# Approval of Elahere Expands Treatment Options for Some Advanced Ovarian Cancers

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Although people with advanced ovarian cancer can initially be treated successfully with platinum-based chemotherapy drugs, the cancer often comes back. Platinum-resistant ovarian cancer has proven difficult to treat, but with the Food and Drug Administration’s recent full approval of mirvetuximab soravtansine-gynx (Elahere), some people in this situation now have a new treatment option.

Under the approval, Elahere can be used to treat people with advanced, platinum-resistant ovarian cancer whose tumors produce an excessive amount of a protein called FR-α. About 80% of people with high-grade serous epithelial ovarian cancer, the most common form of the disease, have tumors that overexpress FR-α.

The FDA approval was based on the results of a large randomized clinical trial called MIRASOL. Results showed that people with FR-α-positive, platinum-resistant ovarian tumors who were treated with Elahere lived longer overall than people treated with standard chemotherapy. It also improved how long they lived without their cancer getting worse, known as progression-free survival. Participants treated with Elahere also had fewer serious side effects.

Elahere’s approval is a long-awaited milestone in the treatment of advanced ovarian cancers, said Kathleen N. Moore, M.D., of the University of Oklahoma Health Sciences Center, who led the MIRASOL trial.

For people whose disease has become resistant to platinum-based chemotherapy drugs, “this is the first novel therapy ever … to improve overall survival,” Dr. Moore said, adding that “it is also the first medication in a decade to improve progression-free survival.”

Having this new treatment available makes testing tumors for FR-α a must, Dr. Moore continued. “We really need to know the FR-α status of our patients’ tumors so that we can use this medication as early as possible once their tumors are resistant to platinum [chemotherapy].”

## Targeting a protein found only in cancer cells

Ovarian cancer is the fifth most common cause of cancer death in women in the United States. In 2023, there were an estimated 19,710 new cases and 13,270 deaths from the disease. Most people aren't diagnosed until they are at an advanced stage because the signs or symptoms of early disease are not specific.

Treatment of advanced disease typically involves surgery followed by platinum-based chemotherapy. But the disease will return in about 80% of people, often because it becomes resistant to the chemotherapy.

One standard treatment for such patients, a combination of the targeted therapy bevacizumab (Avastin) and (nonplatinum) chemotherapy, has been shown to modestly increase progression-free survival in people with platinum-resistant ovarian cancer, but not how long they live overall.

Researchers have tried to help people whose cancer has become resistant to platinum chemotherapy by developing drugs that target FR-α. Not only is FR-α frequently overexpressed in many ovarian cancers, about 30% to 40% of high-grade serous ovarian cancers produce particularly high levels.

Elahere is an antibody–drug conjugate made up of a monoclonal antibody called mirvetuximab attached to a highly potent chemotherapy drug called DM4. After being infused into patients, mirvetuximab seeks out and binds to FR-α on the surface of ovarian cancer cells. The drug is then pulled into the cancer cell where the DM4 is released, killing the cells. Because FR-α is primarily found on cancer cells, healthy cells are largely spared.

In a large clinical trial of patients with FR-α-positive, platinum-resistant ovarian cancer, Elahere looked particularly promising against tumors that had the highest levels of the FR-α protein. In a subsequent trial limited to people with high levels of FR-α, dubbed SORAYA, Elahere shrank tumors in nearly 40% of people.

Based on these results, FDA gave Elahere an accelerated approval in November 2022. The MIRASOL trial was required by FDA to confirm that the drug could indeed provide clinical benefits, including improving survival.

## Helping patients live longer

In the MIRASOL trial—which was funded by ImmunoGen, the drug's manufacturer—453 people with FR-α-positive, platinum-resistant ovarian cancer were randomly assigned to receive either Elahere as an intravenous infusion every 3 weeks or chemotherapy.

Not only did treatment with Elahere increase overall and progression-free survival, people who received it were nearly three times as likely to have their tumors shrink as those treated with chemotherapy. In some people who received the drug, their cancer disappeared entirely for a

period.

People treated with Elahere had fewer severe side effects, such as low blood cell counts, than people treated with chemotherapy. Eye problems, including blurred vision and a disease of the cornea called keratopathy, were among the most common side effects from Elahere.

Elahere comes with a special warning for patients about eye-related side effects. According to Dr. Moore, they can usually be managed with steroid eye drops or by changing the treatment to give a lower dose more frequently.

“We haven’t had patients with permanent eye damage. And once it resolves, it doesn’t tend to happen again, so patients can stay on the drug,” Dr. Moore said.

Caroline Billingsley, M.D., of the University of Cincinnati College of Medicine who specializes in treating gynecologic cancers, noted that it’s important for oncologists prescribing Elahere to work closely with optometrists and ophthalmologists to help manage any eye-related symptoms that might arise.

Dr. Billingsley, who was not involved in the trial, said, overall, patients she’s treated with Elahere have a good quality of life.

“They’re not experiencing the side effects that they typically see with standard chemotherapy,” she said. “This drug allows them not to have alopecia (hair loss), which is really great. It’s also a little better on neuropathy (nerve pain).”

## A new era for the treatment of ovarian cancer

Clinical trials are now evaluating Elahere in people with platinum-sensitive, FR-α-positive ovarian cancer that has returned after earlier treatment. Researchers are also studying whether Elahere is effective as an initial, or first-line, treatment for advanced ovarian cancer and in combination with bevacizumab.

According to Dr. Moore, it “will take a number of years to figure out” the best way to use Elahere to treat ovarian cancer.

Many other antibody–drug conjugates to treat ovarian cancer aren’t far behind, she continued, most with targets other than FR-α.

“It heralds a new era,” she said of the recent approval. “I expect that we’ll have an even better drug in a few years.”

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