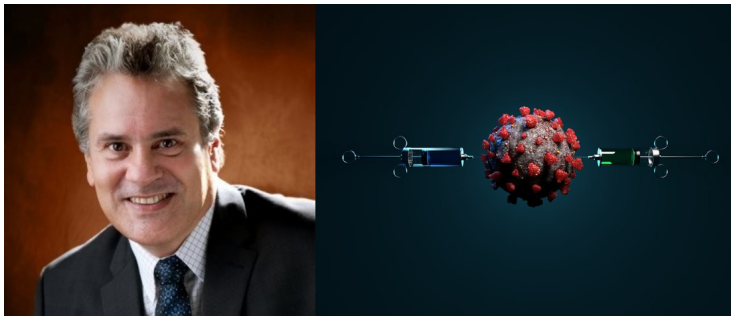
BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

We are advancing two bivalent candidates for utilisation in global vaccination efforts

07 October 2022 | Opinion | By Hithaishi C Bhaksar

"Bivalent booster strategy provides high levels of durable neutralising antibodies which broadens immuneresponse to better respond to variants of concern as they emerge", explains Patrick Bergstedt, Senior Vice President of commercial vaccines at Moderna



Singapore Health Sciences Authority (HSA) has granted an interim authorisation for the use of Moderna's Omicron-targeting bivalent booster vaccine. Also referred as Spikevax Bivalent Original/Omicron (mRNA-1273.214) is ahead in the race for active immunisation to prevent COVID-19 disease in individuals 18 years of age and older. Moderna is working with the HSA and the Government of Singapore to make Spikevax the next-gen Bivalent Original/Omicron available to people in Singapore during September. Moderna has received authorization decisions for omicron-targeting bivalent boosters in the United States, Australia, Canada, Europe, Japan, South Korea, Switzerland, Taiwan, and the UK to date and has completed regulatory submissions worldwide. **Patrick Bergstedt, Senior Vice President of commercial vaccines at Moderna** shared more insights on the next-gen bivalent vaccine.

- **How do you define the significance of booster vaccines amidst the declining pandemic phase?**

In June, the World Health Organization stated that a modified COVID-19 vaccine composition might be warranted to broaden immune protection against divergent SARS-CoV-2 S protein antigens, given that there has been substantial virus evolution since the first cases of COVID-19. We are now seeing the arrival of these next-generation vaccines, which is good news for global public health.

New Omicron-targeting bivalent vaccines target the original and Omicron strains of the virus. They are now available and will help broaden immunity against COVID-19, regardless of which sub-variant they are exactly designed against.

- **Can you summarise Moderna's perspectives for the COVID-19 vaccine in APAC, especially Singapore?**

The Asia-Pacific region represents an integral part of Moderna's business, with established subsidiaries in Japan, South Korea, and Australia. Earlier this year, we also announced plans to expand our commercial network across Asia with four new subsidiaries in Malaysia, Taiwan, Singapore, and Hong Kong.

Our plan to establish a local subsidiary in Singapore reflects the strategic role of the country as a leading biomedical sciences hub. Singapore offers a high number of skilled workers, government support for the sector, and a business-friendly regulatory environment. Our planned Singapore presence will also support Brunei.

COVID-19 vaccines have been instrumental in helping prevent infection and, more importantly, severe disease, hospitalisations, and death. We wish to commend the Government of Singapore for its prompt action in procuring COVID-19 vaccines and achieving high vaccination rates across the population, highlighting its leadership in health security. However, we still see that Omicron sub variants are causing fluctuating infection rates across the Asia Pacific region, which impact the ability of countries to reopen safely.

We believe our Omicron-targeting bivalent COVID-19 vaccines will help protect people across the Asia Pacific region, and these next-generation vaccines have already been approved in Australia, Taiwan, Japan, Singapore, and Taiwan.

It is important to note that Asia bears the highest burden of infectious diseases, and the burden of non-communicable diseases is increasing as the population ages. Moderna's growing portfolio in prophylactic vaccines, cardiovascular diseases, oncology, and rare diseases presents an unparalleled opportunity to use mRNA technology to maximise the potential impact the Company can have on human health in the region.

- **Can you elaborate on the comparison of .214 and .222 booster vaccines and Moderna's strategy on the two iterations in protecting us from COVID-19 and its sub-variants.**

The goal of our bivalent booster strategy is to provide high levels of durable neutralising antibodies that help broaden the body's immune response to better respond to variants of concern as they emerge. By targeting both the ancestral strain – from our original Spikevax – and a new variant of concern in our booster, we are not just fighting the dominant variant of the virus. We are also potentially broadening protection against future variants, even ones our bivalent vaccines weren't explicitly designed to target.

We are advancing two bivalent candidates for utilisation in global vaccination efforts. The mRNA-1273.214 bivalent booster candidate is based on the Omicron subvariant BA.1 and has demonstrated positive clinical data against variants of concern, including Omicron. The second bivalent booster candidate, mRNA 1273.222, is based on the BA.4/5 strain. Both bivalent candidates contain 25 µg of the currently authorised booster (mRNA-1273) and 25 µg of an Omicron-specific subvariant.

We were the first company to disclose clinical data on our bivalent mRNA platform, and the superiority of our Omicron-targeting bivalent COVID-19 vaccine against our prototype vaccine, mRNA-1273.214, highlighting our scientific leadership in this area.

- **How do you foresee the FY 22-23 prospects for Moderna? Will there be any challenges with commercialisation in the months to come with COVID-19 cases declining?**

We continue to have advance purchase agreements for expected delivery in 2022 of around $21 billion of sales. As we look to 2023, we expect public health authorities to remain key purchasers of vaccines. We continue to follow the market, with the potential move from a pandemic to endemic stage, and identifying markets where there may be a private commercial market as well.

We continue to work with countries around the world on potential additional orders for our bivalent vaccines as many countries are continuing to assess their public health needs, as well as their booster population recommendations and considering potential expansions to those populations. It is important we remain humble in light of the continued evolution of SARS-CoV-2 virus – this virus is likely here to stay with us, and may require an annual booster similar to what we see with the influenza market today.

In terms of 2023 orders, we have already signed deals with five countries that we have previously announced; the United Kingdom, Canada, Australia, Kuwait, and Taiwan. We have also signed options with Canada, Switzerland, and Taiwan. We are well positioned for the transition as we have invested in building our commercial infrastructure globally.

Hithaishi C Bhaskar