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Diving into Developments in Ovarian Cancer Detection

Announcer:
You're listening to *Medical Breakthroughs from Penn Medicine* on ReachMD, advancing medicine through precision diagnostics and novel therapies. Here's your host, Dr. Charles Turck.

Dr. Turck:
Welcome to *Medical Breakthroughs from Penn Medicine* on ReachMD. I'm Dr. Charles Turck and joining me today to discuss new developments in ovarian cancer detection and treatment is Dr. Janos Tanyi, Associate Professor of Obstetrics and Gynecology at the Hospital of the University of Pennsylvania. Dr. Tanyi, welcome to the program.

Dr. Tanyi:
Thank you very much for having me.

Dr. Turck:
So, let's begin by taking a look at the current screening landscape for ovarian cancer. Dr. Tanyi, what tools are presently being used and what are their limitations?

Dr. Tanyi:
So, the major limitation is that there is no tool, there is no screening for ovarian cancer today. There were a couple of trials testing, CA 125, and ultrasound to identify any way to screen patients for ovarian cancer and it's all failed. So, today there is no screening methodology which can prevent or diagnose ovarian cancer in an early stage. And as we know in early stage, stage 1 and stage 2, these patients have no symptoms and most of the patients diagnosed in stage 3 and stage 4 is over 70 percent of the patients diagnosed where disease already advanced. And this is a major problem. If you can imagine that ovarian cancer is the number one cause of gynecologic cancer death in the United States with an estimated 21,000 new cases and about 13-14,000 deaths every single year. In fact, every 23 minutes, another woman is diagnosed with ovarian cancer. So, this is a major problem.

Dr. Turck:
So, with that being said, let's focus on the FDA's recent approval of a new imaging drug for ovarian cancer. What can you tell us about that?

Dr. Tanyi:
So, the FDA just recently approved in November 29, 2021 Cytalux in adult patients with ovarian cancer as an adjunct for intraoperative identification of malignant lesions. Cytalux is the first targeted fluorescence imaging agent that illuminates ovarian cancers intraoperatively, real time, enabling the detection of more cancer for removal.

Today, the surgeon's ability to achieve a complete resection in ovarian cancer patients impacts their long-term prognosis proven by multiple prior clinical studies. Cytalux serves as a tool, as an adjunct for surgeons to intraoperatively identify malignant ovarian cancer lesions that may otherwise be missed during surgery.

Dr. Turck:
And as I understand it, that imaging agent works in conjunction with TumorGlow®, which is an intraoperative molecular imaging technology that relies on injectable dye to identify cancerous tissues. Can you tell us how these two components come together in fluorescence-guided surgery to help identify rogue ovarian cancer cells?

Dr. Tanyi:
Absolutely. So, Cytalux is composed of two different agents. It's one folate or folic acid analogue conjugated together with near-infrared fluorescence dye. Why this methodology or these agents were developed and used first come in with the name, Cytalux, syt, S-Y-T in Latin means cell. L-U-X, lux in Latin means light. So, lighted cells. Cancer cells quickly divide and require lots of vitamins and other component to build up the intracellular DNA of the quickly-dividing cell. These particle cancers have expressed lots of folate alpha receptors to catch more and more folate for quick cell division. We use the folate analogue to occupy these folate receptors and we conjugate it together with a fluorescence near-infrared fluorescence dye. So, this particle dye is infused to the patients, this goes all over the patient's body and gets stuck under folate alpha receptors on the surface of ovarian cancer cells and endocytose internalized into the cancer cells and more and more accumulated inside the cancer cells. And this is the way we are able to see the cancer cells better.

We use near-infrared imaging technology, previously we used non-near-infrared imaging technology, but normal wavelength with visual inspection by normal eyes. But with near-infrared imaging technology, we reached that the tumor background ratio is much bigger so we can see these tumor cells much better.

Dr. Turck:
For those just tuning in, you're listening to *Medical Breakthroughs from Penn Medicine* on ReachMD. I'm Dr. Charles Turck and today I'm speaking with Dr. Janos Tanyi about new developments in ovarian cancer detection and treatment.

So, now that we understand how this new drug and TumorGlow® work together, let's take a look at the data. Dr. Tanyi, can you share some of the key findings from the study investigating this new approach?

Dr. Tanyi:
Absolutely. So, I was a principal investigator of the phase 3 study but I was deeply involved in the phase 2 study also. The primary endpoint of the phase 3 study was the percentage of the patients where we were able to identify extra disease which would have otherwise been missed and not identified by visual inspection and palpation during the surgery. Interestingly, we were able to identify extra tumors, which otherwise would have been left behind. So, interestingly, we were able to identify extra disease in 27 percent of the patients which was not detected with visual inspection or palpation, but was found with Cytalux and intraoperative molecular imaging.

In the phase 3 study, it was exciting that in the subpopulation of interval debulking surgery, this percentage elevated up to 40 percent. It means that in 40 percent of the patients during interval debulking surgery, we were able to identify extra disease, which were not identified with the visual inspection and palpation. Also, we evaluated the safety profile of this agent and as was proven in the phase 2 study, we further proved that in the phase 3 study that this agent is very safe; only mild and moderate adverse events were found such as nausea, vomiting, abdominal pain, headache, which usually resolved within one or two hours after the infusion of the agents, but never last longer than 24 hours.

Dr. Turck:
With all that in mind, how do you think this new drug in combination with TumorGlow® will impact patients with ovarian cancer?

Dr. Tanyi:
The ovarian cancer patient survival depends on the hands of the surgeons. Multiple studies showed that if the patient can do a debulking surgery with no gross residual left behind, the survival is significantly better compared to the optimal debulking, where it's less than 1.0 cm in diameter of tumor left behind or compared to sub-optimal debulking when more than 1.0 cm in diameter tumor left behind. This study was closed recently, we don't have survival data to prove it. But theoretically with helping the surgeon to find extra disease, we will reach better debulking and better done surgeries and it will be long-term possible an impact of the survival of the patients. But at this moment, as I mentioned, as we closed the study recently, we don't have the survival data available yet to prove it.

Dr. Turck:
And before we close, I'd like to take a moment to look ahead to the future. Could this new approach be used for other types of cancer or even in other fields of medicine?

Dr. Tanyi:
Absolutely. First, it's very exciting that the phase 3 study in lung is ongoing and close to completion. Many quickly dividing tumor cells express in folate alpha receptors. So, this imaging agent can be used in multiple different tumor types who over-express folate alpha receptors including endometrial cancer, colorectal cancers. And also with the lung study, which is closing very soon, possibly will be the second tumor which will receive FDA approval of this agent. But, absolutely, multiple other tumor types can be targeted and identified with this imaging agent.

Dr. Turck:

Well, with those forward-looking thoughts in mind, I want to thank my guest, Dr. Janos Tanyi for speaking with us today. Dr. Tanyi, it was great having you on the program.

Dr. Tanyi:
Thank you very much.

Announcer:
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