Alper Ureten – VP, General Manager for Biosimilars Business, Amgen

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Alper Ureten, Amgen VP and General Manager, sits down with PharmaBoardroom to set out his ambitions and objectives for its Biosimilars Business Unit. Ureten also reveals the strategy behind their success with biosimilars and emphasises the need for competition and high quality to foster eco-system maturity.

Alper, congratulations on your recent appointment as the general manager for the biosimilars business unit. Why were you chosen for this role with your experience as VP for the Middle East, Africa, and Turkey and what are your main goals and objectives?

My mandate is to bring biosimilars to the next phase. The previous team has done so much groundwork over the last ten years and I feel privileged to now be part of this success story.

During my time with Amgen in the last five years, I had the opportunity to manage a generics business in Turkey, which was acquired by Amgen in 2012. The generics market possesses some similarities with the biosimilars market, although there are important differences. In addition, from an experience perspective, I come from an area of the world where volatility and ambiguity are commonplace, and the market is fluid. Moreover, I spent a number of years in Europe where I

gained first-hand experience operating in countries that were transitioning to manage pharmaceuticals in a more cost-effective way. I believe this experience is now very relevant for the US market which is beginning to enter this cycle.

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Amgen is without a doubt one of the heavyweights in the biosimilars market. You have ten products in your portfolio, four with FDA approval. To what can you attribute this early success?

There is a combination of several factors at play. If you consider Amgen as a company, it is advanced in its science and its innovation. It took a lot of vision stretching back ten years to enter this type of business. Senior management certainly took a bold decision at the time, which is something to recognise and commend. While it appears obvious now, the trajectory for biosimilars was far less clear ten years ago.

Amgen’s success story can be traced to its reliability when it comes to product quality. Amgen has built success over 30 years by doing something quite different with an immensely high focus on quality and this has been a pillar of our achievement. Working with biosimilars is difficult and requires significant investment in the region: USD 250 million per product. In total, we have invested an excess of USD 2 billion. In addition, biosimilar development requires long-term commitment as development cycles can stretch many years. And compromising on quality is simply not an option in such an endeavour.

Amgen’s biosimilars business is not structured into a separate subsidiary, but instead is tightly integrated with your innovative portfolio. What makes this structure work?

Having an innovative portfolio alongside a biosimilars portfolio offers a very unique point of view. Many of our innovative products are actually facing competition from biosimilars. Having both portfolios tightly integrated actually allows us to obtain a dual perspective, both from navigating the IP landscape, all the way to commercialisation on both sides of the business. Through this model, we can create a symbiotic relationship, leveraging the learnings from one side to aid the other.

For example, engagement in the biosimilars space enables Amgen to work with antibodies and mechanisms of action across a wide range of innovative applications. These capabilities and the learnings we take from them allow us to grapple with the challenges involved in establishing biosimilarity. Moreover, in this line of business, efficiencies such as cost containment, matter considerably – and these can often be readily reapplied across the broader portfolio.

In terms of mitigating potential conflicts of interest, Amgen firmly believes in fair competition. If we are careful to uphold that principle at all times, then there is little discordance between our different business lines from a philosophical standpoint.

Since launching last year, your oncology biosimilars KANJINTI™ and MVASI™ have been able to establish a very strong foothold in the US market. What has been the secret of their success?

Amgen is renowned for its excellence when it comes to quality, consistency and reliability. Considering the rather demanding external operating environment in the US and, in particular, the market's insistence on exceptional standards at all times, whether that be in navigating the regulatory process or in carving out a niche within the IP landscape, the fact that we never compromise on quality has definitely been a contributing factor to our successes to date.

Moreover, our previous experience in managing an innovative business and competing against biosimilars has fostered Amgen's understanding of commercialising these types of drugs. Managing both product lines as one company is what sets us apart and ultimately gives us an edge over our competition.

In July 2020, we launched AVSOLA™, a biosimilar infliximab. The nature of this product is consistent with our two existing oncology products, so we have been able to leverage the learning from those previous launch experiences for the roll out of AVSOLA™.

Many would argue that the US biosimilars market has underperformed, looking at the gap between approvals and commercialisation and the fact that the nine percent cost savings projected a decade ago by the Congressional Budget Office have not materialised. Do you agree?

We now have a year of direct involvement in this market since commercialising our first product. So far, our experience has been positive and does not align with that perspective. In terms of regulation, the number of products that have been registered in the USA is greater than in Europe after a similar period of time, so products are now coming to the market.

One key question is how we define what success for biosimilars looks like in the USA. We do not believe that using the generics market as a reference is suitable, given the production costs involved for biosimilars and the high standards demanded. A biosimilar generally takes five times longer and can cost upwards of 25 time more to develop than a generic. When these are taken into account, the market behaves differently to generics.

Nonetheless, we do expect biosimilars to perform better than we have seen in earlier launches. Our launches to this point have been strong and we have established a 30 percent market share with our two oncology products. That for me is a balanced and successful start on this journey.

Looking at what the future holds, novel innovation is the core of pharmaceuticals and brings value to patients as well as the ecosystem. However, biosimilars create a balance. The system needs to be able to allocate resources effectively to sustainably fund that innovation. As that need for sustainability becomes a more pressing issue in the USA, appreciation for alternatives such as biosimilars will grow.

What approach is Amgen advocating to support the development of a vibrant US market for biosimilars?

There is an ongoing debate in the US about the role of biosimilars, with a number of bills being considered in the Senate. One such bill proposes a reimbursement for biosimilars at ASP (average sales price) plus 8 percent instead of the standard ASP plus 6 percent. We do not expect intervention by regulators or outside forces to favour one category of portfolio products. However, we have seen over the years that there are clear standards expected of companies involved in biosimilars. Our achievements in only our first year demonstrates that if you adhere to these expectations, you can succeed in this market

When you step back and look at the bigger picture, biosimilars were produced to create competition. Competition is what creates a sustainable marketplace and price savings over the long term. There are some companies who are taking a short-term strategy and are trying to tilt the playing field through legislation. We do not feel that this is needed at all. If you observe how

medical reimbursement currently looks, whether a biosimilar or a reference product is purchased, the same add on payment is received. This creates the necessary level playing field. What is most important is to let the manufacturers compete. The more players that are out there, the more and better the ideas available in the eco-system.

Moreover, commercial insurers have all the tools needed to support the adoption of biosimilars. Thinking of competition at a broader level, biosimilar manufacturers will compete on a number of different factors, such as their services for patients and their reliability for supply. We do not want a repeat of the situation unfolding in the generic injectable market where unsustainable prices have caused manufacturers to either fail to invest in a reliable supply, or leave the market entirely, creating shortages. When supply and demand are inconsistent, it hinders the ability of the market to have a preference for these types of products

How has Covid-19 affected your operations?

Covid-19 has accelerated inevitable transformations in the industry. The crisis has both exposed and worsened cost pressures worldwide, which will have a negative impact on healthcare structures. If anything, we expect that the Covid-19 crisis could create a rise in demand for competition from products like biosimilars given the potential for added pressure on prices. This has not been observed in the US at this time but has been observed in other markets worldwide.

Amgen is based in a competitive space within the life sciences arena in California, between the Bay Area and San Diego. How do you communicate your value propositions to attract the best talent?

Being part of a thriving biosimilars business offers unique personal development opportunities and challenges; since the biosimilars market is subject to high volatility, there is a need for real risk management. Amgen is often cited as an example of a biosimilars success story. This gives people an appetite to be part of the biosimilars business division at Amgen. We not only see this externally but internally as well.

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