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Pfizer R&D Chief Mikael Dolsten Reflects On The COVID-19 Pandemic Experience

Part 1 Of 2

by Jessica Merrill

"I still remember how I screamed 'oh my god, it's just unbelievable,'" worldwide president R&D Mikael Dolsten told *Scrip*, reflecting on the moment he heard the first COVID-19 vaccine results.

For *Pfizer Inc.* President-Worldwide R&D Mikael Dolsten, the experience of overseeing the development of the COVID-19 vaccine Comirnaty, in partnership with *BioNTech SE*, and the antiviral Paxlovid have been unlike any other experience in his 13-year career leading the R&D team at the big pharma.

Dolsten sat down with *Scrip* at the Galien Foundation's Prix Galien USA Forum in New York on 26 October and reflected on the experience and the remaining challenges and opportunities when it comes to the evolving SARS-CoV-2 virus.

Dolsten stood out early in the pandemic for publicly outlining an aggressive vaccines development timeline and a goal to make a COVID-19 vaccine available for an emergency use authorization (EUA) in late October of 2020 – a timeline that seemed ambitious at the time given traditional vaccine development timelines but ultimately slipped by only a few weeks. (Also see "*Pfizer Rose To The COVID-19 Challenge And The Stars Aligned*" - Pink Sheet, 11 Dec, 2020.) A key part of that process was deciding quickly to move forward with a novel mRNA technology developed by BioNTech.

"It was a very special moment, one of those life-changing moments," Dolsten said of what it was like when he found out the mRNA vaccine Pfizer had bet on to help end the global health crisis was more than 90% effective at preventing COVID-19 infection. The interim data from the Phase III trial released in November 2020, more than nine months into the pandemic, were arguably the

most widely watched clinical trial data in history as lives around the world were shaken by the outbreak. (Also see "*The World Celebrates Pfizer's 90% COVID-19 Vaccine Efficacy Data, With Cautious Caveats*" - Pink Sheet, 9 Nov, 2020.)

The US Food and Drug Administration had set a 50% efficacy threshold for the vaccines in development, and both of the two original mRNA vaccines from Pfizer/BioNTech and *Moderna, Inc.* that eventually reached the market surpassed that bar by a notable margin.

"It was a moment of hope, of fear, curiosity, of optimism, but cautiousness, because you can believe in your science but until you open the code to the trials, you never know," Dolsten said. At the same time, he felt a weight resting on his shoulders about what it would mean for the world if the clinical trial data were disappointing.

"It was really a feeling of if this wouldn't work, what a despair we all would be in – humanity, society," he said.

Instead, the representatives who had discussed the results with the independent data monitoring committee shared with Pfizer management the astounding news that the vaccine was more than 90% effective.

"For me, it felt like flying up like a bird leaving the tree," Dolsten said. "I still remember how I screamed, 'Oh my god, it is just unbelievable.'"

Two years later, Pfizer has emerged as the clear leader in the COVID-19 vaccine and treatment market although COVID-19 continues to be a global health challenge as the virus has mutated and evolved. Pfizer has attempted to keep pace and address the constantly changing threat, most recently with an updated bivalent booster of Comirnaty that includes the original virus as well as the Omicron BA.4 and BA.5 subvariants. (Also see "*Coronavirus Update: Pfizer/BioNTech Announce Positive Early Booster Data*" - Scrip, 13 Oct, 2022.)

Pfizer also developed Paxlovid (nirmatrelvir/ritonavir), the first oral antiviral authorized by the FDA to treat people infected with COVID-19 at high risk for progressing to severe disease, which has been an important tool in the armamentarium for reducing the most serious outcomes, including hospitalization and death. Paxlovid was granted an emergency use authorization by the FDA in December 2021. (Also see "*Pfizer First: Oral Antiviral Paxlovid Wins EUA As Merck's COVID Pill Languishes At US FDA*" - Pink Sheet, 22 Dec, 2021.)

Hearing the positive data results from the Phase II/III EPIC-HR study showing Paxlovid reduced the risk of death for non-hospitalized, high-risk COVID-19 patients by 89% was a bit like déjà vu one year after the positive vaccine data results, according to Dolsten.

"That was almost like hoping to win the Olympics of the century twice," Dolsten said. "We had many patients who still weren't doing well and many high-risk patients, and we also had issues, of course, with vaccine hesitancy, so to be able to have a second intervention that could enable us to open up society again ... it was fantastic."

Taking Stock

While the challenges of COVID-19 persist, Dolsten is also relishing some of the positive outcomes that have come with contributing to the development of the vaccine and treatment.

"I've heard numbers that more than 10 million lives have been saved by the vaccines, of which I think the Pfizer/BioNTech is more than two thirds, probably now even maybe three out of four," he said. "We have given in the US, I think, 6 million treatments with Paxlovid, so a lot of patients' lives have been saved who had COVID. It feels extraordinarily good sitting here."

Nonetheless, the work on the COVID-19 front is far from over and Pfizer continues to recognize the threat that exists.

"We are committed to continue to make sure our vaccine is as close as possible to the most dominant circulating variants," Dolsten said. "We will continue to look at ways to strengthen the protection of the vaccine and durability and the resilience [against] new variants."

Pfizer also tests Paxlovid against every new variant to make sure it stays therapeutically active, which it has thus far. The company has also initiated clinical testing for next-generation antivirals.

"On top of that, we need to be prepared that there may come new viral pandemic-like threats, whether more distant relatives to SARS-CoV-2 or maybe even other viruses," he added.

"You always need to continue. Science must go on," he said.

For Pfizer, Comirnaty and Paxlovid have also changed the financial trajectory of the firm. Comirnaty, which Pfizer shares profits on equally with BioNTech, is expected to generate an astounding $34bn in 2022 and Paxlovid, which Pfizer has full ownership of, is expected to generate $22bn.

Pfizer was notably the only early leader in the vaccines race not to partner with the US development effort Operation Warp Speed, which the company said allowed it to move more quickly on the development and also may have given Pfizer more leverage when it came to negotiating government contracts.

Pfizer is now planning for the transition of the market away from government contracts to a

commercial market, which is likely to happen in 2023. During Pfizer's third quarter sales and earnings call, CEO Albert Bourla said that the business is poised to become something more akin to the flu market in terms of volume but that the business will remain a "multi-billion-dollar" franchise for several years.

The windfall is money that Pfizer has been able to direct toward business development and R&D investment, with the goal of bringing new drugs to market in the second half of the decade to make up for the anticipated loss of some top-selling drugs like Ibrance (palbociclib) and Eliquis (apixaban).

[Editor's note: In the second part of the two-part interview, Dolsten discusses Pfizer's business development strategy and advances in the non-COVID pipeline.]