Stanley Erck Opening Statement European Parliament – COVI Committee Hearing Delivered: October 10, 2022

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Introduction

Good afternoon. My name is Stan Erck, and I'm President and CEO of Novavax. I want to start by thanking the esteemed Committee for the opportunity to be here. The partnerships between governments and the companies present today made possible the unprecedented response to the COVID-19 pandemic. The work this Committee will do to carry these lessons forward is critically important to be ready for future pandemics, and Novavax is eager to contribute.

Novavax is a biotechnology company that promotes improved global health through the discovery, development, and commercialization of innovative vaccines to prevent serious infectious diseases. Our protein-based COVID-19 vaccine, Nuvaxovid™, is authorized in over 40 countries. Nuvaxovid is the first, and only, protein-based COVID vaccine currently available in the EU. Our vaccine provides a differentiated option to individuals and serves to diversify Europe's vaccine portfolio.

Our Company

Unlike many other biopharmaceutical companies, Novavax is focused exclusively on developing life-saving vaccines to fight infectious diseases. For the past ten years, we have refined our recombinant protein platform technology and adapted it for various emerging diseases.

We know that vaccines don't save lives, vaccinations do. To realize the benefits of vaccines, there must be robust uptake. Critical to uptake is both access and availability of COVID-19 vaccines, as well as public confidence in the safety and efficacy of these products. And to that end, Novavax is committed to transparency and accountability. Our company has been transparent around our clinical trial protocols and scientific data, which we believe is one of the best ways to ensure public confidence in any vaccine that is ultimately authorized and recommended for use.

We also know that pandemics don't observe country borders, and although there is a worldwide surplus of COVID-19 vaccines, this will not always be the case. Novavax is committed to reasonable pricing, equitable distribution and allocation, and expansive vaccine access.

Our COVID-19 Vaccine in the EU

Early in 2020, our scientists knew that our protein-based platform could be applied to address the emerging threat of SARS-CoV2, and we began working on our candidate. Just two years later, Nuvaxovid has been authorized for use in over 40 countries.

The European Medicines Agency granted Conditional Marketing Authorization for Nuvaxovid in December of 2021. This approval was for immunization to prevent COVID-19 for adults aged 18 and older.

In July, this authorization was expanded for use as a primary series for adolescents aged 12 through 17, and in September, the authorization was further expanded for use as a booster for adults aged 18 and older regardless of previous vaccine history.

We are continuing our research and development to make Nuvaxovid broadly available to all populations. This summer we launched a clinical trial to evaluate the safety and efficacy of two doses of the Novavax COVID-19 vaccine in younger children aged six months through 11 years, followed by a booster at six months after the primary vaccination series. In addition, we have begun studies to evaluate a combination vaccine against both COVID-19 and Influenza, as it seems there may be a need for recurrent boosters to fight both COVID-19 and seasonal influenza.

Our Footprint

I'd like to share more about our footprint in Europe. Vaccines like ours can be efficiently produced at massive scale to help meet global demand. Novavax vaccines are manufactured, transported, and stored at standard refrigeration temperatures. This is a very important feature as it helps simplify production, worldwide distribution, and use.

In mid-2020, we began to build a global manufacturing operation to produce our COVID-19 vaccine at commercial scale worldwide. For the year that followed there were significant constraints on supplies, raw materials, and facilities with vaccine manufacturing capabilities. Novavax engaged in extensive partnerships and technology transfers to meet the challenges of these constraints.

Today, much of our supply chain is based in Europe. We acquired a state-of-the-art vaccine manufacturing facility in the Czech Republic to produce our antigen, and our facility in Sweden has long been producing our adjuvant. We have also partnered with organizations in Germany, Ireland, Belgium, Spain, Poland, and the Netherlands that will produce our final packaged product for European and global use. Beyond Europe, we have partnered with manufacturers around the world, including SK bioscience in the Republic of Korea, Takeda in Japan, and the Serum Institute of India.

Lessons Learned

Before I close, I'd like to address the key lessons from the COVID-19 pandemic from the Novavax perspective. These takeaways can support vaccine innovation and access in Europe and improve the speed of our response to future public health challenges.

First, COVID-19 vaccines were made available in record-breaking timeframes, not because any shortcuts were taken, but because of

- regulatory agencies' review speed and active engagement with product developers,
- at-risk manufacturing by the vaccine industry before regulatory authorization, and
- robust public-private partnerships.
- The range of regulatory flexibilities, such as
    - rolling reviews,
    - facile meeting opportunities,
    - and efficient regulatory review processes should continue even post-pandemic.
- Other positive examples include
    - the use of virtual and digital methods for executing routine tasks,
    - flexibilities on language and labeling to address shortages and supply constraints,
    - and flexibilities in administrative processes such as registration variations, importation testing, and protocol amendments.

Second, supply chains for vaccines are extremely complex, and in many cases, involve several partners spread across the EU and the globe. We have learned that actions at the Member State level must be coordinated to avoid unnecessary burdens and challenges in getting vaccines where they are needed most.

During major EU public health emergencies, monitoring of supply and forecasting demand for medical countermeasures should take place at the EU level. It is also important that the Commission maintains an open dialogue among EU Member States, the US, and key international organizations on potential bottlenecks to supply chains that could hinder the effective manufacturing of countermeasures.

Third, the R&D ecosystem that has provided the major solutions to health threats such as COVID-19, is built on intellectual property rights. Europe needs a dynamic and well-funded research ecosystem. This means ensuring long-term investment in R&D, skills, networks, and health data infrastructure. It also requires regulatory flexibility and a supportive IP framework. Novavax has partnered with dozens of organizations worldwide to take advantage of every opportunity to grow capacity so that we may deliver on our commitment to accelerating equitable access to safe and effective COVID-19 vaccines, particularly in countries where vaccination rates are currently low.

Over the course of the pandemic, we spent months transferring know-how to our partners to ensure they can manufacture vaccine that meets regulators' strict standards for safety and effectiveness. Weakening IP rights weakens those partnerships and undermines the ability to continue to invest in capacity building and R&D. Governments should continue to invest in public health infrastructure, manufacturing capabilities, and early-stage research for medical countermeasures that can be advanced through commercialization by industry.

Fourth, people want choice in vaccines. They must be informed to be confident in those choices and decide which is the best option for themselves. Our differentiated vaccine delivers an important choice as we see ongoing surges of COVID-19 and work to increase vaccination rates. The special report recently issued by the European Court of Auditors also stressed that the existing EU vaccine portfolio heavily relies on a single technology. Diversifying vaccine availability in Europe's portfolio will be critical in bolstering preparedness levels and enabling the EU to live with and mitigate the impacts of COVID-19.

As I mentioned at the start, the work of this Committee to carry the lessons learned from this pandemic forward is critically important. I hope that my contribution to the hearing today helps advance your efforts, and I look forward to continuing to serve as a resource.

Close

In closing, as COVID-19 evolves, we remain committed to increasing access to diversified vaccine options in the EU and around the globe.

It is vital that the EU has a strong, diverse vaccine portfolio reflecting multiple vaccine platforms to ensure the broadest access to, and uptake of, vaccines. I believe that our vaccine has an important and long-term role to play in protecting the people of the world against COVID-19.

Going forward, Novavax will draw on our experience in COVID to continue the development of vaccine candidates for some of the world's toughest viral threats and use the power of our innovative vaccine platform to reduce the human toll of vaccine-preventable diseases.