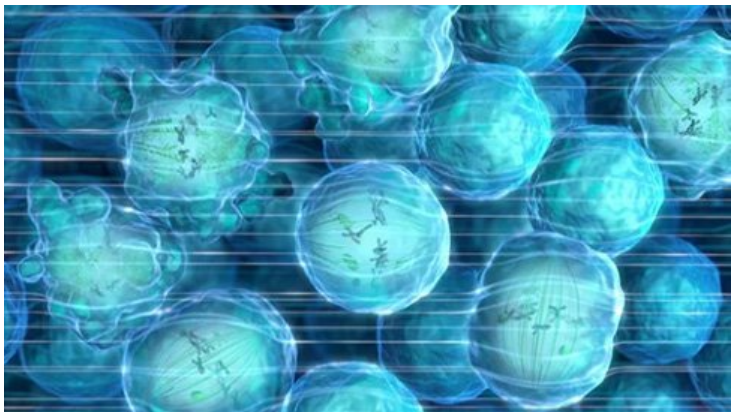


CNMPA grants Innovative Medical Device Designation to Optune

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Optune is a Tumor Treating Fields delivery system



Zai Lab Limited, a Shanghai-based innovative commercial stage biopharmaceutical company, and Novocure, a global oncology company with a proprietary platform technology called Tumor Treating Fields, have announced that the China National Medical Products Administration (CNMPA) 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.