



China National Medical Products Administration Grants Innovative Medical Device Designation for Optune® in China

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SHANGHAI & ST. HELIER, Jersey--(BUSINESS WIRE)--Aug. 12, 2019-- Zai Lab Limited (NASDAQ: ZLAB), a Shanghai-based innovative commercial stage biopharmaceutical company, and Novocure (NASDAQ: NVCR), a global oncology company with a proprietary platform technology called Tumor Treating Fields, today announced that the China National Medical Products Administration (NMPA) granted Innovative Medical Device Designation for Optune, a Tumor Treating Fields delivery system that uses electric fields tuned to specific frequencies to disrupt cancer cell division, inhibiting tumor growth and causing affected cancer cells to die.

"We are excited that Optune has been granted the Innovative Device Designation as it will allow our team to accelerate dialogue with the NMPA and bring us closer to commercializing Optune in China," said Dr. Samantha Du, Founder and CEO of Zai Lab. "Our launch in Hong Kong has provided valuable insight into the impact that this device can have on patients with GBM, which is an area of high unmet clinical need in China and globally. We look forward to working closely with the NMPA as Optune advances through the regulatory process in China."

The Innovative Device Designation allows Zai Lab to take advantage of an expedited approval procedure for Optune that offers opportunities for pre-consultation with and input from the NMPA throughout the approval process. Novocure granted Zai Lab an exclusive license for Tumor Treating Fields, including the brand name Optune, in Greater China in September 2018 and Zai Lab successfully launched the product in Hong Kong for the treatment of glioblastoma (GBM) late last year. Novocure markets Optune in the United States, European Union, Japan and certain other countries for the treatment of GBM and the NovoTTF-100L System, another Tumor Treating Fields delivery system, in the U.S. for the treatment of malignant pleural mesothelioma. Tumor Treating Fields is in late stage clinical development for four solid tumor indications including non-small cell lung cancer, brain metastases, pancreatic and ovarian cancers. Tumor Treating Fields was included and recommended with Level 1 evidence as a treatment for GBM in China's Glioma Treatment Guideline published in 2018.

"We are committed to bringing Optune to as many patients who may benefit as possible," said Novocure's Executive Chairman Bill Doyle. "Zai Lab has been an excellent partner as we strive to extend survival in some of the most aggressive forms of cancer by developing and commercializing Tumor Treating Fields therapy. We are pleased that together with our partners at Zai Lab we are one step closer to commercializing Optune in China."

About Tumor Treating Fields

Tumor Treating Fields is a cancer therapy that uses electric fields tuned to specific frequencies to disrupt cell division, inhibiting tumor growth and causing affected cancer cells to die. Tumor Treating Fields does not stimulate or heat tissue and targets dividing cancer cells of a specific size. Tumor Treating Fields causes minimal damage to healthy cells. Mild to moderate skin irritation is the most common side effect reported. Tumor Treating Fields is approved in certain countries for the treatment of adults with glioblastoma and mesothelioma, two of the most difficult cancer types to treat. The therapy shows promise in multiple solid tumor types – including some of the most aggressive forms of cancer.

About Zai Lab

Zai Lab (NASDAQ: ZLAB) is a China and U.S.-based innovative commercial stage biopharmaceutical company focused on bringing transformative medicines for cancer, autoimmune and infectious diseases to patients in China and around the world. Zai Lab's experienced team has secured partnerships with leading global biopharma companies, generating a broad pipeline of innovative drug candidates targeting the fast-growing segments of China's pharmaceutical market and addressing unmet medical needs. Zai Lab's vision is to become a fully integrated biopharmaceutical company, discovering, developing, manufacturing and commercializing its partners' and its own products in order to impact human health worldwide.

About Novocure

Novocure is a global oncology company working to extend survival in some of the most aggressive forms of cancer by developing and commercializing its innovative therapy, Tumor Treating Fields. Tumor Treating Fields is a cancer therapy that uses electric fields tuned to specific frequencies to disrupt solid tumor cancer cell division. Novocure's commercialized product is approved for the treatment of adult patients with glioblastoma and malignant pleural mesothelioma. Novocure has ongoing or completed clinical trials investigating Tumor Treating Fields in brain metastases, non-small cell lung cancer, pancreatic cancer, ovarian cancer and liver cancer.

Headquartered in Jersey, Novocure has U.S. operations in Portsmouth, New Hampshire, Malvern, Pennsylvania and New York City. Additionally, the company has offices in Germany, Switzerland, Japan and Israel. For additional information about the company, please visit www.novocure.com or follow us at [www.twitter.com/novocure](https://twitter.com/novocure).

Approved Indications

Optune is intended as a treatment for adult patients (22 years of age or older) with histologically-confirmed glioblastoma multiforme (GBM).

Optune with temozolomide is indicated for the treatment of adult patients with newly diagnosed, supratentorial glioblastoma following maximal debulking surgery, and completion of radiation therapy together with concomitant standard of care chemotherapy.

For the treatment of recurrent GBM, Optune is indicated following histologically- or radiologically-confirmed recurrence in the supratentorial region of

the brain after receiving chemotherapy. The device is intended to be used as a monotherapy, and is intended as an alternative to standard medical therapy for GBM after surgical and radiation options have been exhausted.

The NovoTTF-100L System is indicated for the treatment of adult patients with unresectable, locally advanced or metastatic, malignant mesothelioma (MPM) to be used concurrently with pemetrexed and platinum-based chemotherapy.

Important Safety Information

Contraindications

Do not use Optune in patients with GBM with an implanted medical device, a skull defect (such as, missing bone with no replacement), or bullet fragments. Use of Optune together with skull defects or bullet fragments has not been tested and may possibly lead to tissue damage or render Optune ineffective. Do not use the NovoTTF-100L System in patients with MPM with implantable electronic medical devices such as pacemakers or implantable automatic defibrillators, etc.

Use of Optune for GBM or the NovoTTF-100L System for MPM together with implanted electronic devices has not been tested and may lead to malfunctioning of the implanted device.

Do not use Optune for GBM or the NovoTTF-100L System for MPM in patients known to be sensitive to conductive hydrogels. Skin contact with the gel used with Optune and the NovoTTF-100L System may commonly cause increased redness and itching, and may rarely lead to severe allergic reactions such as shock and respiratory failure.

Warnings and Precautions

Optune and the NovoTTF-100L System can only be prescribed by a healthcare provider that has completed the required certification training provided by Novocure®.

The most common (≥10%) adverse events involving Optune in combination with chemotherapy in patients with GBM were thrombocytopenia, nausea, constipation, vomiting, fatigue, convulsions, and depression.

The most common (≥10%) adverse events related to Optune treatment alone in patients with GBM were medical device site reaction and headache. Other less common adverse reactions were malaise, muscle twitching, and falls related to carrying the device.

The most common (≥10%) adverse events involving the NovoTTF-100L System in combination with chemotherapy in patients with MPM were anemia, constipation, nausea, asthenia, chest pain, fatigue, device skin reaction, pruritus, and cough.

Other potential adverse effects associated with the use of the NovoTTF-100L System include: treatment related skin toxicity, allergic reaction to the plaster or to the gel, electrode overheating leading to pain and/or local skin burns, infections at sites of electrode contact with the skin, local warmth and tingling sensation beneath the electrodes, muscle twitching, medical site reaction and skin breakdown/skin ulcer.

If the patient has an underlying serious skin condition on the treated area, evaluate whether this may prevent or temporarily interfere with Optune and the NovoTTF-100L System treatment.

Do not prescribe Optune or the NovoTTF-100L System for patients that are pregnant, you think might be pregnant or are trying to get pregnant, as the safety and effectiveness of Optune and the NovoTTF-100L System in these populations have not been established.

Zai Lab Forward-Looking Statements

This press release contains statements about future expectations, plans and prospects for Zai Lab, including plans for commercializing Optune in China. All statements, other than statements of historical fact, included in this press release are forward-looking statements, and are identified by words such as "anticipates", "believes", "expects", "plan" and other similar expressions. Such statements constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are not statements of historical fact nor are they guarantees or assurances of future performance. Forward-looking statements are based on Zai Lab's expectations and assumptions as of the date of this press release and are subject to inherent uncertainties, risks and changes in circumstances that may differ materially from those contemplated by the forward-looking statements. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including but not limited to (1) Zai Lab's ability to obtain additional future funding, (2) Zai Lab's results of clinical and pre-clinical development of its drug candidates, (3) the content and timing of decisions made by the relevant regulatory authorities regarding regulatory approvals of Zai Lab's drug candidates, (4) Zai Lab's ability to generate revenue from its drug candidates, and (5) other factors discussed in Zai Lab's Annual Report on Form 20-F for the fiscal year ended December 31, 2018 and its other filings with the Securities and Exchange Commission. Zai Lab anticipates that subsequent events and developments will cause Zai Lab's expectations and assumptions to change and undertakes no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required by law. These forward-looking statements should not be relied upon as representing Zai Lab's views as of any date subsequent to the date of this press release.

Novocure 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, regulatory and political conditions as well as more specific risks and uncertainties facing Novocure such as those set forth in its Quarterly Report on Form 10-Q filed on July 25, 2019, 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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