Interview: JÃ¼rgen Pohle â?? CEO (as from January 2018), Neovii Pharmaceuticals, Switzerland

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JÃ¼rgen Pohle provides both a fascinating and open account of the latest movements of Neovii; a company that possesses the ability to make decisions at the speed of a startup but also has a heritage dating back to the 1970s.

After an outstanding career spanning 25 years with Big Pharma players (Bayer, Novartis, GSK), you joined Neovii as Chief Commercial Officer in March 2016. Why at this stage of your career did you choose to join a pioneering biotech?

There were two reasons for that. First of all, working for an independent company has provided me with the freedom to work towards long term goals, and as a pioneering biotech firm, we are not so concerned with quarterly figures, and can engage on long-term strategic thinking. Secondly, Neovii is a particularly special start up as it has a very identifiable entrepreneurial spirit but equally heritage. This combination was very compelling and attractive for me. The field of stem cell therapy is one of the most dynamic and collectively we see a huge opportunity moving forward.

Despite having a name that sounds new, Neovii is far from being a â??start upâ?• company. Your history dates back to 1979 when what is today your lead product known as Grafalon was called ATG-Fresenius, and was manufactured by Fresnius Biotech. Fresenius Biotech then became Neovii in 2013 and ATG was rebranded to Grafalon just 2 years ago. Could you please run us through the evolution of the company?

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Initially, our lead product was a treatment for acute rejection after organ transplantations. It then became clear that the product had the potential to prevent chronic GVHD after stem cell transplantations. The product itself was developed in such a way that it became a pharmaceutical product rather than a biomedical product that was subject to continual study. We were able to fully focus our capabilities when another product acquired (Removab) failed to deliver on its potential. Given the legal ramifications we re-branded ATG-F and named our new product Grafalon.

Mr Sudarskis is stepping down as CEO next year, and you will be taking over. What objectives you are setting yourself to truly make Neovii the leading provider of life-saving, innovative drugs in the transplantation and rare diseases field?

The company has made huge strides in recent years from being a subsidiary to an independent pharmaceutical outfit with its own footprint and from a commercial aspect one that is capable of entering huge markets like France for instance. Mr Sudarskis has also been very successful in creating a leadership team to oversee the immediate period following his departure. Turning to the next phase, we will develop our US business. We have just published the results of our pivotal phase III trial in the US and we will engage with the FDA on the outcome of that study. Given we started work on the study in 2009, that is quite exciting as in coordination with the FDA we have the opportunity to develop a really great product. This objective will take up a considerable amount of my time but elsewhere we will be focussing on our second largest market China. Here, we will exploit the opportunities that exist there more than we have in the past. Also, we have just started to build a new production facility in Munich and will invest strongly in our talent. If all of these aspects of the business develop as predicted, we will move away from being a purely Grafalon driven company. Whilst Grafalon has been very successful, we are looking to obtain new product licenses and really evaluate current opportunities with the goal to becoming a fully-fledged pharmaceutical outfit with the exception of the research side of the business. We will continue to license research opportunities in accordance with our targets.

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Manufacturing has historically always taken place in Germany, and we are not considering to change this. to. That being said, parts of the supply chain may be developed in the future in Switzerland.

What is the therapeutic potential of Grafalon?

Historically, the product was used to prevent acute rejection of the organ during transplantation. It has been developed into a stem cell transplantation setting; a development that has been well documented in relevant medical journals. We have seen opportunities to develop the product further. For example, we can transfer the product into allogenic paediatric stem cell transplantation and hub flow haploidentical stem cell transplantation. We are also looking at opportunities to enter autologous stem cell transplantation as well. This aspect of pharmaceutical study has been brought to our attention through recent scientific publications. So essentially, we are looking at expanding Grafalonâ??s value both from a patientâ??s and a physicistâ??s perspective. Specifically, we are interested in cells that are transplanted into the patient.

The potential is huge. We work closely with various scientists to fully understand the potential of Grafalon. This connection has always been part of our heritage and we have always open mindedly listened to clinicians in regard to the value of potential products.

You have an expanding portfolio of novel life-transforming therapies, particularly in the areas of transplantation, hemato-oncology and immune disorders. What do you see as the

emerging trends (in demand and scientific advancement) in these niche areas?

Currently, stem cell transplantation for oncology diseases are therapeutically standard areas. However, stem cell therapy in other settings is still in the early stages of development. This is a very interesting area for us to explore. For example, a lot of research has been conducted in the field of autoimmune diseases but still there is no scientific breakthrough. So, there is certainly a lot more to come from this niche area.

There have been quite a few recent movements in your portfolio with, for example the in-licensing of certain rights for Arcalyst from Regeneron whilst experiencing the withdrawal of Removab. What does your portfolio look like today and what are the most promising candidates in the pipeline?

We are rather flexible when it comes to licensing. For instance, we were able to in-license the rights from Regeneron in regard to a specific type of paediatric fever syndromes more commonly known as Mediterranean fever. We are closely cooperating with Regeneron and generally we are in a position to assist companies that have successful products in their portfolios, but their potential profit scales do not interest large pharmaceutical firms. We can develop their products in such a way that both companies are satisfied and the patients receive good quality treatments.

We notice you recently concluded an out-licencing agreement with Zydus. Tell us about your in-licensing and partnerships strategy.

Zydus has been our partner in India for Grafalon for approximately a year. We are very happy with this partnership and they appear to share the same vision and ethical approach with us. They are intensively engaging with the key opinion leaders and we view this as a long-term partnership.

You maintain an affiliate office in the United States. What are your plans for increasing your geographical footprint? And how would you describe your ambitions in the US today?

We decided that we would like to create our own footprint in all of our key markets where the environment and the scale of our company permits us. Clearly in the case of the US we would like to establish our own footprint there. In European markets we are progressing well although we donâ??t have marketing authorisation for the UK yet. We are hoping to obtain this within the next two years. For historical reasons the product has never been filed for approval in the UK, but our aim is to reverse this situation in the near future.. We would like to be present in the UK market however, along with the four other leading European markets. Our German affiliate, Neovii Biotech GmbH, is not only a production site, but has very strong commercial resources. We also have presences in France, Italy and Spain, partnerships in the China, MEA and Asian markets and are continuously pursuing opportunities for partnerships in other markets for instance Russia and Latin America. Generally speaking, we have an open pragmatic approach to partnerships.

Neovii has been stationed in Switzerland for nearly 4 years now, but still keeps its biologics manufacturing facility in Germany. What does this country mean to the company? What do you value most in the Swiss life sciences ecosystem?

Switzerland has a number of advantages to offer pharmaceutical and biotech outfits. For instance, the highly-skilled talent available here is immense. The country also has a very positive attitude towards innovation and business as well as a reputation for being extremely stable politically. This backdrop allows independent companies to put reliable long-term plans into action. Also, work force loyalty and reliability is very high.

As a small independent company, we have found the talent that we seek quite easily so perhaps difficulties only arise if you have a large number of vacant positions. We get all the support from the authorities of Canton St. Gallen that we need and in some ways, we feel somewhat spoilt to get such support,.

On a more personal note, what qualities do you feel you bring from your â??Big Pharmaâ?? career to a company like Neovii?

Firstly, I would say global experience. Equally, the ability to quickly evaluate opportunities and to decide on the attractiveness for the firm in question is a significant skill that I have brought from previous roles. In an SME such an Neovii, the decision-making process is much faster and naturally involves much more dialogue, which I truly appreciate.

Where will Neovii be when we come back in roughly 5 yearsâ?? time?

We aim for having approval in the US for Grafalon. and for becoming one of the leading players in innovative transplant products i.e. not generic immune system focussed products. I would like to have a very diverse and high performing team. We are trying to bring in new talent from different backgrounds, and are committed to diversity in all sense of the term.. We leverage Switzerlandâ??s appeal and also bring in international talent.

We are constantly striving to become one of the leading figures in rare diseases (with a specific focus on transplantation). We are more than happy to engage with any scientist or firm to explore opportunities in these fields. As an independent company, we can be very flexible in our approach and very fast in our decision making.

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