Baxter BioPharma Solutions and Moderna Announce Agreement for Fill/Finish Manufacturing of the Moderna COVID-19 Vaccine in the U.S.

March 8, 2021

- Agreement to perform fill/finish services for approximately 60–90 million doses in the U.S. this year
- Manufacturing will take place at Baxter BioPharma Solutions’ Indiana facility

DEERFIELD, Ill., AND CAMBRIDGE, Mass.--(BUSINESS WIRE)--Mar. 8, 2021-- Baxter International Inc. (NYSE: BAX), a global leader in sterile medication production and delivery, and Moderna, Inc. (Nasdaq: MRNA), a biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines, today announced that they have entered into an agreement for Baxter BioPharma Solutions to provide fill/finish sterile manufacturing services and supply packaging for approximately 60-90 million doses of the Moderna COVID-19 Vaccine in 2021. Baxter’s BioPharma Solutions business is a premier contract manufacturing organization that specializes in parenteral (injectable) pharmaceuticals, including vaccines.

“We have seen a remarkable demonstration of scientific and health care expertise in the effort to develop vaccines for COVID-19,” said Marie Keelley, vice president, Baxter BioPharma Solutions. “Baxter is honored to provide our deep expertise in vaccine manufacturing to help partners like Moderna bolster the supply of their vaccine.”

The manufacturing of the Moderna COVID-19 vaccine will take place at the BioPharma Solutions fill/finish sterile manufacturing facilities located in Bloomington, Ind. The site has capabilities and expertise in parenteral delivery systems and clinical and commercial vaccine manufacturing, including preventive and seasonal vaccines for global markets. In addition, Bloomington offers a range of production and commercialization services, including clinical development, formulation, packaging and commercial launch capabilities. Baxter BioPharma Solutions has operated in Bloomington for approximately 20 years and employs more than 700 individuals on its 600,000 square foot campus.

“We welcome the opportunity to work with Baxter BioPharma Solutions on fill/finish manufacturing for the Moderna COVID-19 Vaccine in the U.S.,” said Juan Andres, Moderna’s Chief Technical Operations and Quality Officer. “This additional production will help us continue to scale up our manufacturing capacity in the United States.”

Additional details of the agreement were not disclosed.

About Baxter's BioPharma Solutions Business

Baxter’s BioPharma Solutions business supports leading pharmaceutical companies in meeting their commercialization objectives by providing scientific expertise, sterile manufacturing solutions, parenteral delivery systems and customized support services needed to meet the unique challenges that parenteral products face. For more information, please visit www.baxterbiopharmasolutions.com.

About Baxter

Every day, millions of patients and caregivers rely on Baxter’s leading portfolio of critical care, nutrition, renal, hospital and surgical products. For more than 85 years, we’ve been operating at the critical intersection where innovations that save and sustain lives meet the healthcare providers that make it happen. With products, technologies and therapies available in more than 100 countries, Baxter’s employees worldwide are now building upon the company’s rich heritage of medical breakthroughs to advance the next generation of transformative healthcare innovations. To learn more, visit www.baxter.com and follow us on Twitter, LinkedIn and Facebook.

About Moderna

In 10 years since its inception, Moderna has transformed from a science research-stage company advancing programs in the promising-but-still-unproven field of messenger RNA (mRNA), to an enterprise with its first medicine having treated millions of people, a diverse clinical portfolio of vaccines and therapeutics across six modalities, a broad intellectual property portfolio in areas including mRNA and lipid nanoparticle formulation, and an integrated manufacturing plant that allows for both clinical and commercial production at scale and at unprecedented speed. Moderna maintains alliances with a broad range of domestic and overseas government and commercial collaborators, which has allowed for the pursuit of both groundbreaking science and rapid scaling of manufacturing. Most recently, Moderna’s capabilities have come together to allow the authorized use of one of the earliest and most-effective vaccines against the COVID-19 pandemic.

Moderna’s mRNA platform builds on continuous advances in basic and applied mRNA science, delivery technology and manufacturing, and has allowed the development of therapeutics and vaccines for infectious diseases, immuno-oncology, rare diseases, cardiovascular diseases and auto-immune diseases. Today, 24 development programs are underway across these therapeutic areas, with 13 programs having entered the clinic. Moderna has been named a top biopharmaceutical employer by Science for the past six years. To learn more, visit www.modernatx.com.

Baxter Forward-Looking Statements

This release includes forward-looking statements regarding Baxter’s production of the Moderna COVID-19 vaccine, including expectations with regard to the approval of the vaccine, its availability in the United States and the timing and volume thereof. The statements are based on assumptions about many important factors, including the following, which could cause actual results to differ materially from those in the forward-looking statements: satisfaction of regulatory and other requirements; actions of regulatory bodies and other governmental authorities; product quality, manufacturing or supply, or patient safety issues; inability to create additional production capacity in a timely manner or the occurrence of other manufacturing or supply difficulties (including as a result of a natural disaster, public health crises and epidemics/pandemics, regulatory actions or otherwise); changes in law and regulations; and other risks identified in Baxter’s most recent filings on Forms 10-K and 10-Q and other SEC filings, all of which are available on Baxter's website. Baxter does not undertake to update its forward-looking statements.
This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including regarding: Moderna’s development of a vaccine against the novel coronavirus, and an arrangement pursuant to which Baxter will provide sterile manufacturing services for the Moderna COVID-19 Vaccine. In some cases, forward-looking statements can be identified by terminology such as “will,” “may,” “should,” “could,” “expects,” “intends,” “plans,” “aims,” “anticipates,” “believes,” “estimates,” “predicts,” “potential,” “continue,” or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. The forward-looking statements in this press release are neither promises nor guarantees, and you should not place undue reliance on these forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, many of which are beyond Moderna’s control and which could cause actual results to differ materially from those expressed or implied by these forward-looking statements. These risks, uncertainties, and other factors include, among others: the fact that there has never been a commercial product utilizing mRNA technology approved for use; the fact that the rapid response technology in use by Moderna is still being developed and implemented; the safety, tolerability and efficacy profile of the Moderna COVID-19 Vaccine observed to date may change adversely in ongoing analyses of trial data or subsequent to commercialization; despite having ongoing interactions with the FDA or other regulatory agencies, the FDA or such other regulatory agencies may not agree with Moderna’s regulatory approval strategies, components of our filings, such as clinical trial designs, conduct and methodologies, or the sufficiency of data submitted; Moderna may encounter delays in meeting manufacturing or supply timelines or disruptions in its distribution plans for the Moderna COVID-19 Vaccine; whether and when any biologics license applications and/or emergency use authorization applications may be filed and ultimately approved by regulatory authorities; potential adverse impacts due to the global COVID-19 pandemic such as delays in regulatory review, manufacturing and clinical trials, supply chain interruptions, adverse effects on healthcare systems and disruption of the global economy; and those other risks and uncertainties described under the heading “Risk Factors” in Moderna’s most recent Quarterly Report on Form 10-Q filed with the U.S. Securities and Exchange Commission (SEC) and in subsequent filings made by Moderna with the SEC, which are available on the SEC’s website at www.sec.gov. Except as required by law, Moderna disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this press release in the event of new information, future developments or otherwise. These forward-looking statements are based on Moderna’s current expectations and speak only as of the date hereof.

Baxter is a registered trademark and BioPharma Solutions is a trademark of Baxter International Inc.