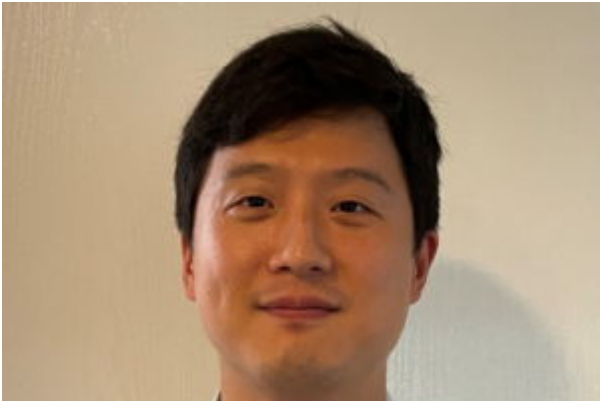


SeokHoon Kang General Manager Turkey, Celltrion Healthcare



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Best known as the company that launched the world's first antibody biosimilar, Celltrion is looking to continue its growth as a global biopharmaceutical company. Its general manager for Turkey, SeokHoon Kang and commercial director, Mahmut Uyar, outline the Korean company's strong performance in 2020, how they are leveraging their commercial and manufacturing presence in Turkey, and the strategy to expand their portfolio, which currently consists of three approved products in the country.

Can you start by introducing your career, how you got involved with Celltrion and the current scope of your responsibilities?

SeokHoon Kang (SHK): I majored in biotechnology at Kyung Hee University and joined Celltrion in 2012. I did not know much about the company itself but received recommendations from my seniors who explained the potential of biotechnology. Not long after joining Celltrion, I was impressed by a concept that at the time was not clearly defined: biosimilars. It became clear that I had been lucky to join a pioneer in biosimilars since it allowed me to be part of the sector's opportunities from the beginning.

I started my career in business development because, at the time, Celltrion was focused on R&D and obtaining regulatory approval and we did not have the know-how on penetrating markets without having local entities or expertise in local markets. Hence, we operated through strategic partnerships with local distributors.

As part of my business development assignments, I worked with big partners' accounts such as Hospira, which was later acquired by Pfizer. In 2018, when Celltrion was moving towards direct sales with its own international infrastructure, aiming to engage with healthcare professionals, I was named general manager for Germany. That role provided me with the opportunity to launch our Infliximab, the first antibody biosimilar approved by the European Medicines Agency (EMA), which, compared to the reference drug, had a subcutaneous formulation.

After one and a half years, the company sent me to Turkey in order to help improve the launching process of its products. The healthcare environment in Turkey is different from what I was accustomed to, but I have observed similarities between Turkey and South Korea given the countries' historical connections; there are many economic ties.

Celltrion launched the first-ever approved antibody biosimilar in Europe and has the ambition of becoming a top 10 pharmaceutical company. How would you describe the company to the readers that have not heard of it yet?

SHK: Celltrion is a true pioneer in biosimilars. Our objective at the moment is to launch at least one product per year; we try to be very competitive in the biosimilar market considering our leading position. Having said that, Celltrion is aiming to expand to new drug development which is the most important part of our strategy. The company so far has been able to position itself as a leader and innovator because it has its own integrated in-house process that covers all areas of development, including R&D, clinical trials, regulatory affairs, manufacturing and sales.

Our approach is about simplifying the process. We try to adhere to decisions that have been made in a steady manner. Moreover, we try to have a pragmatic approach to resolve any issue, never giving up while complying with all regulations. We do not allow ourselves to be boxed in by the 'normal way', but rather empower our people to be creative and think about the company as their own.

Fortunately for the Turkish organization, our local team is very proactive, precisely because of the trust awarded to them.

Apart from your commercial presence, Celltrion has one of its three regional manufacturing plants in Turkey. How is the organization leveraging that direct presence?

SHK: Having our own manufacturing in Turkey has helped with the regulatory process. We are leveraging our fill-and-finish plant to supply the demand coming from Celltrion's international markets and, of course, to supply the Turkish market. I cannot share a specific figure on the volume being produced here but we are involved with the manufacturing of Remsima and Herzuma.

What expertise does the Turkey organization have to compete in such a dynamic market?

Mahmut Uyar (MU): Celltrion decided to have a direct presence in Turkey in 2017. Before that, most of our current team was working at Amgen where I was business unit director. Therefore, our team has plenty of experience in the field. I have been working with biologics for over 13 years through different roles with Roche.

Because of that experience, the team understands the Turkish market in great detail and is familiar with the different stakeholders and processes. This experience matters here due to the importance of the tender business, especially for oncology and haematology products. Because of its quality products and local manufacturing, Celltrion enjoys a great reputation with physicians and is well-positioned for the future of the Turkish market, which will be about biosimilars.

Celltrion has been growing in Turkey and will accelerate that growth with our new Truxima (rituximab) launch.

Other Turkish companies investing in biosimilars have discussed the lack of clear biosimilars legislation in the country. Do you agree?

MU: The current legislation in Turkey is not ideal yet, but it is a work in progress. The first company to launch a biosimilar has an advantage because the rest must significantly reduce their prices. Obtaining a label approval after the reimbursement period is a lengthy process, around three years in average. There are good biosimilars available in Europe but it is not easy to launch them in Turkey.

Celltrion Healthcare's advantage is that it is locally manufacturing two strong products (Remsima and Herzuma) that are helping the healthcare system be more sustainable, and even conducting phase III clinical trials.

The company posted impressive financial results for 2020, almost doubling its revenue and net profit. How should we interpret those results and what led to the growth?

SHK: The sharp sales increase from 2019 to 2020 is mainly due to Celltrion's sales in the United States. We have a partnership with Teva which is responsible for our Herzuma and Truxima products in the US and Canada. Our European sales have also contributed to that growth even though competition has put some pressure on sales we enjoyed a high market share. The operating profit margin stayed positive and we anticipate our earnings will continue to grow in the following quarters this year.

The company's business model is focused on direct sales in the key European markets. For Turkey, we will be looking to expand our portfolio after receiving EMA approval for our products. We currently have three approved products in Turkey and others undergoing the regulatory approval process.

Looking at Celltrion's pipeline, the company is developing alternatives for blockbusters such as AbbVie's Humira. How are you planning to leverage those launches?

SHK: Indeed, our development of alternatives to current blockbusters will allow the company to continue its steady growth. Having that revenue base is important to continue financing innovation.

For example, CT-P17 is the first adalimumab biosimilar with a high concentration, low-volume and citrate-free formulation which aims to reduce pain on administration contributing to improved adherence. Celltrion now has biosimilars of both infliximab and adalimumab with value-added features, and CT-P17 could be used sequentially with the subcutaneous formulation of infliximab.

For example, the company is currently developing a Covid-19 antibody treatment called CT-P59 which received conditional approval in South Korea, Indonesia and Brazil, and is undergoing a rolling review from the EMA. The drug is indicated for patients with mild to moderate disease, patients that do not require oxygen treatment, and those who are at high risk for progressing to severe COVID-19. The global Phase III clinical trial demonstrated that CT-P59 met all primary and key secondary endpoints in patients with mild- to moderate symptoms of COVID-19.

Is there a final message you would like to send to our audience?

SHK: Personally, my mission is not only to bring value to the company itself, but also to the people of Turkey. Our team is working hard to be more than a biosimilars company; we want to be an integrated biopharmaceutical company.

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