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Drug Makers Gear Up For 2023-2024 COVID-19 Season With Subvariant Vaccines

Pfizer/BioNTech, Moderna, Novavax Work With Regulators

by Alaric DeArment

The companies are all preparing to make available vaccines targeted to Omicron XBB subvariants, with the expectation that demand in the US will be about 50 million to 100 million doses.

The World Health Organization declared an end to COVID-19 as a public health emergency in May, but it warned at the time that the virus was still causing deaths and still mutating, and the emergence of the latest subvariants of the Omicron variant of SARS-CoV-2 has triggered new vaccine activity. The major producers of COVID-19 vaccines – [Pfizer Inc./BioNTech SE](#), [Moderna, Inc.](#) and [Novavax, Inc.](#) – are gearing up to make their vaccines against the new subvariants available by the fall, after a long trend of falling vaccine sales.

The latest is Novavax, which said on 22 August that its 2023-2024 season COVID vaccine induced neutralizing responses to emerging subvariants EG.5.1, XBB.1.16.6, XBB.1.16, XBB.1.5 and XBB.2.3, and that the company was in the process of submitting for authorization from regulatory bodies around the world. The company had said in June that it was preparing multiple candidates to ensure its vaccine would be available in the fall, with the US Food and Drug Administration's Center for Biologics Evaluation and Research working with it on manufacturing. (Also see "[Novavax Readying Multiple COVID-19 Vaccine Candidates To Ensure Fall Availability](#)" - Pink Sheet, 1 Jun, 2023.)

Moderna said 17 August that trial data confirmed its updated vaccine generated “robust immune response” against the EG.5 and FL.1.5.1 subvariants and the XBB strains more broadly, adding that it had submitted the updated vaccine to the FDA, European Medicines Agency and other regulatory agencies. Pfizer and BioNTech likewise said on 23 June that they had filed for authorization with the FDA and EMA.

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Gearing Up For 2023-2024 Coronavirus Season

On Novavax's second quarter earnings call on 8 August, chief commercial officer John Trizzino said that based on the company's own analysis as well as overall consensus, the demand in the US for COVID-19 vaccines in the fall would range from 80 million to 100 million doses. That is roughly in line with what Moderna forecast as well, with chief commercial officer Arpa Garay telling the company's 3 August second quarter earnings call that demand would be in the range of 50 million to 100 million doses.

That pales in comparison to prior vaccination figures. According to the Centers for Disease Control and Prevention, more than 984.4 million doses have distributed in the US and 676.7 million doses have been administered as of 11 May, with the Pfizer/BioNTech and Moderna vaccines constituting the overwhelming majority and Novavax's vaccine counting for a small fraction.

Novavax was a latecomer to the COVID-19 vaccine scene, facing regulatory setbacks that resulted in it coming in behind Pfizer/BioNTech and Moderna, which had already largely cornered the market and become major revenue generators – fueling pipeline growth for BioNTech and Moderna in particular – by the time the Novavax vaccine became available. (Also see "[Novavax's COVID-19 Shot Finally Authorized In US, But Could Miss Out Again On Bivalent Booster](#)" - Scrip, 15 Jul, 2022.)

"We continue to believe that the COVID vaccine market dynamics and distribution channel will be comparable to the annual seasonal influenza vaccine market," Novavax told *Scrip*. "And this market intelligence is driving our strategy to make our vaccine available to the commercial, government and public health-affiliated network of vaccine program stakeholders who are responsible for administering the majority of vaccinations."

Moderna's Garay also stated on the biotech's earnings call that the market would likely track the one for influenza.

On Pfizer's 1 August second quarter earnings call, CEO Albert Bourla said it was "common sense" that COVID-19 would follow the seasonality of other respiratory vaccines, with the majority of those vaccinations happening in the third and fourth quarters, but added that the company was waiting to see what would happen.

In terms of emerging subvariants, Novavax said it expected its vaccine would be effective at preventing the FL.1.5.1 strain given that it had shown efficacy against XBB.1.16.6, which shares two of the same mutations with FL.1.5.1, but the firm will conduct tests to demonstrate that.

Regarding another emerging strain, BA.2.86, it expects to learn more about it in the coming weeks, including its spread among the population and whether it has evolutionary advantages compared to the other circulating XBB sublineages.

Pfizer, meanwhile, told *Scrip* that a study in mice indicated the updated vaccine effectively neutralized a number of XBB variants, including XBB.1.5 and EG.5.1.