Jan van de Winkel – President & CEO, Genmab (November 2015)

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The future of drug development is about interacting, sharing and collaborating. The President and CEO of Genmab, an international biotechnology company focusing on differentiated antibody therapeutics for the treatment of cancer, discusses the company's most recent milestones as well as how it is fostering a collaborative model based on partnerships.

How did you first become involved with Genmab?

I'm a scientist and immunologist by training and have worked for more than 25 years with antibodies, both in the academic world and in industry. I started working in the pharmaceutical industry as the scientific director of Medarex Europe, a US-headquartered biotech. In 1997, Medarex acquired a platform technology, which allowed the company to effectively create fully human antibodies in transgenic animals —a big step at that time— and started generating human antibody therapeutics. The company was approached by a group of Danish investors who were interested in establishing a partnership. The idea was to create a new company, Genmab, to be headquartered in Denmark, which would provide an excellent environment for a biotech.

Genmab was thus created in 1999, and human antibody product creation was planned to be performed at the existing Medarex Europe operations in Utrecht, which already had a team of

nearly 30 scientists working on antibody therapy. Medarex was given a 45 percent share in the new entity in return for access to its state-of-the art human antibody technology platform. In June 2000, Genmab completed a large financing round with blue chip investors and raised over USD 60 million, and following this, I became solely focused on Genmab, as head of pre-clinical development and research. I was part of the team that took Genmab public in October 2000. From 2008, I took over responsibility for all R&D at Genmab including all clinical development, which was based in Denmark and the US. In June 2010 I stepped up to become the CEO.

What have been the key milestones for Genmab since you took over the position of CEO in 2010?

In 2010, my main priorities were setting up a new company strategy strongly focused on creating first-in-class differentiated antibody therapeutics for the treatment of cancer and bringing our finances under control – not least by renegotiating the contract with GSK for our marketed antibody Arzerra®. In 2012, we did a transformational deal with one of the companies under Johnson and Johnson, Janssen Biotech, Inc. for daratumumab (HuMax®-CD38), a monoclonal antibody in clinical development for multiple myeloma. Finally, we renegotiated the Arzerra® contract one more time in 2014, when Novartis acquired GSK's cancer portfolio which included our Arzerra/ofatumumab product.

Genmab has been profitable for the past two years and we have given financial guidance for 2015 that we expect to be profitable this year as well. However, this is profitability based on milestones and not product revenues, so we are not yet sustainably profitable, but we very much hope revenues will soon be driven by daratumumab. Marketing applications for daratumumab are currently under review by regulatory authorities in the US and EU. Since 2010 we have not only stabilized the company, but also completed a spectacular turnaround: today Genmab has a market cap of approximately USD 6 billion, making it one of the biggest European biotechs. Today the company has a robust pipeline with six Genmab antibodies in clinical development and more than thirty active pre-clinical product programs. Our vision is to have our own product (defined as Genmab owning fifty percent or more of the product rights) on the market by 2025.

What is so unique about Genmab?

Genmab is a truly innovative company with differentiated product candidates such as Arzerra® and daratumumab, both of which received the US FDA's coveted breakthrough designation. This is pretty unique, as it is the highest level of endorsement one can get in the early clinical stage of a new compound. We also have differentiated new platform technologies: the DuoBody® platform for the effective creation of bispecific antibodies and the HexaBody® technology that creates effector function enhanced antibodies, both developed at our R&D center in Utrecht. Based on these technologies, we are creating more platforms and next generation antibody products. Within our current pipeline, 75 percent of our product candidates are based on the DuoBody® technology, 10 percent on the HexaBody® technology and the remainder are Antibody Drug Conjugates (ADCs), which we believe makes our pipeline one of the most innovative and robust in the industry. We hope to bring many of these projects into clinical development and potentially be able to fundamentally transform the treatment of cancer.

Genmab boasts a pipeline of knock-your-socks-off antibodies to stand out in the global market. What elements allow for such a claim?

It's the expertise we build up over the years. We have a very rigorous approach to pre-clinically select the right antibodies and benchmark them against the best molecules already on the market, or to be launched in the near future. All the molecules we develop need to be profoundly better than the benchmark, and we take only the best of the best into the clinic, as we want to bring to clinical development only molecules that have leapfrog potential.

How does Genmab's footprint look today?

Genmab is headquartered in Copenhagen, Denmark where we have around 50 employees which make up corporate functions, as well as the medical, regulatory and manufacturing (CMC) areas. The company has a large site in Utrecht that hosts pre-clinical development and research areas, with around 125 employees. Utrecht was a strategic choice because it offers an optimal environment to set up a biotech: you have Utrecht University, the largest research university in The Netherlands, with world-class research and ranked number one in the Netherlands, alongside top-notch biomedical and life sciences educations, which allows us to have access to some of the best scientists. We also have a small location in the US focused on finance and business development. Over forty percent of our shareholders are from the US, and today the American market offers huge opportunities in biotech, also in terms of financing so it is important for us to have a foothold

in the US.

In 2015, Genmab announced it would be investing in a new R&D facility on the campus of the Utrecht Science Park. What does this facility imply for Genmab's further growth?

The building we currently occupy is more than ten years old. We not only need space to expand as we are increasing in size, but also a facility that is more optimal for the type of work we do and that can better foster interaction. People need to have regular contact with each other in their daily worklives. We also wanted to be in an eco-system that brings together biotech, academia and pharma. Utrecht is thus the perfect place, because it not only houses the largest research university in the Netherlands, but also features a very large medical center, and will house a new cancer hospital and the new Prinses Maxima Center for Children Oncology. Our neighbors include the Hubrecht Institute, a research institute of the Royal Netherlands Academy of Arts and Sciences working with such ground-breaking technologies as stem cell organoids.

The new building will be state-of-the-art and has been designed to optimally facilitate and stimulate connection and interaction between colleagues. This is how I actually see the future of drug development: very collaborative and strongly based on open innovation. We have different partnering models to ensure we secure access to our technology partnerships for different stakeholders, because we believe it is better to have 10,000 scientists working together than 150. Networking between biotech, pharma and academia is absolutely key to help develop innovative game-changing therapies. The future is about interacting, sharing and collaborating.

What product development are you most proud of thus far in the Genmab story?

Daratumumab is an amazing story: we selected the molecule in 2005, brought it into the clinic in 2008 and had a very slow dose escalation, as we needed to carefully evaluate the side effect profile of this very potent antibody. Daratumumab was the most potent antibody we had ever characterized in animal models. We started with low doses in heavily pretreated multiple myeloma patients, escalated carefully, and got excellent results, which we published in the *New England Journal of Medicine* in August 2015. The molecule followed exactly the pre-clinical results.

You need only one breakthrough molecule to create a success story, and we hope we can do that. We very much look forward to bring daratumumab to the market via our partner Janssen. We have priority review in the US as well as accelerated assessment in Europe. This is the first time the

European Medicines Agency (EMA) has given accelerated assessment to be considered for a drug tested in a single arm trial in phase II. I am very excited about daratumumab as the data seems to show that it uses at least five different mechanisms-of-action to kill cancer cells.

Genmab has an extensive list of partners, from pharma giants such as Novartis and Dutch biotech start-ups such as BioNovion. What is the importance of partnering for the company?

Partnering is absolutely essential. Today the company has fifteen partnerships —seven with pharma and eight with biotech companies. However, we are also partnering in other ways. For instance, we grant access to our technology platforms as a step to create a fixed income stream, which has brought in over USD 50 million since June 2012. BioNovion is a partnership I am very excited about: we have granted them 50 percent ownership of all the resulting molecules we work on with the DuoBody® platform, while they provide world-class expertise in Immuno-Onocology and in antibody screening against so-called immune checkpoint targets. We did a 50:50 agreement for five programs with BioNovion and executed a similar agreement in May 2015 with a German company called BioNTech. BioNovion works on brakes on the immune system, while BioNTech works on agonistic checkpoint molecules. We entered a similar deal with BioNTech, because we need their world-class expertise to select the right Immuno-Oncology product candidates. We presently use access to our unique and proprietary technology platforms as a currency to get access to interesting next generation technologies and science. It’s a more honest state-of-the-art partnering model compared to more traditional agreements in the past.

How do you develop and foster a company culture to develop breakthrough therapeutics that can make it to market?

The company has a very strong innovation mindset: it’s a very creative team of uniquely talented individuals who are truly passionate about creating new drugs that can profoundly impact people’s lives. Our employees are stimulated to move the boundaries, as we allow them to make mistakes so they continue to try new things. We bring in unique talent and get them to work together as one team. It’s very different from academia —and I say that out of experience— which can be a more “solistic” and egoistic environment. What I like about our company is that employees truly work as one team and are continually pushed to think out-of–the-box.

What is your expectation for the evolution of Genmab in the coming five years?

We believe in a world where we can turn cancer into a chronic disease, which you cannot necessarily cure in all patients but does not lead to their death anymore. Our clearest goal is to have our own product on the market by 2025. Therefore, we soon hope to identify a new potential molecule and keep at least 50 percent ownership of the product so that we can achieve our inspirational vision. In five years time, we also would hope to be sustainably profitable from the income stream of our products, rather than profitable on the basis of milestone payments. We very much hope daratumumab will play a key part in this story, as I believe this product could well become a true game-changer in the treatment of multiple myeloma and potentially also in other types of cancer.

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