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Withdrawal of application for the marketing authorisation of Zumrad (sasanlimab)

Pfizer Europe MA EEIG withdrew its application for a marketing authorisation of Zumrad for the treatment of non-muscle invasive bladder cancer (NMIBC), a type of cancer that affects the lining of the bladder.

The company withdrew the application on 13 February 2026.

What is Zumrad and what was it intended to be used for?

Zumrad was developed as a medicine to treat NMIBC that is high-risk (likely to worsen). It was to be used with Bacillus Calmette-Guérin (BCG), a standard bladder cancer treatment that stimulates the immune system, in adults who have not previously been treated with BCG.

Zumrad contains the active substance sasanlimab and was to be available as a solution for injection in pre-filled syringes, given under the skin (subcutaneously).

How does Zumrad work?

The active substance in Zumrad, sasanlimab, is a monoclonal antibody (a type of protein) that has been designed to block a receptor (target) called PD-1 found on certain cells of the immune system called T cells. Some cancers such as NMIBC can make proteins (PD-L1 and PD-L2) that attach to this receptor and switch off the activity of the T cells, preventing them from attacking the cancer. By blocking PD-1, sasanlimab prevents PD-L1 and PD-L2 from switching off T cells, thereby increasing the ability of the immune system to kill cancer cells.

What did the company present to support its application?

The company provided data from a main study involving 1,055 adults with high-risk NMIBC who had either never received treatment with BCG or who had not received treatment with BCG within the past 2 years. Zumrad given with BCG was compared with BCG given on its own. Zumrad was given once every four weeks for up to 2 years while BCG was given once a week for the first six weeks followed by

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maintenance treatment given in five cycles. The main measure of effectiveness was the length of time patients remained free of events that the treatment was intended to prevent or delay. These included the cancer coming back or getting worse, the presence of cancer cells in the lining of the bladder and death due to any cause. The study also looked at how long patients lived after they started treatment.

How far into the evaluation was the application when it was withdrawn?

The application was withdrawn after the European Medicines Agency had evaluated the initial information from the company and had prepared questions for the company. The Agency was assessing the company's responses to these questions at the time of the withdrawal.

What did the Agency recommend at that time?

Based on the review of the data and the company's response to the Agency's questions, at the time of the withdrawal, the Agency had concerns and its provisional opinion was that Zumrad could not have been authorised for the treatment of NMIBC.

The Agency had concerns about the main findings of the study, because major changes were made while the study was ongoing. The statistical method used to determine how effective Zumrad is was also changed, which increased the chance of concluding that the medicine had a beneficial effect.

The Agency also questioned whether the study's main measure of effectiveness was appropriate, because it was assessed by the researchers themselves. As both the researchers and participants knew which treatment was being given, this could have influenced the assessment. The Agency also identified other uncertainties related to the study's main measure of effectiveness. In addition, it was unclear whether the effect seen with Zumrad provides a meaningful benefit to patients. Finally, results from other important measures to evaluate how effective Zumrad is, such as how long patients lived, did not support the findings concerning the main measure of effectiveness.

Giving BCG with Zumrad resulted in more side effects, including side effects affecting the immune system, as well as more interruptions and discontinuations of BCG treatment.

Therefore, at the time of the withdrawal, the Agency's opinion was that the medicine could not have been authorised based on the data from the company.

What were the reasons given by the company for withdrawing the application?

In its letter notifying the Agency of the withdrawal of the application, the company stated that the reason for the withdrawal was to allow for collection of the data and analyses which would be required to address the questions and concerns raised by the Agency.

Does this withdrawal affect patients in clinical trials?

The company informed the Agency that there are no consequences for patients in clinical trials using Zumrad.

If you are in a clinical trial and need more information about your treatment, speak with your clinical trial doctor.