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FDA approves imaging drug that can help surgeons spot ovarian cancers

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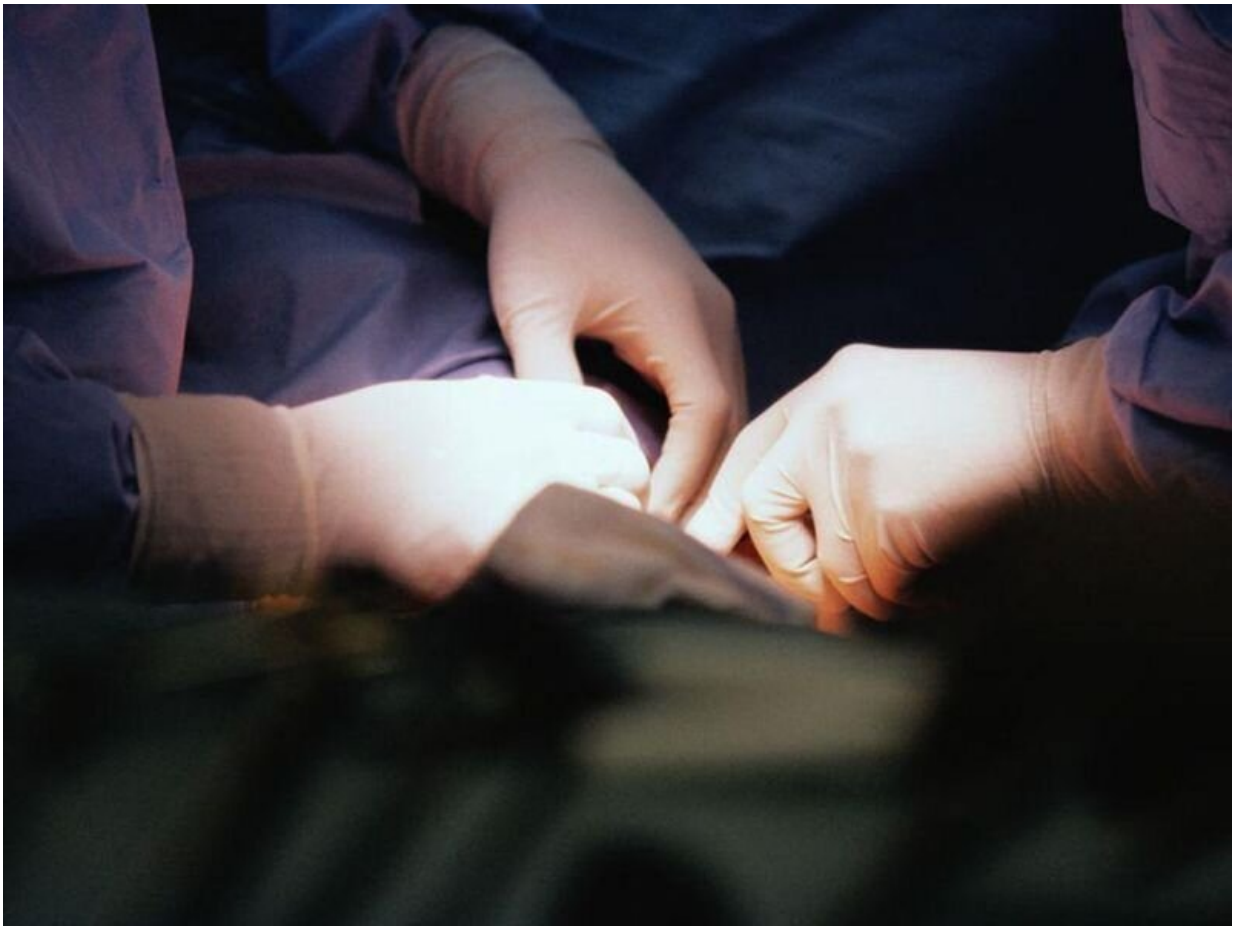

Early detection of ovarian cancer helps boost a woman's survival, and the

U.S. Food and Drug Administration on Monday approved a new imaging drug that can help spot tumors during surgery.

The drug, Cytalux (pafolacianine), is meant to improve a surgeon's ability to detect ovarian cancer while operating on a patient.

It is administered intravenously before surgery and is used in conjunction with a near-infrared fluorescence imaging system approved by the FDA for use with the drug.

"The FDA's approval of Cytalux can help enhance the ability of surgeons to identify deadly ovarian tumors that may otherwise go undetected," said Dr. Alex Gorovets, deputy director of the Office of Specialty Medicine in the FDA's Center for Drug Evaluation and Research.

"By supplementing current methods of detecting ovarian cancer during surgery, Cytalux offers health care professionals an additional imaging approach for patients with ovarian cancer," Gorovets added in an agency news release.

Conventional treatment for ovarian cancer includes surgery to remove as many tumors as possible, as well as chemotherapy or other targeted therapy to identify and attack specific cancer cells.

Currently, surgeons rely on preoperative imaging, visual inspection of tumors under normal light or examination by touch to identify ovarian cancer tumors.

The FDA's approval of Cytalux is based on a study of 134 women, aged 33 to 81. They received a dose of Cytalux and were evaluated under both normal and fluorescent light during surgery.

Of those women, about 27% had at least one cancerous lesion detected

that was not found by standard visual or touch inspection.

The most common side effects of Cytalux included nausea, vomiting, abdominal pain, flushing, indigestion, chest discomfort, itching and hypersensitivity. Also, Cytalux may cause harm to the fetus when given to a pregnant woman, the FDA warned.

It also said that women should not take folate, folic acid or folate-containing supplements within 48 hours before administration of Cytalux.

The agency further cautioned there is a risk of false negatives and false positives with use of Cytalux. The drug— marketed by On Target Laboratories, LLC—was previously fast-tracked for approval by the FDA.

There will be more than 21,000 new cases of ovarian cancer and more than 13,000 deaths from this disease this year in the United States, according to the American Cancer Society.

More information: The American Cancer Society has more on ovarian cancer.