Jan Børge Jakobsen – MD, Bayer Norway



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Jan Børge Jakobsen, managing director of Bayer Norway, shares how he came to lead Bayer's Norwegian affiliate after 30 years within the Norwegian pharma industry; Norway's innovation capabilities in radiopharmaceuticals; and his excitement surrounding Bayer's portfolio and upcoming product launches in Norway.

Jan, could you introduce your background and share a little regarding your journey to become managing director of Bayer Norway?

I have a Master's in Biotechnology from the Norwegian University of Science and Technology as well as a Master's in Biochemical Engineering from Duke University in the US. I have worked in the pharmaceutical sector for over 30 years, beginning my career at Apothekernes Laboratorium, then moved to Nycomed Imaging which transformed into Amerham and later acquired by GE Healthcare, overseeing preclinical and clinical production as well as pharmaceutical process and analytical development.

In 2010, I had the opportunity to join Algeta, a Norwegian start-up developing first-in-class oncology products. As director of commercial production and then SVP of operations, I was involved in the late-stage CMC development of Algeta's oncology product, XOFIGO®, as well as establishing Algeta's first commercial manufacturing facility in Oslo. In August 2014, nine months after the approval of the product, we were acquired by Bayer and I continued in my role as project lead for

establishing a second manufacturing plant in USA and supporting the global rollout of XOFIGO® in more than 50 countries worldwide. In October 2018, I was appointed managing director of Bayer Norway.

What made Algeta and Bayer complementary partners?

When I joined Algeta, I could see that the company had a very competent international management team with great connections to the global market. This gave me trust in the company's potential. Algeta was also working on first-in-class radiopharmaceutical R&D. However, as a start-up company, they lacked the financial resources to complete the international registrational trials as well as global marketing capability for later worldwide launches and Bayer came in as a licensing partner. The NOK 4.8 billion (EUR 430 million) development and commercialization collaboration between Bayer and Algeta in 2009 remains the largest ever of its kind for a Norwegian pharmaceutical company.

Once Algeta's first product, XOFIGO®, received US FDA approval in 2013, Bayer acquired Algeta in 2014 and has continued the global roll-out. The product has since been approved in 54 countries, including most recently, China, at the end of August 2020.

When Bayer acquired Algeta in 2014, they did a full integration of the Norwegian company into the global organization. That being said, Bayer was very open and receptive to Algeta as a small start-up company with a unique competence and know-how. The integration was adaptable and smooth with the aim of maintaining Algeta's competences and keeping its core teams together, not suddenly overwhelming them within a giant organization. Algeta's R&D portfolio also became one of the cornerstones of the Bayer Oncology portfolio; given Algeta's niche focus on radiopharmaceuticals, our R&D was very complementary to Bayer's portfolio at that time.

Do you see radiopharmaceuticals as a niche area of pharma innovation in Norway?

Certainly. Through the acquisition and integration of Algeta, Bayer's Norwegian operations have become one of the company's global R&D and innovation hubs for radiopharmaceuticals. Radiopharmaceuticals in Norway, and especially the Oslo area, as such has developed into an international centre of excellence. There is an ecosystem here, with global industry players like Bayer and GE Healthcare, internationally well recognized innovation clusters such as the Oslo Cancer Cluster, and collaboration with university hospitals and universities such as the unique

collaboration agreement between the University of Oslo and Bayer. There is also relatively good access to venture capital and several new radiopharmaceutical start-ups like Nordic Nanovector and Oncoinvent have kicked-off over the last few years. All in all, a very potent ecosystem for radiopharmaceuticals exists here, in both therapeutics and diagnostics.

This is one of the reasons Bayer has invested over NOK 1.5 billion (EUR 130 million) into our R&D here over the past six years, including the expansion of our R&D laboratory in Oslo. We have around 70 scientists working on our R&D portfolio of radiopharmaceuticals. Through our R&D facility here, in conjunction with our contract manufacturing partner IFE, we also produce radiopharmaceuticals for global export, including the commercial supply of XOFIGO® as well as the clinical supply of multiple clinical candidates. Bayer has continued the work on the research that Algeta initiated on Radium-223 and Thorium-227 and value-creation in Norway.

How do you assess the dynamics of the Norwegian market when it comes to access to innovation, pricing, clinical trial enrollment and so on?

This is an important topic. The approval process for new medicines takes longer in Norway than European benchmarks and it is one of our key objectives, together with our local pharma association LMI, to improve this KPI so that Norwegian patients can benefit from earlier access to new treatments and medicines.

At the same time, as an industry, we are one of the parties in the health sector, and together with the public health services we share the goal of providing good treatment to patients. We will continue to work with health authorities to help them be confident that they are receiving the best service and value for the money spent.

When it comes to clinical trials, the unfortunate fact is that they have been declining in number in Norway over the past decade. This affects patient access to innovative treatments. I believe we should work together with all stakeholders to increase the clinical trial capacity and capabilities in Norway. This would help patients access novel medicines at an early stage, lower costs for the health system, and generate opportunities to create more value in Norway. Algeta, for instance, began with clinical trials in Norway before building up manufacturing for clinical supply and ultimately developing and establishing commercial production in the country for the worldwide market.

In our opinion, the hospitals and clinics should increase the resources and infrastructure dedicated to managing clinical trials, and companies have to start the necessary dialogue sufficiently early so that clinical trials can be conducted in Norway. There needs to be a common vision within the whole ecosystem. For instance, as a country with a relatively small population, I think it is important that Norway focuses on attracting early-stage clinical trials so we can be involved as early as possible within the drug development cycle and production for clinical supplies.

How has the Bayer Norway affiliate performed in 2019 and what are your expectations for 2020, which has been a really unusual year?

We saw positive growth in 2019 and we had a good start to the first half of 2020. However, the second half of the hear has been more challenging, partly driven by the very complex situation created by the COVID-19 pandemic.

Looking forward, we are very excited about Bayer's innovative portfolio, and with Norwegian glasses, especially within radiopharmaceuticals, where Bayer is definitively the world leader in alpha-emitters. We expect growth and we hope to contribute significantly to the global Bayer oncology franchise with more successes like XOFIGO® in the future. We are also investigating this product with regard to more indications in clinical trials

In other areas, we also have novel therapies we are excited to bring to Norway such as a product for chronic heart failure, which received US FDA Priority Review designation in July 2020; and our new prostate cancer drug and the gene fusion cancer medicine approved by the EMA earlier this year.

Therefore, moving into 2021 and beyond, we will be preparing for new product launches. Thankfully, we have been able to attract the necessary talents with the right competences for our growth strategy, including international talents. Bayer Norway actually employs staff of over 17 different nationalities on our site, which we are quite proud of.

Having worked across the Norwegian pharma industry for over 30 years, where do you think Norway's strength in pharma innovation lies?

Besides the global players and start-ups that exist in radiopharmaceuticals, we have a lot of excellent research, experts, and innovation within the field of cancer. Norway also has a high number of start-ups focusing on cancer, especially immunotherapy, there is a robust VC ecosystem

here, as well as high-quality institutions like the Radiumhospitalet, the University of Oslo, and the Oslo Cancer Cluster. I hope that we can maximize Norway’s innovation potential in cancer treatments and build on the novel research in neuroscience and the Nobel Prizes awarded to Dr May-Britt Moser and Dr Edvard Moser.

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