation for this setting from Korea's Ministry of Food and Drug Safety.

Having recently received the completed clinical study report, Genexine updated its primary

efficacy numbers in the Phase II trial, which evaluated the efficacy and safety of the combination of GX-188E and *Merck & Co., Inc.*'s anti-PD-1 drug Keytruda (pembrolizumab) in a total of 65 patients (safety population) with HPV 16- and/or HPV 18- positive recurrent or metastatic advanced cervical cancer.

The final efficacy analysis evaluated in 60 patients showed an objective response rate of 35.0% (21 of 60 patients), indicating that of the 60 patients with advanced cervical cancer, 21 patients saw either an over 30% reduction in tumor size or complete remission. (Also see "*Genexine Advances DNA Vaccine With Mid-Stage Cervical Cancer Success*" - Scrip, 8 Sep, 2022.)

Along with GX-188E for cervical and head and neck cancers, Genexine's three other key products are GX-I7, a long-acting recombinant interleukin-7 for multiple cancers, GX-H9, a recombinant human growth hormone fused to hyFc for growth hormone deficiency, and GX-E4, a novel long-acting erythropoietin-hybrid Fc fusion protein. The company is talking with potential partners for licensing out opportunities for these programs.

Pipeline Opportunities In Oncology, Rare Disease

To strengthen its R&D, the Korean firm has spent a lot of time over the past several months looking at new pipeline opportunities. It has so far developed most of its molecules from its proprietary technology, the long-acting hyfc platform.

It is looking at internal capacity using this platform to generate new assets and at ways to take forward bispecific or monoclonal antibodies, but also assessing outside candidates as well.

Because the company has expertise in oncology, this will be a primary focus along with rare diseases. “I think one of the things in the past, we've been a little bit too broad in our disease area coverage and I think that's come a little bit from our long-acting platform," Warma conceded.

"We generated new products off the platform and not really focused in one area because the platform has a lot of potential there. But I think for us now, going forward, we need to be a little bit more specialized in certain regions, in certain disease areas.”

Longer-Term Global Positioning

Warma believes Genexine is now facing an inflection point in terms of expanding beyond Korea's borders to generate revenue and growth. “So, the inflection comes from pushing to the US, opening an office and hiring some people in the US to be able to conduct business outside of Korea in order to do drug development in all parts of the world - which is really where the value is generated.”

There are a number of reasons to be present in the US. It's not only about accessing the Food and

Drug Administration and the US clinical trials environment but it's also important for the firm to expand its shareholder base and access new investors to capital. Some of the more sophisticated long-term investors are in the US, the CEO noted.

While the company is not trying to do everything globally, it aims to "own this part of the world" in Asia and including the Middle East, as it has a strong base with talented people and multiple partnerships, connections and relationships.

“For Genexine, if we can kind of be an owner…if we can be very strong and dominate this part of the world…while we partner in the US and Europe, that could be a really interesting model, because I think large pharma tend to not know how to address 'rest of the world' countries because they're smaller diverse, and have different health authorities,” Warma observed.

Listen to the full audio interview below to hear what more the CEO has to say on these and other topics. This and all our other podcasts are available on the Pharma Intelligence channel on *Apple Podcasts*, *Google Podcasts*, *SoundCloud*, *TuneIn* and *Spotify Podcasts*, and via smart speakers if one of these platforms has been set up as your default podcast provider.

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