China NMPA Approves Optune® for the Treatment of Newly Diagnosed and Recurrent Glioblastoma

May 13, 2020

Optune is the first innovative treatment for glioblastoma approved in China in over 15 years

A large, global phase 3 pivotal clinical study in newly diagnosed glioblastoma showed adding Optune to chemotherapy more than doubled the five-year overall survival rate[1]

Optune is Zai Lab's second product approval in mainland China in six months

SHANGHAI and ST. HELIER, Jersey, May 13, 2020 (GLOBE NEWSWIRE) -- Zai Lab Limited (NASDAQ: ZLAB), an innovative commercial stage biopharmaceutical company, and Novocure (NASDAQ: NVCR), a global oncology company with a proprietary platform therapy called Tumor Treating Fields, today announced that the China National Medical Products Administration (NMPA) has approved the Marketing Authorization Application (MAA) for Optune in combination with temozolomide for the treatment of patients with newly diagnosed glioblastoma (GBM), and also as a monotherapy for the treatment of patients with recurrent GBM. GBM is the most common form of primary brain cancer, and Optune is the first treatment for glioblastoma approved in China in over 15 years.

"The NMPA's approval of Optune is a significant treatment advance for GBM patients in China and another important milestone for Zai," said Dr. Samantha Du, Founder, Chairperson and Chief Executive Officer of Zai Lab. "Optune was previously granted the Innovative Medical Device Designation, which highlights the differentiation and importance of this novel treatment for GBM patients. We appreciate the NMPA for their partnership through this rapid and thorough assessment of the Optune application, recognizing the high unmet medical need it serves. We look forward to working with Novocure to bring Tumor Treating Fields to GBM and other difficult to treat cancer indications."

"Novocure is working to extend survival in some of the most aggressive cancers through the development and commercialization of Tumor Treating Fields," said William Doyle, Novocure's Executive Chairman. "Approval of Optune for GBM in Greater China extends the promise of Tumor Treating Fields therapy to patients in the world's largest market. We thank Zai Lab for their commitment and hard work and congratulate them on their second product approval in six months."

Optune delivers Tumor Treating Fields therapy to the region of the tumor. Globally, more than 15,000 GBM patients have been treated with Optune, to date. Tumor Treating Fields is also approved by the U.S. FDA under the Humanitarian Device Exemption pathway for the treatment of malignant pleural mesothelioma (MPM), which is anticipated to be the next MAA filed with the NMPA. In addition to GBM and MPM, Tumor Treating Fields is under evaluation in global phase 3 pivotal trials for the treatment of brain metastases, non-small cell lung cancer, pancreatic cancer and ovarian cancer, and in phase 2 pilot trials for liver cancer and gastric cancer. Approximately 1.5 million patients a year in China are diagnosed with non-small cell lung cancer, pancreatic cancer, ovarian cancer and gastric cancer, collectively.

"In China, there are more than 45,000 patients diagnosed with GBM each year and this approval marks the first new treatment option for these patients in over 15 years," said Jiang Tao, M.D., Ph.D., Head of Beijing Neurosurgical Institute, Founder of Chinese Glioma Genome Atlas, and Professor of Beijing Tiantan Hospital. "Optune was recommended with Level 1 evidence as a treatment for newly diagnosed GBM patients in China's Glioma Treatment Guideline in 2018, and we are excited to now have Optune available as part of the standard of care for GBM patients in China."

About Optune
Optune is a noninvasive, antimitotic cancer treatment for GBM. Optune delivers Tumor Treating Fields to the region of the tumor.

Tumor Treating Fields is a cancer therapy that uses electric fields tuned to specific frequencies to disrupt cell division. 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 GBM and in the U.S. for MPM, 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.

Approved Indications (China)
Optune is intended as a treatment for adult patients (22 years of age or older) with recurrent supratentorial glioblastoma multiforme (GBM) diagnosed by histopathology or imaging, and newly diagnosed supratentorial GBM.

Newly diagnosed GBM
Optune with temozolomide (TMZ) is indicated for the treatment of adult patients with newly diagnosed GBM after surgery and radiotherapy.

Recurrent GBM
Optune is indicated for the treatment of recurrent GBM as a monotherapy.

About Zai Lab
Zai Lab (NASDAQ:ZLAB) is an innovative commercial stage biopharmaceutical company focused on bringing transformative medicines for cancer, infectious and autoimmune diseases to patients in China and around the world. To quickly target the large, fast-growing segments of China's pharmaceutical market and address unmet medical needs, Zai Lab's experienced team has secured partnerships with leading global biopharma companies, generating a broad pipeline of innovative drug candidates. Zai Lab has also built an in-house team with strong drug discovery and

translational research capabilities, aiming to establish a global pipeline of proprietary drug candidates against targets in our focus areas. Zai Lab's vision is to become a fully integrated biopharmaceutical company, discovering, developing, manufacturing and commercializing its portfolio in order to impact human health worldwide.

For additional information about the company, please visit www.zailaboratory.com or follow us at www.twitter.com/ZaiLab_Global.

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 and in the U.S. for the treatment of adult patients with 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, liver cancer and gastric 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.

Zai lab Forward-Looking Statements
This press release contains statements about future expectations, plans and prospects for Zai Lab, including, without limitation, statements regarding the prospects of and plans for commercializing Optune in China. 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, (5) the effects of the novel coronavirus (COVID-19) pandemic on general economic, regulatory and political conditions and (6) other factors discussed in Zai Lab's Annual Report on Form 20-F for the fiscal year ended December 31, 2019, filed on April 29, 2020, 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 issues arising from the COVID-19 pandemic 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 27, 2020 and its Quarterly Report on Form 10-Q filed on April 30, 2020 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.

---

[1] Stupp R., et. al. JAMA. 2017 Dec 19;318(23):2306-2316.

Contact:

Zai Lab
Billy Cho, CFO
+86 137 6151 2501
billy.cho@zailaboratory.com

Media: Ryo Imai / Robert Flamm, Ph.D.
Burns McClellan, on behalf of Zai Lab
212-213-0006, ext. 315 / 364, rimai@burnsmc.com / rflamm@burnsmc.com

Investors: Pete Rahmer / Mike Zanoni
Endurance Advisors, on behalf of Zai Lab
415-515-9763 / 610-442-8570
prahmer@enduranceadvisors.com / mzanoni@enduranceadvisors.com

Novocure Media and Investors:
Ashley Cordova
acordova@novocure.com
212-767-7558



Source: Zai Lab Limited