Novocure Provides Regulatory Update on U.S. FDA Premarket Approval Application for Optune Mya® for Brain Metastases from Non-Small Cell Lung Cancer

November 9, 2026

BAAR, Switzerland--(BUSINESS WIRE)--Nov. 9, 2026-- Novocure (Nasdaq: NVCR) announced today that it has received a Not Approvable Letter from the U.S. Food and Drug Administration (FDA) in response to its Premarket Approval (PMA) application for Optune Mya® for the treatment of adult patients with brain metastases from non-small cell lung cancer following stereotactic radiation.

The Not Approvable Letter indicates that the FDA determined that uncertainty around the degree of clinical benefit provided by Optune Mya prevented approval of the PMA application. The FDA did not raise concerns related to the safety profile of Optune Mya. Novocure is evaluating the feedback and plans to meet with the FDA to determine if there are any options that would support approval of the PMA application that would not require additional clinical studies. There can be no assurance that these discussions or any future submissions regarding this PMA application will lead to an approval.

About Novocure

Novocure is a global oncology company working to extend survival in some of the most aggressive forms of cancer through the development and commercialization of its innovative therapy, Tumor Treating Fields. Novocure's commercialized products are approved in certain countries for the treatment of adult patients with glioblastoma, pancreatic cancer, non-small cell lung cancer, malignant pleural mesothelioma and pleural mesothelioma. Novocure has several additional ongoing or completed clinical trials exploring the use of Tumor Treating Fields therapy in the treatment of glioblastoma, non-small cell lung cancer and pancreatic cancer.

Novocure's global headquarters is located in Baar, Switzerland, with U.S. headquarters located in Portsmouth, New Hampshire and research and development facilities located in Haifa, Israel. For additional information about the company, please visit Novocure.com and follow @Novocure on LinkedIn and X.

Forward-Looking Statements

In addition to historical facts or statements of current condition, this press release may contain forward-looking statements. Forward-looking statements provide Novocure's current expectations or forecasts of future events. These may include statements regarding anticipated scientific progress on its research programs, clinical trial progress, development of potential products, interpretation of clinical results, prospects for regulatory approval, manufacturing development and capabilities, market prospects for its products, coverage, collections from third-party payers and other statements regarding matters that are not historical facts. You may identify some of these forward-looking statements by the use of words in the statements such as "anticipate," "estimate," "expect," "project," "intend," "plan," "believe" or other words and terms of similar meaning. Novocure's performance and financial results could differ materially from those reflected in these forward-looking statements due to general financial, economic, environmental, regulatory and political conditions and other more specific risks and uncertainties facing Novocure such as those set forth in its Annual Report on Form 10-K filed on February 26, 2026, and subsequent filings with the U.S. Securities and Exchange Commission. Given these risks and uncertainties, any or all of these forward-looking statements may prove to be incorrect. Therefore, you should not rely on any such factors or forward-looking statements. Furthermore, Novocure does not intend to update publicly any forward-looking statement, except as required by law. Any forward-looking statements herein speak only as of the date hereof. The Private Securities Litigation Reform Act of 1995 permits this discussion.

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Investors:
Adam Daney
investorinfo@novocure.com

Media:
Catherine Falcetti
media@novocure.com

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