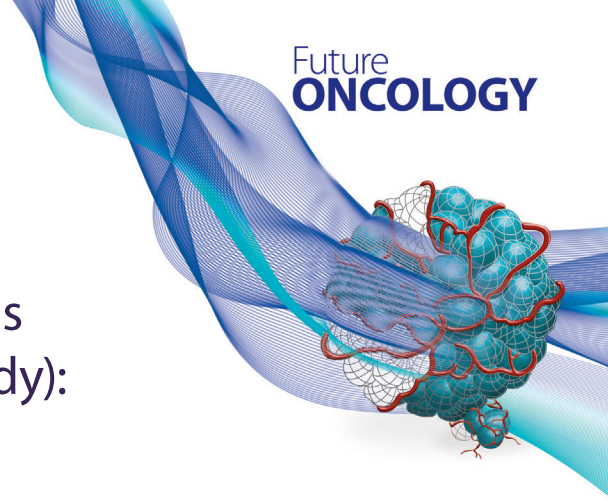
Plain Language Summary of Publication



Future ONCOLOGY

Treatment of advanced urothelial cancer with nivolumab plus chemotherapy versus chemotherapy alone (CheckMate 901 study): a plain language summary

Michiel S van der Heijden[a,*], Guru Sonpavde[b,*], Thomas Powles[c], Andrea Necchi[d], Mauricio Burotto[e], Michael Schenker[f], Juan Pablo Sade[g], Aristotelis Bamias[h], Philippe Beuzeboc[i], Jens Bedke[j], Jan Oldenburg[k], Gurkamal Chatta[l], Yüksel Ürün[m], Dingwei Ye[n], Zhisong He[o], Begoña P Valderrama[p], Ja Hyeon Ku[q], Yoshihiko Tomita[r], Jeiry Filian[s], Lily Wang[s], Daniela Purcea[t], Miraj Y Patel[s], Federico Nasroulah[r] & Matthew D Galsky[u]
*Contributed equally to this article
Author affiliations can be found at the end of this article

First draft submitted: 28 June 2024; Accepted for publication: 13 December 2024

Where can I find the original article on which this summary is based?

You can read the original article titled, 'Nivolumab plus Gemcitabine–Cisplatin in Advanced Urothelial Carcinoma,' which was published in *The New England Journal of Medicine*, for free at: https://www.nejm.org/doi/pdf/10.1056/NEJMoa2309863

Summary

How to say (download PDF and double click sound icon to play sound)...

- **Nivolumab:** Nih-VOL-you-mab
- **Urothelial:** YOOR-oh-THEE-lee-ul
- **Immunotherapy:** IH-myoo-no-THEH-ruh-pee
- **Chemotherapy:** Kee-mo-THEH-ruh-pee

What is this summary about?

This article describes the results of a clinical research study called 'CheckMate 901', which was published in *The New England Journal of Medicine*. CheckMate 901 was a study that looked at a specific type of cancer called urothelial cancer, which impacts parts of the urinary system. Participants in the study had urothelial cancer that was either **unresectable** (meaning that it cannot be removed by surgery) or **metastatic** (where the cancer has spread from the urinary system to other parts of the body).

Unresectable or metastatic urothelial cancer is normally treated with **chemotherapy** (treatment using chemicals to kill fast-growing cancer cells), but researchers are looking for more effective treatment options. The CheckMate 901 study aimed to find out if using a combination of chemotherapy and the drug nivolumab would work better and last longer than chemotherapy alone for people with advanced urothelial cancer. Immunotherapies are a family of cancer treatments that use the body's own immune system to fight the cancer.

What happened in the study?

In the CheckMate 901 study, researchers looked at nivolumab plus chemotherapy given together compared with chemotherapy alone as **first-line treatment** (the first treatment used) for people with metastatic urothelial cancer. The goal of the study was to see if this combination (nivolumab plus chemotherapy) would work better than chemotherapy alone in terms of how long people survived (lived) and how long they survived without their cancergetting worse. The study also looked at any **side effects** (undesirable effect of the drug) and other health problems that might come from these treatments.

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What do the results mean?
In comparing people who received nivolumab plus chemotherapy together, followed by nivolumab by itself, with people who received chemotherapy alone, the results showed that people in the nivolumab plus chemotherapy group not only survived (lived) longer, but also survived (lived) longer without their cancer getting worse. They were also more likely to have their tumors (an abnormal growth of body tissue) shrink, and were more likely to have their tumors shrink completely (and maintain complete shrinkage for a longer period of time). Also, they experienced no difference in overall health-related quality of life, and had similar side effects to those seen in other studies of nivolumab or chemotherapy.

What is the purpose of this plain language summary?

The purpose of this plain language summary is to help you to understand the findings from recent research.

Nivolumab in combination with cisplatin is approved to treat the condition that is discussed in this study summary. The results of this study may differ from those of other studies. Health professionals should make treatment decisions based on all available evidence, not on the results of a single study.

Who is this summary written for?

This summary was written for people who want to learn more about clinical research in urothelial cancer and about the results of the CheckMate 901 study, as well as family, friends, and healthcare professionals of those with urothelial cancer.

Who sponsored this study?

The study was **sponsored** by Bristol Myers Squibb and Ono Pharmaceutical.

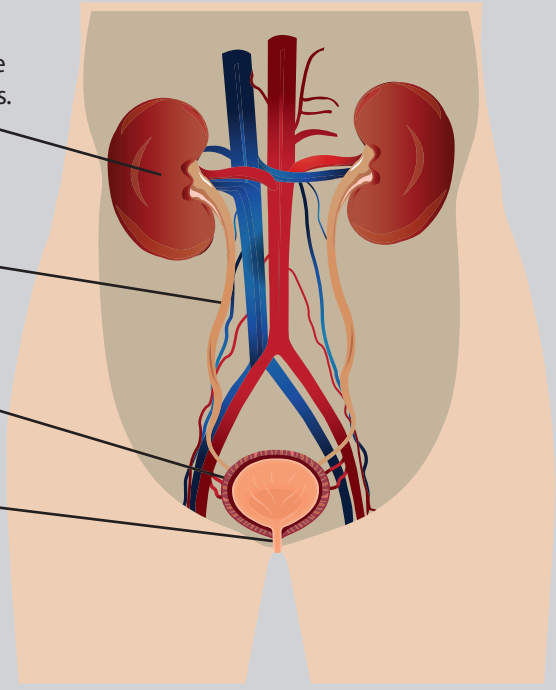
Sponsor: A company or organisation that oversees and pays for a clinical research study. The sponsor also collects and analyses the information from the study.

What is metastatic urothelial cancer?

Urothelial cancer is a cancer of the urinary tract, which includes the renal pelvis (the part of the kidney that connects to the ureter), ureters, bladder, and urethra. Urothelial cancer usually starts in cells called **urothelial cells**, which are found in the inner lining of the organs in the urinary system.

The most common type of urothelial cancer is bladder cancer. In some people, when bladder cancer is first diagnosed, the cancer may only affect the innermost tissue layers. However, in others, the cancer may have already grown into deeper layers of the bladder (known as advanced bladder cancer) or have already spread beyond the bladder to other parts of the body (known as metastatic bladder cancer).

What treatments are used for metastatic urothelial cancer?



If urothelial cancer is only in the bladder (or other parts of the urinary system), surgery (also called resection) to remove the tumor (an abnormal growth of body tissue) is usually the first treatment. However, in advanced or metastatic (cancer that has spread to other parts of the body) urothelial cancer, surgery may no longer be an option. In this case, the cancer is known as 'unresectable,' and chemotherapy (medicines that slow the growth of or kill cancer cells) is typically the first treatment option.

Normally, this chemotherapy involves more than one chemotherapy drug, one of which is usually a drug called cisplatin. However, only about 4 out of 10 people receiving cisplatin-based chemotherapy will show a good response and have their tumor shrink. Therefore, it is important to develop other treatments that could be used alongside chemotherapy for people with unresectable or metastatic urothelial carcinoma.

What was the CheckMate 901 study?

In the CheckMate 901 study, researchers compared a combination of nivolumab and chemotherapy (gemcitabine plus cisplatin) to chemotherapy alone (gemcitabine plus cisplatin) in people with advanced urothelial cancer. Patients received either 1) nivolumab combined with chemotherapy, followed by the drug nivolumab itself, or 2) chemotherapy alone.

Patients in this study had not yet received chemotherapy or immunotherapy for unresectable (not able to be surgically removed) or metastatic (cancer that has spread) urothelial cancer. The researchers wanted to understand whether nivolumab and chemotherapy together helped people live longer overall and live longer without the cancer getting worse. The trial also studied the side effects people had with treatment.

What is nivolumab?

Nivolumab is a type of **immunotherapy**. Immunotherapies are a family of cancer treatments that use the body's own immune system to fight the cancer. The immune system is a complex network of organs, cells, and proteins that helps the body fight against infections and diseases. Immunotherapies work differently from chemotherapy, which kills cancer cells that are in the process of dividing.

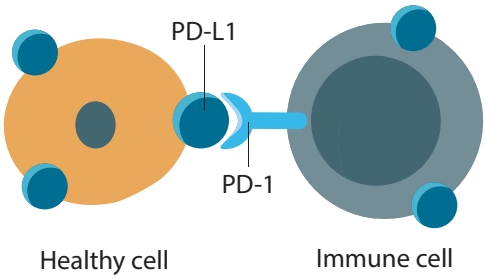
In the body, **immune cells** come into contact with foreign cells such as bacteria and viruses and recognize these cells do not belong to the body, and attack and kill them. Healthy cells have proteins called **immune checkpoints** on their surface that protect them from being attacked by immune cells. One of these proteins is called programmed death ligand 1 (**PD-L1**). When an immune cell comes into contact with a healthy cell, similar proteins on the surface of the immune cell (called programmed death-1 [**PD-1**]) recognize the PD-L1 on the healthy cell. This effectively switches off the immune cell so that it does not attack.

Cancer cells can use this system too, because some cancer cells also have PD-L1 on their surfaces. This helps them trick the immune system so that it does not detect and destroy them.

Nivolumab blocks PD-1 on immune cells, which allows the immune system to recognize the cancer cells as foreign. It basically switches the immune cell back on so that it can detect and destroy the cancer cells.

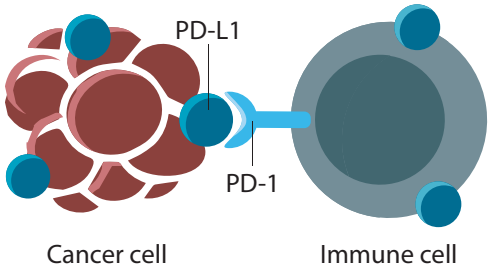
How does nivolumab work?

1



The immune checkpoints on immune cells (PD-1) can recognize the checkpoints on healthy cells (PD-L1). When PD-1 and PD-L1 attach, the immune cell knows not to attack the healthy cell.

2



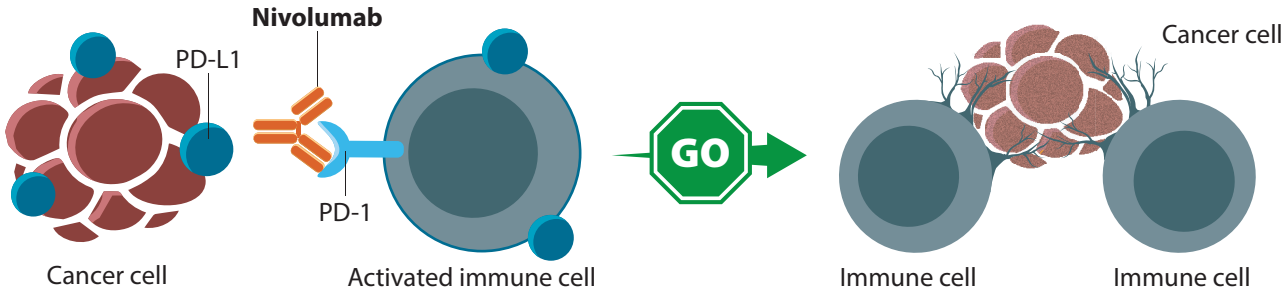
The problem is that many types of cancer cells also have PD-L1 on their surface. When PD-1 on the immune cell attaches to PD-L1 on the cancer cell, the immune cell no longer attacks it because it thinks it is a healthy cell.

There are proteins on cell surfaces called immune checkpoints that prevent immune cells from destroying healthy cells. Immune checkpoint inhibitors are drugs that block checkpoint proteins like PD-1 on immune cells and stop them from attaching to cancer cells. Nivolumab is an immune checkpoint inhibitor.

3

Nivolumab attaches to PD-1 on the immune cells before they are able to attach to PD-L1 on the cancer cells.

Blocking PD-1 from attaching to PD-L1 helps the immune cells get activated. They can now recognize and kill the cancer cells.



By binding to PD-1, nivolumab stops PD-L1 on the cancer cells from binding to immune cells. This helps the immune cells to activate, and then recognize and kill the cancer cells. This means that nivolumab can potentially reduce or stop cancer growth. Nivolumab has been studied in different types of cancer including urothelial cancer.

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What did the CheckMate 901 study investigate?

The 2 main goals of the CheckMate 901 study were to:

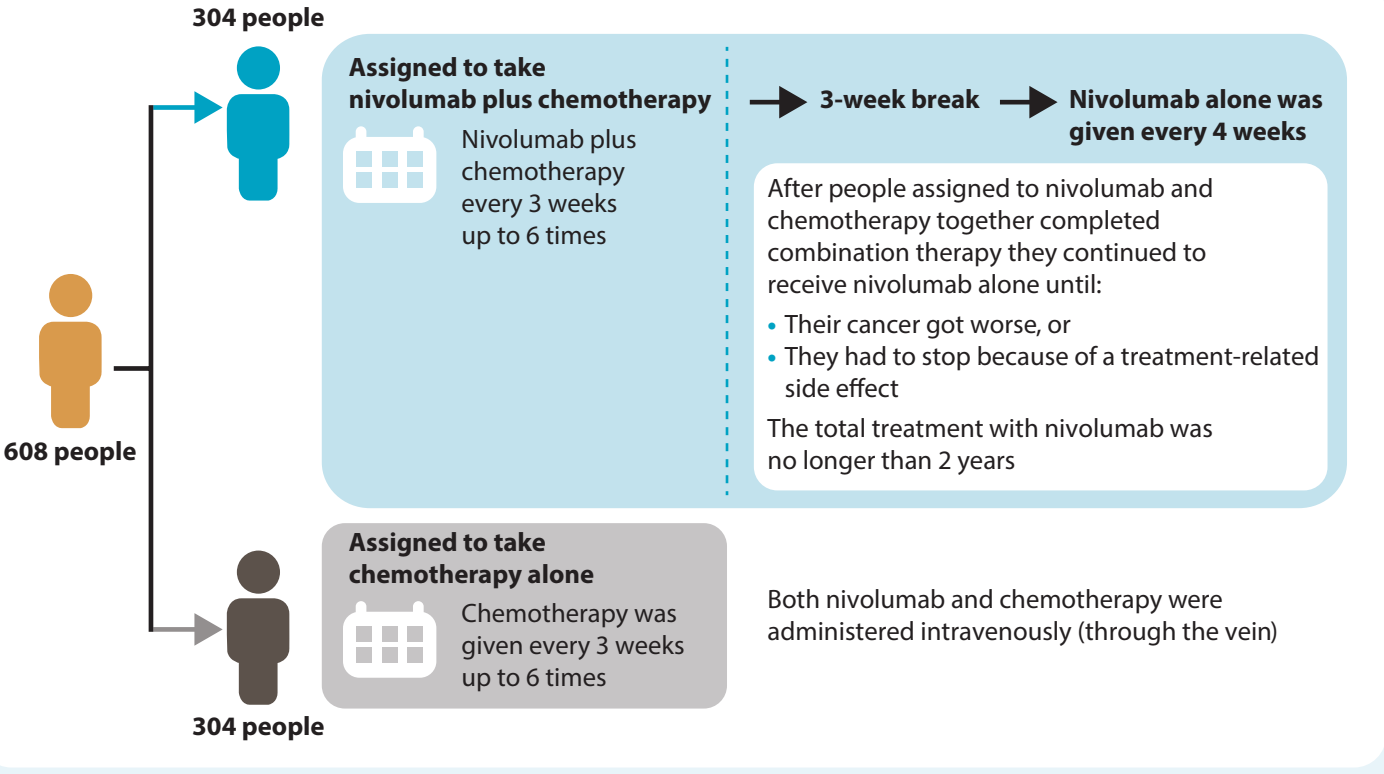
- Determine how long people survived (lived) after starting treatment. This is called **overall survival** (shortened to OS).
- Determine how long each person lived without their cancer getting worse after the start of treatment. This is called **progression-free survival** (shortened to PFS).

The other goals of this study were to:

- Measure the **objective response rate** (a response), which is the proportion of people whose tumors partly or completely shrink on a CT scan (imaging test that helps detect disease and injury) after treatment. The CT scan indicates whether there was a response.
  - » Measure the **duration of response**, which is the length of time that the response continues.
- Measure the **complete response rate**, which is the proportion of people whose tumors completely shrink after treatment.
  - » Measure the **duration of complete response**, which is the length of time that the complete response continues.
- Determine the side effects that people experienced with treatment.
- Determine the impact of the treatment on a person's overall health-related quality of life.

What patient outcomes were studied?	What was measured?	What do the results mean?
Overall survival	Time that a person remained alive after starting the trial	A longer time means that the treatment is more likely to help people live longer
Progression-free survival	Time that a person remained alive and the cancer did not get worse after starting treatment	A longer time means that the treatment is more likely to help people live longer without the cancer growing or spreading
Objective response rate	The proportion of people whose tumors partly or completely shrink (a response) after treatment	A higher rate means that more people's tumors partly or completely responded to the treatment
Complete response rate	The proportion of people whose tumors completely shrink (complete response) after treatment	A higher rate means that more people's tumors completely responded to the treatment
Side effects	All side effects that occurred during the study were recorded	Side effects can range in severity; however, they may or may not have been caused by the treatments people received during the study
Health-related quality of life	Questionnaires were used to measure the health-related quality of life of patients with cancer	Health-related quality of life measures an individual's health, comfort, and ability to participate in or enjoy life events

How was the study designed?



Who could take part in this study?

Patients must have had:

- **Unresectable** (not able to be surgically removed) or metastatic urothelial cancer
- Tumor located in the renal pelvis, bladder, ureter, or urethra
- No prior chemotherapy treatment given for metastatic urothelial cancer
- Eligibility for cisplatin-containing chemotherapy

Patients could not have had:

- Urothelial cancer that had spread to the brain
- Prior treatment with immunotherapy

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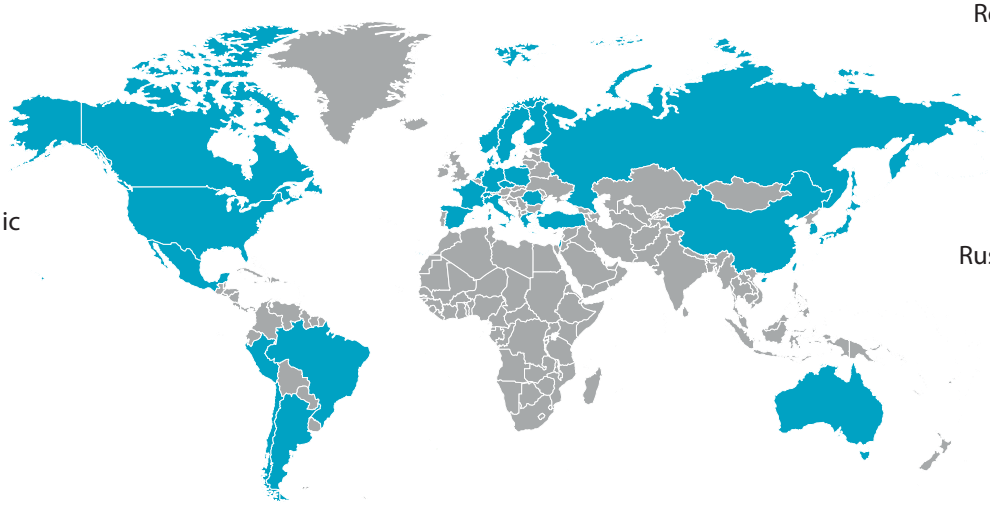
Who participated in this study?

The study was conducted in 30 countries

Argentina
Australia
Brazil
Canada
Chile
China
Czech Republic
Denmark
Finland
France
Germany
Greece
Israel
Italy
Japan



Republic of Korea
Mexico
Netherlands
Norway
Peru
Poland
Romania
Russian Federation
Singapore
Spain
Sweden
Switzerland
Taiwan
Turkey
United States

608 **Adults with unresectable or metastatic urothelial carcinoma**

Average age 65 years

Sex

77% male

23% female

Race

72% White

23% Asian

Less than 1% American Indian or Alaska native

Less than 1% Black

5% Other

Disease stage

87% metastatic

12% locally advanced or nonmetastatic

Less than 1% Not reported

Tumor location

75% bladder

13% renal pelvis

13% other

What were the results of the study?

In this study, among those who received **nivolumab plus chemotherapy** compared with those who received **chemotherapy** alone:

Overall survival

People lived longer after starting treatment

22% lower risk of death on nivolumab plus chemotherapy

Progression-free survival

People lived longer without the cancer getting worse after starting treatment

28% lower risk of the cancer getting worse or dying on nivolumab plus chemotherapy

Objective response rate and complete response rate

More people had their tumor partially or completely shrink after treatment (objective response rate)

Objective response rate

Nivolumab plus chemotherapy: **58%** (about 6 out of 10 people had an objective response)

Chemotherapy: **43%** (about 4 out of 10 people had an objective response)

More people (almost double) had their tumor completely shrink after treatment (complete response)

Complete response rate

Nivolumab plus chemotherapy: **22%** (about 2 out of 10 people had a complete response)

Chemotherapy: **12%** (about 1 out of 10 people had a complete response)

Responses lasted longer (duration of response)

Nivolumab plus chemotherapy **9.5 months**

Chemotherapy **7.3 months**

Complete response lasted nearly 3 times longer (duration of complete response)

37.1 months

13.2 months

Health-related quality of life

Health-related quality of life did not worsen during treatment with nivolumab plus chemotherapy, and health-related quality of life scores were similar in both treatment groups.

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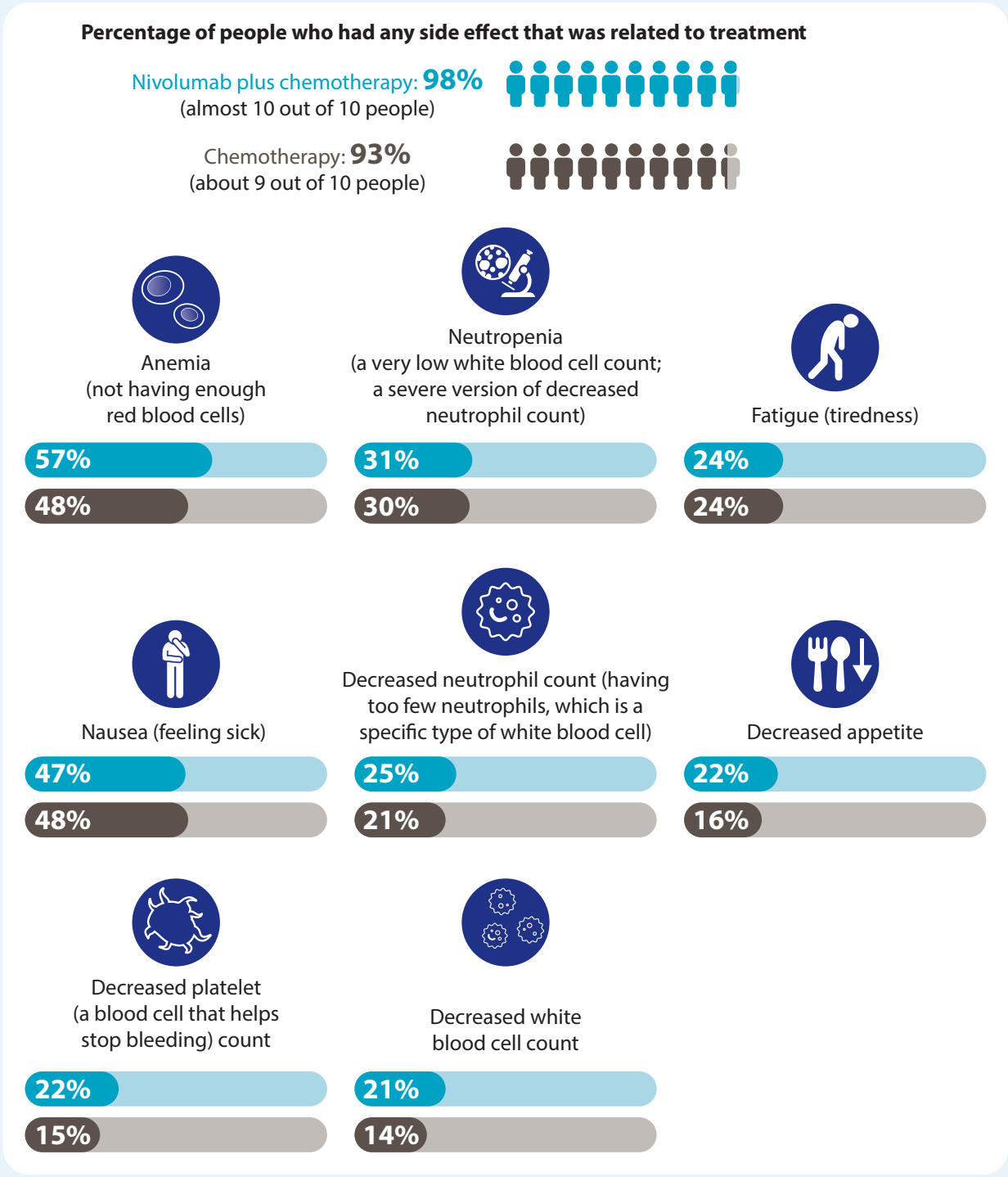
What were the most common side effects?

The most common treatment-related side effects with nivolumab plus chemotherapy were **nausea** (feeling sick) and lower levels of red blood cells (known as **anemia**, which can cause tiredness, shortness of breath, and irregular heartbeats) and very low levels of white blood cells (known as **neutropenia**, which can increase risk of infection). These are known side effects of these treatments.



What do the results of this study mean?

- In summary, among people in this study who were treated with nivolumab plus chemotherapy compared with people treated with chemotherapy alone, there was better survival and a lower risk of their cancer getting worse.
- The proportion of people responding was higher, and there were almost twice as many people with a complete response. Additionally, the length of time that people maintained a complete response was nearly 3 times as long. Health-related quality of life did not worsen and was similar with both treatments.
- Finally, the side effects that people experienced were similar to what is expected for nivolumab and for chemotherapy.

KEY FINDINGS

In this study, among those who received **nivolumab plus chemotherapy** compared with those who received **chemotherapy** alone:

Overall survival

People lived longer after starting treatment

22%
lower risk of death on nivolumab plus chemotherapy

Progression-free survival

People lived longer without the cancer getting worse after starting treatment

28%
lower risk of the cancer getting worse or dying on nivolumab plus chemotherapy

Limitations

Some people in this study who received chemotherapy only had gone on to receive treatment outside this study with a different immunotherapy drug called avelumab. Although this could have had some influence on the end results of people in this study who received chemotherapy only, the high number of complete responses and long duration of complete responses in people who received nivolumab plus chemotherapy still support taking nivolumab plus chemotherapy at the same time.

Where can I find more information?

The original article, titled "Nivolumab plus Gemcitabine–Cisplatin in Advanced Urothelial Carcinoma," is free to access at: https://www.nejm.org/doi/pdf/10.1056/NEJMoa2309863

Full citation: van der Heijden MS, Sonpavde G, Powles T, et al. Nivolumab plus Gemcitabine-Cisplatin in Advanced Urothelial Carcinoma. *N Engl J Med.* 2023;389(19):1778-1789. doi:10.1056/NEJMoa2309863

NCT identifier number: NCT03036098

Study start date: March 24, 2017

Study end date: January 6, 2028

Acknowledgements

The authors would like to thank the participants and their families for making the study possible, the CheckMate 901 investigators and the clinical study teams, and Bristol Myers Squibb (Princeton, NJ, USA) and Ono Pharmaceutical Co. Ltd (Osaka, Japan).

Disclosure statement

Michiel S van der Heijden reports consulting or advisory roles to institution with AstraZeneca, Bristol Myers Squibb (BMS), Janssen, MSD, Seagen, and Pfizer; research funding to institution from BMS, Roche, AstraZeneca, and 4SC; and steering committee membership (institution) with BMS, AstraZeneca, MSD, Janssen, and Seagen. Guru Sonpavde reports employment with Myriad Genetics at the time of the study; consulting or advisory roles with Aktis Oncology, Astellas Pharma, Bicycle Therapeutics, BMS, Daiichi Sankyo/Astra Zeneca, EMD Serono, Exelixis, G1 Therapeutics, Genentech, Gilead Sciences, Janssen, Kura Oncology, Loxo/Lilly, Lucence, Merck, Pfizer, Scholar Rock, Seagen, Syapse, and Vial; honoraria from Grand Rounds in Urology, Ideology Health, Onviv, PeerView, PrecisCa, and UpToDate; research funding to institution from BMS, EMD Serono, Gilead Sciences, and Jazz Pharmaceuticals; travel, accommodations, expenses from Astellas Pharma and BMS; speaker's bureau with Astellas Pharma, AVEO, Bayer, Exelixis, Gilead Sciences, Informação Brasileira de Oncologia, Janssen Oncology, Medscape, Merck, Natera, Pfizer, Research to Practice, and Seagen; and other relationships with BMS, Elsevier, G1 Therapeutics, Mereo BioPharma, and QED Therapeutics. Thomas Powles reports consulting or advisory roles with AstraZeneca, BMS, Exelixis, Incyte, Ipsen, Merck, Novartis, Pfizer, Seattle Genetics, Merck Serono, Astellas Pharma, Johnson & Johnson, Eisai, Roche, and MSD; travel, accommodations, expenses with Roche, Pfizer, MSD, AstraZeneca, and Ipsen; honoraria from Gilead; sponsorship from Mashup Labs; and research funding to institution from AstraZeneca, Roche, BMS, Exelixis, Ipsen, Merck, MSD, Seattle Genetics, Novartis, Pfizer, Merck Serono, Astellas Pharma, Johnson & Johnson, Eisai, and Gilead. Andrea Necchi reports consulting or advisory roles with Merck Sharp & Dohme, Roche, Bayer, AstraZeneca, Clovis Oncology, Janssen, Incyte, Seattle Genetics/Astellas Pharma, BMS, Rainier Therapeutics, GlaxoSmithKline, Basilea Pharmaceutical, and CatalYm; travel, accommodations, expenses from Roche, Merck Sharp & Dohme, AstraZeneca, Janssen, Rainier Therapeutics, and Pfizer; honoraria from Roche, Merck, AstraZeneca, Janssen, Foundation Medicine, BMS, and Astellas Pharma; research funding to institution from Merck Sharp & Dohme, AstraZeneca, Ipsen, and Gilead Sciences; and employment, other relationship, and stock and other ownership interests (family member) with Bayer. Mauricio Burotto reports consulting or advisory roles with Roche/Genentech, BMS, MSD Oncology, Novartis, and AstraZeneca; and speaker's bureau with Roche/Genentech, MSD Oncology, BMS, and AstraZeneca. Michael Schenker reports travel, accommodations, expenses from BMS; and research funding from BMS, Roche, Amgen, MSD, Pfizer/EMD Serono, Lilly, Astellas Pharma, AstraZeneca, GlaxoSmithKline, Regeneron, Novartis, AbbVie, Gilead Sciences, Sanofi/Regeneron, Mylan, BIOVEN, Clovis Oncology, Tesaro, BeiGene, and Five Prime Therapeutics. Juan Pablo Sade reports no conflicts of interest. Aristotelis Bamias reports consulting or advisory roles with BMS, Pfizer, AstraZeneca, MSD, Roche, Ferring, and Ipsen; honoraria from BMS, MSD, Astellas Pharma, Sanofi, and Debiopharm Group; and research funding to institution from Roche, AstraZeneca, Pfizer, BMS, and Ipsen. Philippe Beuzeboc reports travel, accommodations, expenses from Pfizer; and honoraria from Astellas Pharma. Jens Bedke reports consulting or advisory roles with AstraZeneca, Astellas Pharma, BMS, Eisai, Ipsen, MSD, Merck Serono, Pfizer, Roche, and Janssen; and honoraria to institution from BMS, Pfizer, AstraZeneca, Astellas Pharma, BMS, Eisai, MSD, Ipsen, Novartis, Nektar, Pfizer, Roche, and Seagen. Jan Oldenburg reports consulting or advisory roles with Accord Healthcare, Bayer, BMS Norway, Astellas Pharma, AstraZeneca, Merck KGaA, MSD Oncology, Eisai, Roche/Genentech, Janssen Oncology, and Pfizer; and speaker's bureau with Astellas Pharma. Gurkamal Chatta reports consulting or advisory roles with Cardinal Health; travel, accommodations, expenses with Cardinal Health; and research funding to institution from AbbVie and Taiho Oncology. Yüksel Ürün reports consulting or advisory roles with Astellas Pharma, BMS, Janssen, Pfizer, Roche, Abdi Ibrahim, AstraZeneca, Eczacıbaşı, Gilead Sciences, Merck Serono, MSD, Novartis, and Gen; speaker's bureau with Astellas Pharma, BMS, Janssen Novartis, Pfizer, Roche, Abdi Ibrahim, AstraZeneca, Eczacıbaşı, Merck Serono, MSD, and Gen; travel, accommodations, expenses from BMS, Pfizer, Roche, Abdi Ibrahim, Eczacibasi, and Gen; and honoraria from Astellas Pharma, BMS, Janssen, Novartis, Pfizer, Roche, Abdi Ibrahim, AstraZeneca, Eczacibasi, Gilead Sciences, Merck Serono, MSD, and Gen. Dingwei Ye reports no conflicts of interest. Zhisong He reports no conflicts of interest. Begoña P Valderrama reports consulting or advisory roles with BMS/Medarex, MSD Oncology, Astellas Pharma, AstraZeneca, Novartis, Bayer, and Advanced Accelerator Applications/Novartis; travel, accommodations, expenses from Merck/Pfizer and BMS; and honoraria from BMS/Medarex, EUSA Pharma, Pfizer, Astellas Pharma, Bayer, Merck/Pfizer, Merck, AAA HealthCare, Ipsen, and MSD Oncology. Ja Hyeon Ku reports no conflicts of interest. Yoshihiko Tomita reports consulting or advisory roles with Eisai, MSD, Ono Pharmaceutical, and Taiho Pharmaceutical; honoraria from Astellas Pharma, BMS Japan, Chugai Pharma, Ono Pharmaceutical, Takeda, Merck, Pfizer, and MSD; and research funding to institution from Astellas Pharma, AstraZeneca, Chugai Pharma, Eisai, MSD, Ono Pharmaceutical, Pfizer, and Takeda. Jeiry Filian was employed by BMS at the time of the study, and reports no conflicts of interest. Lily Wang reports employment, travel, and stock ownership with BMS. Daniela Purcea reports employment, travel, and stock ownership with BMS. Miraj Y Patel was employed by BMS at the time of the study, and reports no conflicts of interest. Federico Nasroulah reports employment, travel, and stock ownership with BMS at the time of the study. Matthew D Galsky reports consulting or advisory roles with Janssen, Merck, GlaxoSmithKline, Eli Lilly, Astellas Pharma, Genentech, BMS, Pfizer, EMD Serono, AstraZeneca, Seagen, Incyte, Alligator Biosciences, Rappta Therapeutics, AbbVie, Asieris, Bicycle, Gilead Sciences, Curis, and Fujifilm; steering committee member (institutional) with Merck, Genentech, and BMS; coordinating PI with AstraZeneca and Jazz; and local PI with Seagen. The authors have no other relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript apart from those disclosed.

Professional writing support for this summary was provided by Jen Reinhold, PharmD, of Parexel, funded by Bristol Myers Squibb.

Patient reviewers on this PLSP have received honoraria from *Future Oncology* for their review work but have no other relevant financial relationships to disclose.

Funding

This work was supported by Bristol Myers Squibb (Princeton, New Jersey, USA). The funders contributed to the study design, data analysis, and data interpretation in collaboration with the authors. The funders did not have a role in data collection.

Author affiliations

[a]Department of Medical Oncology, Netherlands Cancer Institute, Amsterdam, the Netherlands; [b]Medical Oncology, Genitourinary Section, Dana-Farber Cancer Institute, Harvard Medical School, Boston, MA, USA; [c]Department of Genitourinary Oncology, Barts Cancer Institute, Queen Mary University of London, London, UK; [d]Department of Medical Oncology, Fondazione IRCCS Istituto Nazionale dei Tumori, Milan, Italy; [e]Department of Oncology, Bradford Hill Clinical Research Center, Santiago, Chile; [f]Department of Medical Oncology, Sf. Nectarie Oncology Center, Department of Oncology, University of Medicine and Pharmacy, Craiova, Romania; [g]Department of Clinical Oncology, Alexander Fleming Institute, Buenos Aires, Argentina; [h]Second Propaedeutic Department of Medicine, National and Kapodistrian University of Athens, ATTIKON University Hospital, Athens, Greece; [i]Oncology Department, Hôpital Foch, Suresnes, France; [j]Department of Urology, Eberhard Karls University Tübingen, Tübingen, Germany; [k]Department of Oncology, Akershus University Hospital (Ahus), Lørenskog, Norway; [l]Roswell Park Comprehensive Cancer Center, Buffalo, NY, USA; [m]Department of Medical Oncology, Ankara University, Ankara, Turkey; [n]Department of Oncology, Fudan University Shanghai Cancer Center, Shanghai, China; [o]Department of Urology, Peking University First Hospital, Beijing, China; [p]Department of Medical Oncology, Hospital Universitario Virgen del Rocío, Sevilla, Spain; [q]Seoul National University Hospital, Seoul, Republic of Korea; [r]Department of Urology, Niigata University Graduate School of Medical and Dental Sciences, Niigata, Japan; [s]Oncology Clinical Development, Bristol Myers Squibb, Princeton, NJ, USA; [t]Division of Biostatistics, Bristol Myers Squibb, Boudry, Switzerland; [u]Department of Medicine, Tisch Cancer Institute, Icahn School of Medicine at Mount Sinai, New York, NY, USA
At the time of the study:
Dr. Sonpavde's current institution is AdventHealth Cancer Institute and University of Central Florida, Orlando, FL, USA.
Dr. Necchi's current institution is Department of Medical Oncology, IRCCS San Raffaele Hospital, Vita-Salute San Raffaele University, Milan, Italy.
Dr. Bedke's current institution is Department of Urology & Transplantation Surgery and Eva Mayr-Stihl Cancer Center, Klinikum Stuttgart, Stuttgart, Germany.
Dr. Nasroulah's current affiliation is Daiichi Sankyo Inc, Basking Ridge, NJ, USA.