

Takafumi Horii - SVP, Head of Japan Oncology Business Unit, Global Oncology Business Unit, Takeda



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Experienced global leader Takafumi Horii explains the rationale behind returning to his home nation of Japan to head up Takeda's Japan Oncology operations. Horii also touches on the significant burden of cancer in Japan, how Takeda's solutions help meet some of the country's most significant unmet cancer needs, as well as the access challenges that the company - a relative newcomer in the oncology field - is currently facing.

In January 2020, you moved from being Takeda's area head of Near East, Middle East & Africa (NEMEA), based in Dubai, to return to your home country and take up a new position as head of the Japan Oncology Business Unit. What is the significance of this Business Unit and what mandate have you been given?

I really enjoyed my time out in Dubai, which coincided with the first year of Takeda's integration of Shire. We spent a lot of time developing a new strategy and were preparing to implement it when I was asked to return to Japan to take up my current position.

Oncology is one of Takeda's core therapeutic areas, with a dedicated president Teresa Bitetti, based in Cambridge, MA (part of the greater Boston area) in the US overseeing operations for the US, Japan, Europe, and Canada. These big markets are run independently, while smaller markets belong to regional organisations. On a global level, Takeda sees oncology as having a high level of

need where novel approaches are required to enable more patients to benefit from potentially life-transforming medicines, and this is reflected in both the market's growth to date and its future potential.

However, many other Big Pharma players also have a very strong emphasis on oncology, meaning that it is an extremely competitive market where the speed of innovation is tremendous. Therefore, we at Takeda must be very agile to compete. Our oncology business is structured within Takeda to ensure a tight connection from research to development to commercialization and rapidly meet the needs of the cancer community, optimizing our ability to bring transformative medicines to market. Although our Oncology headquarters is in the US, we do have R&D people here in the firm's mother country of Japan as well.

On top of these overall market trends, 2020 was a particular moment for Takeda Oncology Japan. Back in 2019, we only had three oncology products on the market in Japan, but in 2020 we launched an additional three brands including in-licensing 2 products, meaning that we had new molecule launches in almost every quarter. We are now preparing for further new launches as well as expanding the indications of our existing portfolio.

Takeda - which is this year celebrating its 240-year anniversary - has been the leading pharma company in Japan for multiple decades. We have built upon that heritage in oncology, developing and delivering transformative treatments for patients with hematologic and solid cancers. Today, that mission drives us to continue delivering novel medicines to patients with cancer worldwide through a commitment to science, collaboration, and innovation

We have great external stakeholder recognition as well as strong development and commercialisation capabilities which mean that other firms often look to us to launch their products in Japan and fulfil the unmet medical needs of Japanese patients. Our Japan Oncology staff numbers have more than doubled since I returned to the country in January 2020, and we have had to work hard to build up the capacity and capability to launch our highly innovative new products with flawless execution.

Personally, I have been out of Japan for almost nine years and - while I thoroughly enjoyed my overseas assignments and have learned a lot - the opportunity to return home and contribute to Japanese patients was too good to turn down. Takeda's Japan Oncology Business Unit is relatively small, containing only 500 people, and has the flexibility of a biotech company with the agility to adapt quickly to a rapidly changing environment.

Cancer survival rates in Japan hold up well to international comparison and Japanese people are relatively healthy. What are the main characteristics of the oncology landscape in the country and where are the unmet medical needs that Takeda wants to cover?

Japanese life expectancy is still the highest in the world and we are, in general, a very healthy country. However, cancer is one of the top three causes of death here, meaning that there are still huge unmet medical needs.

The Japanese pharmaceutical market is worth around USD 100 billion, a number that has not altered in the last five years and which is not projected to change over the next five. However, over these five years, oncology has grown from 11 percent of this market to 16 percent today, a growth of five percentage points, and IQVIA projects that it will grow by another five-to-six percentage points over the next five years. That means that by 2025, oncology will represent one fifth of the entire Japanese pharma market.

This growth will be driven by a Japanese government and regulator that increasingly values innovation in oncology and which recognises and approves true breakthroughs in the field. This dovetails with Takeda's own strategy and our post-Shire acquisition portfolio of what we call 'curative or transformative potential treatments.'

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What kind of national plan for cancer does Japan have in place and how is Takeda's strategy adapted to it?

Given the high incidence of cancer in Japan, the government has laid out several strategic cancer plans, the most recent being the third version of the Basic Plan to Promote Cancer Control. The focus of the Plan is realising patient-oriented cancer treatment, which resonates with Takeda Oncology's ultimate aspiration to cure cancer. On top of that, the Plan aims to realise and drive cancer genomic medicine, something Takeda is also focusing on through the utilisation of artificial intelligence (AI) and big data. Takeda Oncology Japan is working together with external partners on this, including a project with the National Cancer Centre Hospital EAST and Fujitsu on better utilising electronic medical records to create more meaningful insights into the ovarian cancer patient journey. This is just one example of our work adding value on top of the innovative

medicines we are bringing to market.

Leveraging data will presumably be particularly important as Takeda attempts to bring oncology drugs developed outside of Japan to the Japanese market and proving their safety and efficacy for Japanese patients. What work are you engaging in on this front?

As a truly global company, Takeda wants to maximise the value of its products wherever the patient sits. Therefore, Japan is always prioritised in our global clinical trial designs. However, there are significant differences in cancer incidence rates between countries and ethnicities. Additionally, clinical trials are often not able to cover the broad spectrum of Japan's large elderly population.

Our dedicated 50-person oncology medical team works closely with KOLs and principal investigators to identify Japan-specific medical needs and often launches its own studies where necessary. Completely segregating Japanese and non-Japanese clinical trial data is not our strategy, but our regulatory and development colleagues do align closely with the PMDA from a clinical perspective.

What do you see as the main challenges of launching new oncology products into the Japanese market?

In 2020, against the backdrop of the COVID-19 pandemic, our biggest challenge was delivering information. As Takeda was entering a new therapeutic area in cancer, the inability to visit hospitals and have face-to-face interactions with doctors and KOLs was problematic.

However, we also saw an opportunity to develop new methods of stakeholder interaction. Japanese healthcare practitioners tend to work very hard, as do almost all Japanese people, and have had the additional burden of COVID-19 to deal with on top of their normal responsibilities. For these HCPs, finding a work-life balance has been next to impossible, therefore virtual interactions and greater connectivity are good solutions to freeing up their time and removing the need to travel.

Another challenge was building greater resilience into our organisation. The homeworking situation and lack of face-to-face interactions was disheartening for many of our staff. I have several new colleagues who I have only ever met virtually! Therefore, we had to work hard to maintain connectivity.

Despite these challenges, Takeda Oncology Japan's new launches were very successful, and our business grew by 22 percent in 2020, compared to an eight percent overall market growth.

Where are the barriers in terms of approvals and pricing for innovative oncology products in Japan? Is the country moving towards a value-based pricing model?

The current pricing system is broadly similar to those of other developed markets where, for example, a molecule is looked at in terms of mode of action before deciding how innovative it is. The Japanese government have laid out quite detailed criteria and, thankfully, Takeda's oncology products have so far all been recognised as innovative and therefore enjoy a value premium and protection from annual price cuts. Our products fit within the precision medicine spectrum, addressing very specific cancers, and therefore truly meet unmet medical needs for patients without another treatment option.

Takeda is obviously well-known as Japan's largest pharmaceutical company, but what has the reaction of oncology patients and doctors to the company been, given it has only recently entered the field?

You are correct in noting that we are still relatively new to the oncology space, with only around ten years of history in the field. In that sense, Takeda is not number one in oncology in Japan, but in some of our specific cancer areas - such as haematologic malignancies - we are already in top three, having been providing products and engaging with customers for some time.

In other areas, such as lung cancer which we only launched in May, we are not yet there. However, we will continue to build a presence there moving forward, with new pipeline products coming to market in the next few years.

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What is your approach to talent development as you build up the footprint of Takeda Oncology in Japan?

Talent development is one of our key focus areas. Given Takeda's global footprint, there is ample opportunity (post-COVID) to rotate talent across the world to learn from other affiliates.

Having been out of Japan for many years, I have been pleasantly surprised and impressed at how my Japanese colleagues have adapted to the global organisation. Takeda today is culturally very different from other, more traditional, Japanese pharma companies, with colleagues from all over the world and a high degree of female representation in leadership. Indeed, there are three women on my leadership team driving the business forward.

In a global comparison, Japan lags behind on diversity. However, compared to other Japanese companies, Takeda is truly embracing diversity and inclusion. Our global executive team contains ten nationalities and a lot of female leaders, showing that diversity and inclusion is a priority at the top, and this has cascaded down to the rest of the organisation.

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