Speaker Spotlight

Klaus Falk

The Future of Biosimilars
Wed 06/11/19 ~ 10:30-11:40
CPhI Theatre 61D61

We catch up with Klaus Falk, VP of European Operations at Samsung Bioepis to find out what the future holds for the new Biosimilars market.

Q: Tell us about Samsung Bioepis and your role?

I am Vice President of European Operations for Samsung Bioepis, a personal priority for me is working towards increasing patient access to biosimilar therapies across Europe. I've worked for more than 30 years within the healthcare industry, and am particularly proud of Samsung Bioepis becoming the first company to be granted regulatory approval for biosimilars of all three first-generation anti-TNF medicines.

Q: What are the latest developments in the global biosimilar market?

Globally, biosimilars will continue to have significant growth potential as approvals continue to increase and patents expire. Companies like Samsung Bioepis already have a rich pipeline, signalling we will soon have biosimilars available across a broader range of therapies than the current blockbuster oncology and immunology biologics.

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Expect to see an increase of streamlined regulatory processes and policies as complex, low-uptake markets, like the US, look towards Europe. In countries such as Germany, France, and the UK, where there are clear policies around adoption and healthcare professionals have the right level of support, there are already significant cost savings and improvements in patient access. We are hopeful that the implementation of policies such as the FDA's 'Biosimilars Action Plan' will help to close the gap between low-uptake markets and those reaping the benefit of rapid biosimilar adoption.

Our big focus is the ongoing innovation in development and manufacturing. Shaking off legacy processes, whilst harnessing new technologies to bring the best quality biosimilars to the market faster. It is our ambition that this new approach to development will raise the bar in biologic medicines across the industry so that healthcare systems and patients can benefit.

Q: What are the current challenges for Biosimilars?

The complexity of the US regulatory and intellectual property system has been one of the biggest hurdles in that region. For other markets, payers may support biosimilars, but, like the generics in the '80s, work is needed on perceptions for better adoption. Typically, the level of awareness and education amongst healthcare professionals in Europe is varied, which significantly impacts prescribing confidence. Clinicians worry most at the point of switching a patient from a biologic to a biosimilar product, particularly if the patient is stable. As a company, we are investing in the ongoing creation of real-world evidence data around switching and interchangeability to support the need for better education around this challenge.

Q: Which markets offer the most potential and which are you keen to penetrate?

While different markets have different systems and dynamics, they represent equal importance to us, as we continue our work to increase patient access to biosimilar medicines across the world. In Europe, our anti-TNF biosimilars have treated more than 170,000 patients, and

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they have contributed hugely to driving down healthcare costs for European healthcare systems. We also have an infliximab biosimilar marketed in the United States, which has won a national contract with the Department of Veteran Affairs last year and has been showing steady growth. In addition to Europe and the US, we have recently started providing BRENZYS (etanercept) in Brazil, where we hope to deliver meaningful value to healthcare stakeholders throughout the country. We will continue to increase our efforts to expand access to high-quality biosimilars for patients across the world, who don't have access to these life-changing medicines.

Q: The world's largest pharma market (US) is still struggling with biosimilar uptake. Do you see this evolving in the long-term?

The environment in the US is very different from Europe and the slow uptake is a result of complex factors, including different regulatory pathways and legal challenges over intellectual property. Closing the gap between the US and Europe will require a commitment not only from a policy and regulatory standpoint, but also in healthcare professional education.

In Europe we have seen a concerted effort by health bodies to inform physicians and other healthcare professionals about the benefits of biosimilars, including the potential cost savings to the healthcare system and the supportive data on extrapolation and switching. This has been paired with investment from payers in policies that promote biosimilar adoption.

Whilst we are optimistic for the future, it is difficult to predict how quickly biosimilar adoption can meet its full potential in the US. However, the accelerated pathways promised in the new FDA 'Action Plan for Biosimilars' are a promising step in the right direction, but this will also need to be underpinned by local policy initiatives and education.

Q: You will be speaking on the 'Future of Biosimilars' at CPhI Worldwide, what does the future look like for you?

Even since Samsung Bioepis' launch in 2012, the biosimilars industry has made huge strides forward, but I believe there are even more exciting times ahead for the biosimilars industry. We are turning our development talents to the next generation of biosimilars in areas where there are high unmet patient needs, such as in the fields of ophthalmology and haematology. We will see the range of biosimilars expand exponentially as patents expire and we increasingly open up more cost-effective options to patients and healthcare systems.

The experience we have gained will also allow us to start working on our own novel biologics, and competition of this kind will be the driving force behind greater innovation and higher standards of quality across the biopharma industry.

Finally, we are also seeing increased innovation in the way biosimilars are made by companies like Samsung Bioepis. We are not held back by the legacy processes used by our pharmaceutical peers, meaning that manufacturing can be even more efficient than ever before. This allows us to imagine with confidence the possibility of a future where biosimilars offer even greater cost benefit to healthcare systems and payers than they do currently, paving the way for improved access to life-changing medicines for those most in need.

Klaus Falk is the Vice President of European Operations for Samsung Bioepis. He will speak on the panel Global Outlook: The Future of Biosimilars at CPhI Worldwide on Wednesday 6th November at 10:30 in the CPhI Pharma Insights theatre.