

Interview: Dr. Oliver Bleck – General Manager, Roche Switzerland

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As the home market, Switzerland and Roche's Swiss pharma operations play an important and pioneering role within Roche's global organization, with early patient access to innovation and new commercial models taking place in the country.

The working title of the Healthcare & Life Science Review Switzerland is "A Leader Among Giants." For Roche, a Swiss company, how does the Swiss operating unit here in Reinach demonstrate leadership within the global organization?

Indeed, although Roche's global headquarters is just ten minutes away from our offices here, the Roche Swiss pharma unit operates quite independently. Although I only started my new role as general manager three months ago, I can say that our team here truly embodies all of Roche's core values in their daily work; our passion for science, courage, and integrity in the way we do things. It is certainly a great privilege to work for a company like Roche which is truly led by science and has 120 years of history in Switzerland, and having the opportunity to lead this company's pharma operations in the home market means a lot to me.

On a general note, I would say that the Swiss medical and life science industry as a whole demonstrates many aspects of leadership that one can be proud of. The commitment to science, excellence in education and research embodied by the very high global rankings of Switzerland's top universities, and a stable environment overall which is open and supportive of innovation and providing Swiss patients access to the most innovative medical care and therapies.

Within Roche, the Swiss pharma unit is a big contributor to generating new data and advancing the science within our organization as a whole. We are running about 50 clinical trials from phase I through phase IV in Switzerland, and Swiss researchers and teams contribute significantly to the company's global development programs. There is certainly an important interaction between the Roche global organization, our Swiss research teams, our research teams worldwide, and with Genentech in the US, to advance our global pipeline.

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The Swiss market also plays an interesting role for our medicines when it comes to approval and to market access. Swissmedic – who operates independently from EMA – may approve our innovative medicines faster than other health authorities. As such, we very much value the opportunity for fast-track approvals of innovative medicines within the Swissmedic framework that can actually put us in the position where Swiss patients can receive access first, ahead of patients in other European countries and/or the United States. A recent example from our own portfolio was the development and subsequent approval of our new combination therapy for melanoma – the combination of two targeted therapies Cobimetinib and Vemurafenib – which was approved by Swissmedic before either the FDA or EMA.

Here in Reinach, we have a highly skilled cross functional team to work closely with Swissmedic and also with the Swiss regulatory authority BAG once the medicines are approved to provide fast market access in Switzerland, and to interact with the insurers and authorities to provide and discuss data for our medicines.

Internationally, Roche has introduced some very innovative pricing and reimbursement models – how does the Swiss market fit into this global strategy?

The early registration of our combination therapies for example in breast cancer and malignant melanoma were followed by an innovative pricing scheme, the personalized reimbursement model. Under this model the pricing of the individual component follows both the indication it is used to treat and whether it is used in a combination therapy, thus the price paid is directly tied to the value that therapy offers to the specific patient, rather than just the price of a vial. As a prerequisite you need a legal framework that supports such models, and we are lucky that Switzerland is one country that has the needed framework.

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I very much believe that models of this sort will play an important role in the pricing and reimbursement of future oncology or other combination therapies, and that the experience here in Switzerland will offer valuable insights and evidence to be leveraged by Roche and other pharmaceutical companies globally. It is clear from the global life science community’s increasing understanding of tumor biology that combination therapies offer a lot of value to patients today and in the future. Since effective combinations might involve the pairing of our molecules with molecules that were developed by other innovators, the question needs to be answered regarding how such combinations might be managed from a market access and reimbursement perspective – it’s a positive sign that various companies, insurers and TAEs are jointly working in order to develop solutions.

From where you sit now, having assumed the general manager role three months ago, what does the agenda for 2017 and 2018 look like for Roche Switzerland?

From a global perspective, Roche is in a unique position with a leading industry pipeline, and 2017 will be a very important year for patients. Here in Switzerland we are preparing to launch three new molecular entities in 2017 – these include a breakthrough cancer immune therapy, our PD-L1 inhibitor Atezolizumab, which has the ultimate potential to cure more cancers than we currently can in combination with our own portfolio, and in combination with other molecules in the years ahead. I am also very excited we bring the first medicine – a monoclonal antibody against a subset of B cells – forward that has shown not only activity in relapsing multiple sclerosis (MS) but also for the very hard to treat patient population of primary progressive MS, both indications for the medicine are under Swissmedic review now. The third new medicine under Swissmedic review is another truly breakthrough medicine, with best in disease treatment potential for a specific subset of lung cancer

patients.

In addition, we are bringing new indications forward out of our existing portfolio to help advance breast cancer care in the neoadjuvant setting as well as a new front line therapy for Follicular Lymphoma. On top we will offer important improvements for patients, such as the subcutaneous forms of our breakthrough medicines Rituximab and Trastuzumab.

While Roche has an undisputed leadership position in oncology, many other pharma companies have been investing significantly to build their pipelines and portfolios in oncology. How might this put pressure on the way Roche has to operate as a business?

Roche's business model has always been to develop truly innovative products, to focus on trying to achieve breakthrough therapies and doing now what patients need next. Roche has a long tradition of transforming patient care through the company's history, with breakthroughs in immunology, infectious diseases, respiratory, ophthalmology, haematology and neurology and over decades we have played a significant role in oncology as the leading company by introducing a portfolio of breakthrough medicines globally that have helped millions of cancer patients to live longer and better lives and that could even help patients cure their breast cancer or their malignant lymphoma. As such, our business model will continue to follow the science, continue to develop better therapies, and to focus on bringing real breakthroughs to patients, and this means looking to unmet medical needs in all areas of medicine, not just oncology.

That said, Roche has a leading industry product pipeline, and unique opportunities to innovate cancer therapy by combinations of our research and product portfolio and this especially in the field of cancer immunotherapy. In addition, we are excited about our leadership in personalized healthcare, leveraging our diagnostic capabilities, accessing meaningful data from our clinical trials and from the real world, generating insights and advancing cancer care and bringing molecular information via our close collaboration with Foundation Medicine (FMI) into the physician's office; together with the ongoing development of real world data collection infrastructure, we are on the verge of a revolution in the information we can offer to physicians to support better decision making for patient care. Thus, I feel we are well positioned and leading the path of oncology and personalized healthcare to the next level.

If Roche follows the science, where are some areas it might lead outside of oncology?

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The expertise we've developed around personalized healthcare can be a significant asset in areas outside of oncology. Finding patients who will most likely benefit from a certain medication at the right time, are important not only for oncology, but in the other areas of our research, like neuroscience, inflammation, infectious diseases and rare diseases. When we are able to bring molecular information into the mix it will be a game changer in many areas of medicine. The same assets will help us to be fast and nimble in research and development, to access and to generate more real world data and this more quickly, given the increased diagnostic information that can be observed regarding each and every patient.

Thus, Roche has many opportunities ahead to expand the leadership in oncology to other areas of medicine. In the relatively short term, we are in the advanced development phase of a very innovative molecule with significant potential to treat hemophilia more effectively, and have a number of other promising molecules in the pipeline in our established treatment areas and for rare diseases.

Regardless of what area of medicine we focus on, Roche will continue to focus on "doing now what patients need next," and our commitment and passion for science will continue to lead the company. It is this commitment that has made Roche a trusted partner among physicians, researchers and in the industry, as around the world it's known that our decisions are driven by what has the potential to change patients' lives from a scientific perspective. Moreover, it's our responsibility to society and to patients to be as innovative as we can and to focus on developing solutions to healthcare needs that are unmet.

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