



Zai Lab Announces Approval to Commercialize ZEJULA (Niraparib) in Macau for Patients with Relapsed Ovarian Cancer

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SHANGHAI, China and SAN FRANCISCO, June 12, 2019 (GLOBE NEWSWIRE) -- Zai Lab Limited (NASDAQ: ZLAB), a Shanghai-based innovative commercial stage biopharmaceutical company, today announced its approval to commercialize ZEJULA (niraparib), an oral, once-daily poly (ADP-ribose) polymerase (PARP) inhibitor in Macau for adult patients with platinum-sensitive relapsed high grade serous epithelial ovarian cancer who are in a complete response or partial response (CR or PR) on platinum-based chemotherapy. ZEJULA is a potent and highly selective PARP1/2 inhibitor that does not require BRCA mutation or other biomarker testing prior to administration.

Zai Lab in-licensed rights to ZEJULA from Tesaro, which was recently acquired by GlaxoSmithKline, for China, Hong Kong and Macau as an important, new treatment option for patients who suffer from ovarian cancer in this region. ZEJULA is a potential best-in-class PARP inhibitor due to its differentiated efficacy, once-daily dosing and superior pharmacokinetic properties including its ability to cross the blood brain barrier.

Zai Lab obtained approval for marketing ZEJULA in Hong Kong in October 2018 and has been actively commercializing the product. In Mainland China, an NDA was accepted by the China's National Medical Products Administration (NMPA, formerly known as the CFDA) on December 12, 2018, and was granted priority review status on January 28, 2019.

About ZEJULA

ZEJULA (niraparib, ZL-2306) is a highly potent and selective oral, once-daily small molecule poly (ADP-ribose) PARP 1/2 inhibitor. It was approved in March 2017 by the FDA in the United States and in November 2017 by the EMA in the European Union under the trade name ZEJULA® as a maintenance treatment for women with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy. Based on the approval status in the United States and European Union by our partner, Tesaro, Zai Lab obtained the approval for marketing ZEJULA in Hong Kong in October 2018.

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.

Contact:

Zai Lab

Billy Cho, CFO

+86 137 6151 2501

billy.cho@zailaboratory.com

Media: Nancie Steinberg / Robert Flamm

Burns McClellan, on behalf of Zai Lab

212-213-0006, ext. 318 / 364, nsteinberg@burnsmc.com / rflamm@burnsmc.com

Investors: Lee Roth

Burns McClellan, on behalf of Zai Lab

212-213-0006, ext. 331, lroth@burnsmc.com



Source: Zai Lab Limited