# Endo Announces Fill-Finish Manufacturing and Services Agreement for Novavax COVID-19 Vaccine Candidate

September 25, 2020

DUBLIN, Sept. 25, 2020 /PRNewswire/ -- Endo International plc (NASDAQ: ENDP) today announced that its subsidiary, Par Sterile Products, LLC (Par Sterile) has entered into a non-exclusive agreement with Novavax, Inc. to provide fill-finish manufacturing services at its plant in Rochester, Michigan for NVX-CoV2373, Novavax' COVID-19 vaccine candidate.

Under the terms of the agreement, Par Sterile's Rochester facility has begun production of NVX-CoV2373 final drug product, with initial batches to be used in Novavax' pivotal Phase 3 clinical trial in the United States. Par Sterile will also fill-finish NVX-CoV2373 vaccine intended for commercial distribution in the United States. Financial and other terms of the agreement were not disclosed.

"This agreement puts an important piece in place as we finalize our supply chain for the U.S. clinical trial and eventually, commercial distribution of NVX-CoV2373, our nanoparticle vaccine adjuvanted with Matrix-M™," said Stanley C. Erck, President and CEO, Novavax. "Endo's partnership and expertise are enabling rapid delivery of the vaccine for pivotal clinical testing, which we expect to get underway very soon."

"We are very pleased to help bring Novavax' COVID-19 vaccine to the public," said Blaise Coleman, President and CEO of Endo. "Our Rochester, Michigan facility has a long history of manufacturing critical vaccines and sterile injectable products for the U.S. market and we are proud to partner with Novavax on such a critical initiative. This partnership further underscores Endo's commitment to helping everyone we serve live their best life through the delivery of life-enhancing therapies."

NVX-CoV2373 is currently in multiple Phase 2 clinical trials. A Phase 2 clinical trial to evaluate the safety and immunogenicity of NVX-CoV2373 began in August 2020 in the United States and Australia building on positive Phase 1 results and expanding to include older adults. A Phase 2b clinical trial to assess efficacy began in South Africa in August 2020. Interim data for these trials is expected before the end of 2020.

**About NVX-CoV2373**
NVX–CoV2373 is a vaccine candidate engineered from the genetic sequence of SARS–CoV–2, the virus that causes COVID-19 disease. NVX–CoV2373 was created using Novavax' recombinant nanoparticle technology to generate antigen derived from the coronavirus spike (S) protein and contains Novavax' patented saponin-based Matrix-M™ adjuvant to enhance the immune response and stimulate high levels of neutralizing antibodies. In preclinical trials, NVX–CoV2373 demonstrated indication of antibodies that block binding of spike protein to receptors targeted by the virus, a critical aspect for effective vaccine protection. In its Phase 1 portion of the Phase 1/2 clinical trial, NVX–CoV2373 was generally well-tolerated and elicited robust antibody responses numerically superior to that seen in human convalescent sera. Phase 2 clinical trials began in August 2020. Novavax has secured $2 billion in funding for its global coronavirus vaccine program, including up to $388 million in funding from the Coalition for Epidemic Preparedness Innovations (CEPI).

**About Novavax**
Novavax, Inc. (Nasdaq: NVAX) is a late-stage biotechnology company that promotes improved health globally through the discovery, development, and commercialization of innovative vaccines to prevent serious infectious diseases. Novavax is undergoing clinical trials for NVX-CoV2373, its vaccine candidate against SARS-CoV-2, the virus that causes COVID-19. NanoFlu™, its quadrivalent influenza nanoparticle vaccine, met all primary objectives in its pivotal Phase 3 clinical trial in older adults. Both vaccine candidates incorporate Novavax' proprietary saponin-based Matrix-M™ adjuvant in order to enhance the immune response and stimulate high levels of neutralizing antibodies. Novavax is a leading innovator of recombinant vaccines; its proprietary recombinant technology platform combines the power and speed of genetic engineering to efficiently produce highly immunogenic nanoparticles in order to address urgent global health needs.

For more information, visit www.novavax.com and connect with us on Twitter and LinkedIn.

**About Endo International plc**
Endo International plc (NASDAQ: ENDP) is a specialty pharmaceutical company committed to helping everyone we serve live their best life through the delivery of quality, life-enhancing therapies. Our decades of proven success come from a global team of passionate employees collaborating to

bring the best treatments forward. Together, we boldly transform insights into treatments benefiting those who need them, when they need them. Endo has global headquarters in Dublin, Ireland and U.S. headquarters in Malvern, Pennsylvania. Learn more at www.endo.com.

**Forward Looking Statement**

This press release contains certain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and Canadian securities legislation, including the statements by Messrs. Erck and Coleman and other statements regarding product potential, clinical trial outcomes, quality, availability and affordability. Statements including words such as "believes," "expects," "anticipates," "intends," "estimates," "plan," "will," "may," "look forward," "intend," "guidance," "future" or similar expressions are forward-looking statements. Because these statements reflect Endo's and Novavax's current views, expectations and beliefs concerning future events, they involve risks and uncertainties. Although Endo and Novavax believe that these forward-looking statements and information are based upon reasonable assumptions and expectations, readers should not place undue reliance on them, or any other forward-looking statements or information in this news release. Investors should note that many factors, as more fully described in the documents filed by Endo and Novavax with the Securities and Exchange Commission and, in Endo's case, with securities regulators in Canada on the System for Electronic Document Analysis and Retrieval, including under the caption "Risk Factors" in Endo's and Novavax's Form 10-K, Form 10-Q and Form 8-K filings, and as otherwise enumerated herein or therein, could affect Endo's and Novavax's future results and could cause Endo's and Novavax's actual results to differ materially from those expressed in forward-looking statements contained in this communication. The forward-looking statements in this press release are qualified by these risk factors. Endo and Novavax assume no obligation to publicly update any forward-looking statements, whether as a result of new information, future developments or otherwise, except as may be required under applicable securities laws.

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SOURCE Endo International plc

Endo International plc: Media: Heather Zoumas-Lubeski, (484) 216-6829, media.relations@endo.com; or Investors: Pravesh Khandelwal, (845) 364-4833, relations.investor@endo.com