

# AVASTIN® (bevacizumab)

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Avastin is a tumor-starving (anti-angiogenic) medicine. Avastin is designed to block a protein called vascular endothelial growth factor, or VEGF. Normal cells make VEGF, but some cancer cells make too much VEGF. Blocking VEGF may prevent the growth of new blood vessels.<sup>1</sup>

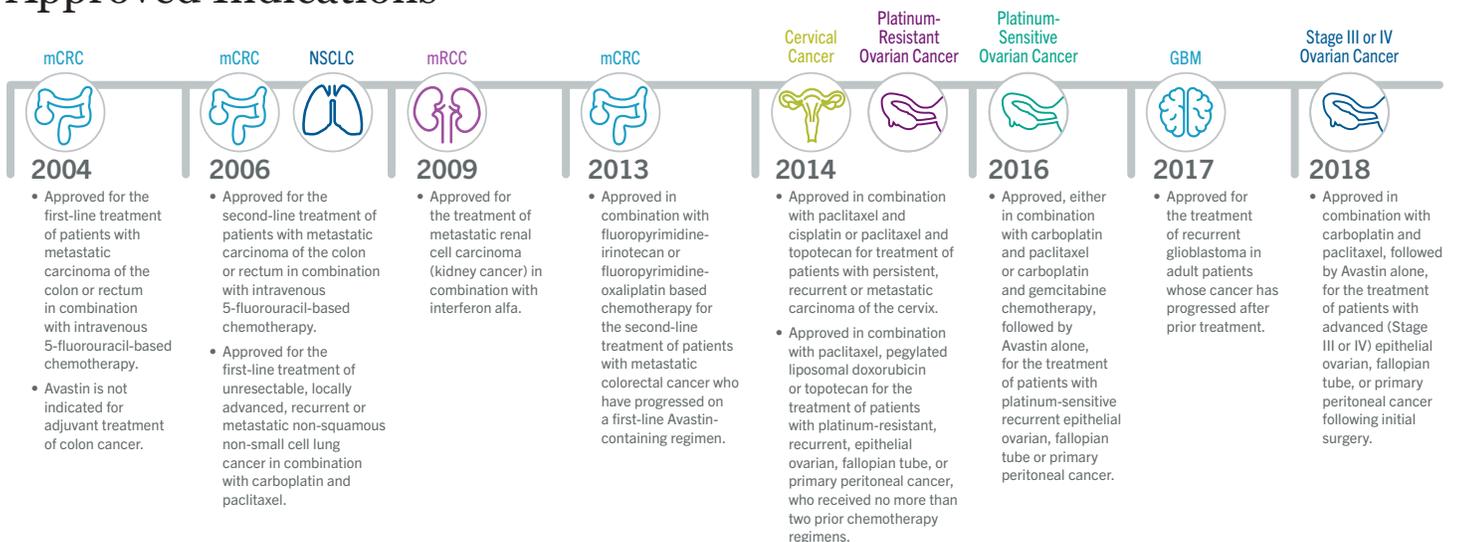
Unlike chemotherapy that attacks fast-growing cells, like cancer cells, Avastin is designed to prevent the growth of new blood vessels. This includes normal blood vessels and blood vessels that feed tumors.<sup>1</sup>



**AVASTIN**<sup>®</sup>  
bevacizumab  
100 MG/4 ML INJECTION FOR IV USE

- It has been **more than 10 years** since Avastin plus IV 5-FU-based chemotherapy was **first approved** as a first-line treatment for metastatic colorectal cancer (mCRC)
- In that time, Avastin has built a **compelling body of evidence** and is now approved for **ten distinct uses across six different types of cancer** in the United States
- **Five Phase III studies** have met a primary endpoint of demonstrating an improvement in **overall survival**

## Approved Indications



## Important Safety Information

### POSSIBLE SERIOUS SIDE EFFECTS

Everyone reacts differently to Avastin therapy. So it's important to know what the side effects are. **Although some people may have a life-threatening side effect, most do not.** Their doctor will stop treatment if any serious side effects occur. **Patients should talk to their doctor if there are any signs of these side effects.**

Most serious side effects (not common, but sometimes fatal):

- **GI perforation.** A hole that develops in the stomach or intestine. Symptoms include pain in the abdomen, nausea, vomiting, constipation, or fever
- **Wounds that don't heal.** A cut made during surgery can be slow to heal or may not fully heal. Avastin should not be used for at least 28 days before or after surgery and until surgical wounds are fully healed
- **Serious bleeding.** This includes vomiting or coughing up blood; bleeding in the stomach, brain, or spinal cord; nosebleeds; and vaginal bleeding. If a patient has recently coughed up blood or had serious bleeding, they should be sure to tell their doctor

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For full Prescribing Information including **Boxed WARNINGS** and other important safety information for Avastin, please visit [www.avastin.com](http://www.avastin.com).

# Avastin Efficacy Profiles

mCRC<sup>2,3</sup> | 2004

## FIRST-LINE TREATMENT

Avastin reduced the risk of death by 34 percent  
(HR=0.66, 95% CI: 0.54-0.81; p<0.001).

AVF2107 Study	Avastin* + IFL N=402	IFL N=411
Median Overall Survival (mOS) (primary endpoint)	20.3 months	15.6 months
Median Progression-Free Survival (mPFS) (secondary endpoint)	10.6 months	6.2 months
HR=0.54, 95% CI: 0.45-0.66; p<0.001		

\*5 mg/kg IV every 2 weeks

### AVF2107 STUDY

The approval of Avastin for first-line treatment of mCRC was based on the results of the AVF2107 study, a Phase III, randomized, double-blind study that evaluated Avastin plus IV 5-FU-based chemotherapy (IFL) compared to IFL alone in 813 people with newly diagnosed mCRC.

NSCLC<sup>2</sup> | 2006

## FIRST-LINE TREATMENT

Avastin reduced the risk of death by 20 percent  
(HR=0.80, 95% CI: 0.68-0.94; p=0.013).

E4599 Study	Avastin* + Chemotherapy N=434	Chemotherapy N=444
mOS (primary endpoint)	12.3 months	10.3 months

\*15 mg/kg IV every 3 weeks

### E4599 STUDY

The approval of Avastin for first-line treatment of non-squamous NSCLC was based on the results of the pivotal randomized, open-label, active-controlled Phase III E4599 study. This study investigated Avastin plus chemotherapy (paclitaxel and carboplatin) compared to chemotherapy alone in 878 people with newly diagnosed, unresectable, locally advanced, recurrent, or metastatic, non-squamous NSCLC.

mCRC<sup>2,3</sup> | 2006

## SECOND-LINE TREATMENT AFTER FIRST-LINE CHEMOTHERAPY

Avastin reduced the risk of death by 25 percent  
(HR=0.75, 95% CI: 0.63-0.89; p=0.001).

E3200 Study	Avastin*+ FOLFOX N=286	FOLFOX N=291
mOS (primary endpoint)	13.0 months	10.8 months
mPFS (secondary endpoint)	7.3 months	4.7 months
HR=0.61; p<0.0001		

\*10 mg/kg IV every 2 weeks

### E3200 STUDY

The approval of Avastin for second-line treatment of mCRC following disease worsening with first-line chemotherapy was based on the results of the E3200 study, a Phase III, randomized, controlled study of Avastin plus FOLFOX chemotherapy compared to FOLFOX alone in 577 Avastin-naïve people that had progressed following previous treatment with chemotherapy.

mRCC<sup>2</sup> | 2009

## FIRST-LINE TREATMENT

Avastin reduced the risk of disease worsening by 40 percent  
(HR=0.60, 95% CI: 0.49-0.72; p<0.0001).

AVOREN Study	Avastin*+Interferon alfa-2a N=327	Interferon alfa-2a N=322
mPFS (primary endpoint)	10.2 months	5.4 months
Overall Response Rate (ORR) (secondary endpoint)	30%	12%
p<0.0001		

\*10 mg/kg IV every 2 weeks

### AVOREN STUDY

The approval of Avastin for first-line treatment of mRCC was based on the results of the pivotal randomized, double-blind Phase III AVOREN study. This study investigated Avastin plus interferon alfa-2a versus interferon alfa-2a alone in 649 people with newly diagnosed mRCC. **The study did not demonstrate a significant difference in overall survival.**

Study data continues on next page.

## Important Safety Information (continued)

### OTHER POSSIBLE SERIOUS SIDE EFFECTS (continued)

- **Abnormal passage in the body.** This type of passage—known as a fistula—is an irregular connection from one part of the body to another and can sometimes be fatal
- **Severe high blood pressure.** Blood pressure that severely spikes or shows signs of affecting the brain. Blood pressure should be monitored every 2 to 3 weeks while on Avastin and after stopping treatment

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# Avastin Efficacy Profiles

## mCRC<sup>2</sup> | 2013

### SECOND-LINE TREATMENT AFTER FIRST-LINE AVASTIN PROGRESSION



Avastin reduced the risk of death by 19 percent (HR=0.81, 95% CI: 0.69-0.94; p=0.0057).

ML18147 Study	Avastin* + Chemotherapy N=409	Chemotherapy N=411
mOS (primary endpoint)	11.2 months	9.8 months
mPFS (secondary endpoint)	5.7 months	4.0 months
	HR=0.68, 95% CI: 0.59-0.78; p<0.0001	

\*5 mg/kg IV every 2 weeks or 7.5 mg/kg IV every 3 weeks

### ML18147 STUDY

The approval of Avastin for second-line treatment of mCRC following progression with an Avastin-based regimen was based on the results of the ML18147 study, a Phase III, randomized, prospective open-label study that evaluated the use of Avastin plus a fluoropyrimidine-based chemotherapy, compared to chemotherapy alone, as a second-line medicine after the disease worsened in 820 patients. In the first-line, all patients received Avastin plus a different fluoropyrimidine-based chemotherapy (irinotecan or oxaliplatin-based). **The study did not demonstrate a significant difference in overall response rates.**

## Cervical Cancer<sup>2</sup> | 2014

### PERSISTENT, RECURRENT OR METASTATIC TREATMENT



Avastin reduced the risk of death by 26 percent (HR=0.74, 95% CI: 0.58-0.94; p=0.0132).

GOG-0240 Study	Avastin* + Chemotherapy N=227	Chemotherapy N=225
mOS (primary endpoint)	16.8 months	12.9 months
ORR (secondary endpoint)	45%	34%

\*15 mg/kg IV every 3 weeks

### GOG-0240 STUDY

The approval of Avastin plus chemotherapy for treatment of patients with persistent, recurrent, or metastatic cervical cancer was based on the results of the GOG-0240 study. This study investigated Avastin plus chemotherapy (paclitaxel and cisplatin or paclitaxel and topotecan) compared to chemotherapy alone in 452 women with persistent, recurrent, or metastatic cervical cancer (Stage IVb).

## Platinum-Resistant Ovarian Cancer<sup>2</sup> | 2014

### RECURRENT, PLATINUM-RESISTANT TREATMENT



Avastin reduced the risk of disease worsening by 62 percent (HR=0.38, 95% CI: 0.30-0.49; p<0.0001).

AURELIA Study	Avastin* + Chemotherapy N=179	Chemotherapy N=182
mPFS (primary endpoint)	6.8 months	3.4 months
mOS (secondary endpoint)	16.6 months	13.3 months
	HR=0.89, 95% CI: 0.69-1.14	
ORR (secondary endpoint)	28%	13%

\*10 mg/kg IV every 2 weeks or 15mg/kg IV every 3 weeks

### AURELIA STUDY

The approval of Avastin in combination with paclitaxel, pegylated liposomal doxorubicin or topotecan for the treatment of patients with platinum-resistant, recurrent, epithelial ovarian, fallopian tube, or primary peritoneal cancer who had received no more than two prior chemotherapy regimens was based on the results of the AURELIA study. The study investigated Avastin plus chemotherapy (paclitaxel, pegylated liposomal doxorubicin or topotecan) compared to chemotherapy alone in 361 women with disease that had recurred within six months from the most recent platinum-based therapy. The addition of Avastin to chemotherapy demonstrated a statistically significant improvement in investigator-assessed PFS, which was supported by a retrospective independent review analysis. Use should be avoided in patients with ovarian cancer who have evidence of recto-sigmoid involvement by pelvic examination or bowel involvement on CT scan or clinical symptoms of bowel obstruction.

Study data continues on next page.

## Important Safety Information (continued)

### OTHER POSSIBLE SERIOUS SIDE EFFECTS (continued)

- **Kidney problems.** These may be caused by too much protein in the urine and can sometimes be fatal
- **Infusion reactions.** These were uncommon with the first dose (less than 3% of patients). 0.2% of patients had severe reactions. Infusion reactions include high blood pressure or severe high blood pressure that may lead to stroke, trouble breathing, decreased oxygen in red blood cells, a serious allergic reaction, chest pain, headache, tremors, and excessive sweating. The patient's doctor or nurse will monitor for signs of infusion reactions
- **Severe stroke or heart problems.** These may include blood clots, mini-stroke, heart attack, chest pain, and the heart may become too weak to pump blood to other parts of the body (congestive heart failure). These can sometimes be fatal
- **Nervous system and vision problems.** Signs include headache, seizure, high blood pressure, sluggishness, confusion, and blindness

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# Avastin Efficacy Profiles

The approval of Avastin for the treatment of platinum-sensitive recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer either in combination with carboplatin and paclitaxel or in combination with carboplatin and gemcitabine chemotherapy, followed by Avastin alone, was based on the results of the OCEANS and GOG-0213 studies.

## Platinum-Sensitive Ovarian Cancer<sup>2</sup> | 2016

### RECURRENT, PLATINUM-SENSITIVE TREATMENT (OCEANS)



Avastin reduced the risk of disease worsening by 54 percent (HR=0.46, 95% CI: 0.37-0.58; p<0.0001).

OCEANS Study	Avastin* + Chemotherapy N=242	Chemotherapy N=242
mPFS (primary endpoint)	12.4 months	8.4 months
ORR (secondary endpoint)	78%	57%
p<0.0001		

\*15 mg/kg IV every 3 weeks

### OCEANS STUDIES

The OCEANS study investigated Avastin plus chemotherapy (carboplatin and gemcitabine) compared to placebo plus chemotherapy in 484 women with disease that had recurred after six months from the most recent platinum-based therapy. Overall survival was not significantly improved with the addition of Avastin to chemotherapy.

### RECURRENT, PLATINUM-SENSITIVE TREATMENT (GOG-0213)



Avastin reduced the risk of death by 16 to 18 percent (eCRF<sup>a</sup> HR=0.82, 95% CI: 0.68-0.996; IVRS<sup>b</sup> HR=0.84, 95% CI: 0.69-1.01).

GOG-0213 Study	Avastin* + Chemotherapy N=337	Chemotherapy N=336
OS (primary endpoint)	42.6 months	37.3 months
mPFS (secondary endpoint)	13.8 months	10.4 months
HR=0.61, 95% CI: 0.51-0.72		
ORR (secondary endpoint)	78%	56%
	Number of patients with measurable disease at baseline	
	274	286

\* 15 mg/kg IV every 3 weeks

<sup>a</sup> Hazard ratio was estimated from Cox proportional hazards models stratified by the duration of platinum free-interval prior to enrolling onto this study per eCRF (electronic case report form) and secondary surgical debulking status.

<sup>b</sup> Hazard ratio was estimated from Cox proportional hazards models stratified by the duration of treatment free-interval prior to enrolling onto this study per IVRS (interactive voice response system) and secondary surgical debulking status.

### GOG-0213 STUDY

The GOG-0213 study investigated Avastin plus chemotherapy (carboplatin and paclitaxel) followed by continued use of Avastin alone compared to chemotherapy alone in 673 women with disease that had recurred after six months from the most recent platinum-based therapy.

Study data continues on next page.

## Important Safety Information (continued)

### SIDE EFFECTS SEEN MOST OFTEN

In clinical studies across different types of cancers, some patients experienced the following side effects:

- High blood pressure
- Rectal bleeding
- Taste change
- Inflammation of the nose
- Too much protein in the urine
- Back pain
- Dry skin
- Watery eyes
- Nosebleeds
- Headache
- Inflammation of the skin

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# Avastin Efficacy Profiles

## Recurrent Glioblastoma<sup>2</sup> | 2017

### RECURRENT TREATMENT

There was **no significant increase in OS** with Avastin-based treatment.

EORTC 26101 Study	Avastin* + lomustine N=283	lomustine N=149
OS (primary endpoint)	HR=0.91; p=0.4578	
mPFS (secondary endpoint) <sup>a</sup>	4.2 months	1.5 months
	HR=0.52, 95% CI: 0.41-0.64	
Corticosteroid Discontinuation <sup>b</sup> (secondary endpoint) <sup>a</sup>	23%	12%

\* 10 mg/kg IV every 2 weeks

<sup>a</sup> As the primary endpoint was not met, all secondary endpoints are descriptive only.

<sup>b</sup> Among the 50% of people taking corticosteroids at baseline who were able to completely stop intake of corticosteroids.

### EORTC 26101 STUDY

The approval of Avastin for the treatment of recurrent GBM in adult patients whose cancer has progressed after prior treatment was based on the results for the EORTC 26101 study. This independent Phase III, multicenter, randomized, open-label study evaluated the addition of Avastin to lomustine chemotherapy in 432 people with previously treated GBM.

## Stage III or IV Ovarian Cancer<sup>2</sup> | 2018

### TREATMENT AFTER INITIAL SURGERY

Avastin plus chemotherapy followed by Avastin alone **reduced the risk of disease worsening by 48 percent** (HR=0.62, 95% CI: 0.52-0.75; p<0.0001).

GOG-0218 Study	Avastin <sup>a</sup> + Chemotherapy followed by Avastin alone N=623	Avastin <sup>b</sup> with chemotherapy N=625	Chemotherapy alone N=625
PFS (primary endpoint)	18.2 months	12.8 months <sup>c</sup>	12.0 months
	43.8 months	38.8 months	
OS (secondary endpoint)	HR=0.89, 95% CI: 0.76-1.05	HR=1.06, 95% CI: 0.90-1.24	40.6 months

<sup>a</sup> 15 mg/kg IV every 3 weeks for up to 22 cycles total

<sup>b</sup> 15 mg/kg IV every 3 weeks for 6 cycles

<sup>c</sup> HR=0.83, 95% CI: 0.70-0.98; p-value=not significant

### GOG-0218 STUDY

The approval of Avastin, in combination with carboplatin and paclitaxel chemotherapy, followed by Avastin as a single agent, for the treatment of patients with stage III or IV epithelial ovarian, fallopian tube, or primary peritoneal cancer following initial surgical resection, was based on results of the Phase III GOG-0218 study. The study investigated chemotherapy alone compared to Avastin plus chemotherapy followed by placebo alone, or Avastin plus chemotherapy followed by Avastin alone in 1,873 women with previously untreated stage III or IV ovarian cancer who already had surgery to remove as much of the tumor as possible.

## Important Safety Information (continued)

### AVASTIN IS NOT FOR EVERYONE

Talk to your doctor if you are:



#### UNDERGOING SURGERY

Avastin should not be used for 28 days before or after surgery and until surgical wounds are fully healed



#### PREGNANT, THINK YOU ARE PREGNANT, PLANNING TO BECOME PREGNANT OR BREASTFEEDING

Data have shown that Avastin may harm your unborn baby. Use birth control while on Avastin. If you stop Avastin, you should keep using birth control for 6 months before trying to become pregnant. Taking Avastin could cause a woman's ovaries to stop working and may impair her ability to have children. Breastfeeding while on Avastin may harm your baby and is therefore not recommended during and for 6 months after taking Avastin.

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# Study Specific Safety

## STUDY ADVERSE EVENTS IN MCRC

In the first-line mCRC trial, the most common severe to life-threatening side effects that increased by 2% or more in people who received Avastin plus IFL (chemotherapy) vs IFL (chemotherapy) alone were weakness (10% vs 7%), abdominal pain (8% vs 5%), pain (8% vs 5%), high blood pressure (12% vs 2%), blood clots in the veins of the body (9% vs 5%), blood clots inside the abdomen (3% vs 1%), a brief loss of consciousness (3% vs 1%), diarrhea (34% vs 25%), constipation (4% vs 2%), reduced white blood cell counts (37% vs 31%), and reduced white blood cell counts that may increase the chance of infection (21% vs 14%).

In the second-line mCRC trial, the most common severe to life-threatening and fatal side effects that increased by 2% or more in people who received Avastin plus FOLFOX4 (chemotherapy) vs FOLFOX4 (chemotherapy) alone were diarrhea (18% vs 13%), nausea (12% vs 5%), vomiting (11% vs 4%), dehydration (10% vs 5%), blockage of the bowel (4% vs 1%), numbness and tingling in fingers and toes (17% vs 9%), nervous system disturbances (5% vs 3%), tiredness (19% vs 13%), abdominal pain (8% vs 5%), headache (3% vs 0%), high blood pressure (9% vs 2%), and severe bleeding (5% vs 1%).

## STUDY ADVERSE EVENTS IN NSCLC

In a NSCLC clinical trial, the most common life-threatening to fatal side effects that increased by 2% or more in patients receiving Avastin plus paclitaxel and carboplatin (chemotherapies) compared with those patients receiving paclitaxel and carboplatin (chemotherapies) alone were lower than normal white blood cell count (27% vs 17%), tiredness (16% vs 13%), high blood pressure (8% vs 0.7%), infection without lower than normal white blood cell count (7% vs 3%), blood clots in the veins (5% vs 3%), fever with lower than normal white blood cell count (5% vs 2%), lung inflammation (5% vs 3%), infection with lower than normal white blood cell count (4% vs 2%), abnormally low sodium that could lead to seizure or coma (4% vs 1%), headache (3% vs 1%), and too much protein in the urine (3% vs 0%).

## STUDY ADVERSE EVENTS IN MRCC

In one trial, severe to fatal side effects that increased by 2% or more in people with metastatic kidney cancer taking Avastin plus interferon alfa compared with interferon alfa alone were fatigue (13% vs 8%), weakness (10% vs 7%), too much protein in the urine (7% vs 0%), high blood pressure (6% vs 1%), and bleeding (3% vs 0.3%; this included nosebleeds, coughing up blood, bleeding of the gums, bleeding in the small and large intestines, and bleeding in the brain, stomach, respiratory tract, and skull).

## STUDY ADVERSE EVENTS IN CERVICAL CANCER

In the CC trial, the most common severe to life-threatening side effects that increased by 2% or more in people who received Avastin plus chemotherapy compared to those receiving chemotherapy alone were abdominal pain (11.9% vs. 9.9%), diarrhea (5.5% vs. 2.7%), abnormal opening at or near the anus (3.7% vs. 0%), pain at the anus or the rectum (2.8% vs. 0%), urinary tract infections (8.3% vs. 6.3%), skin infection (3.2% vs. 0.5%), tiredness (14.2% vs. 9.9%), high blood pressure (11.5% vs. 0.5%), blood clot formation (8.3% vs. 2.7%), low potassium (7.3% vs. 4.5%), abnormally low sodium that could lead to seizure or coma (3.7% vs. 1.4%), dehydration (4.1% vs. 0.5%), lower than normal white blood cell count [neutropenia (7.8% vs. 4.1%), lymphopenia (6.0% vs. 3.2%)], back pain (5.5% vs. 3.2%), and pain in the lower part of your abdomen (5.5% vs. 1.4%).

## STUDY ADVERSE EVENTS IN PLATINUM-RESISTANT OVARIAN CANCER

In the prOC trial, the most common severe to life-threatening side effects that increased by 2% or more in people who received Avastin plus chemotherapy compared to those receiving chemotherapy alone were high blood pressure (6.7% vs. 1.1%) and hand-foot syndrome (4.5% vs. 1.7%).

## STUDY ADVERSE EVENTS IN PLATINUM-SENSITIVE OVARIAN CANCER

In a psOC study, the most common severe to life-threatening side effects that increased by 2% or more in people who received Avastin plus carboplatin and gemcitabine (chemotherapy) compared to those who received placebo plus chemotherapy were lower than normal platelet count (40.1% vs. 33.9%), nausea (4.5% vs. 1.3%), tiredness (6.5% vs. 4.3%), headache (3.6% vs. 0.9%), too much protein in the urine (9.7% vs. 0.4%), shortness of breath (4.5% vs. 1.7%), nosebleeds (4.9% vs. 0.4%) and high blood pressure (17.0% vs. 0.9%). Severe to life-threatening side effects of lower than normal red blood cell count (16.2% vs. 18.9%) and white blood cell count (1.6% vs. 4.3%) increased by 2% or more in the chemotherapy group compared to the Avastin plus chemotherapy group.

In a psOC study, the most common severe to life-threatening side effects that increased by 2% or more in people who received Avastin plus carboplatin and paclitaxel (chemotherapy) compared to those who received chemotherapy were high blood pressure (11.1% vs. 0.6%), tiredness (7.7% vs. 2.7%), fever and lower than normal white blood cell count (6.2% vs. 2.7%), too much protein in the urine (8% vs. 0%), abdominal pain (5.8% vs. 0.9%), lower than normal blood sodium levels (3.7% vs. 0.9%), headache (3.1% vs. 0.9%) and pain in limbs (3.4% vs. 0%).

## STUDY ADVERSE EVENTS IN RECURRENT GLIOBLASTOMA

In a recurrent GBM study, 22% of people discontinued Avastin plus chemotherapy treatment due to adverse reactions compared with 10% of people treated with chemotherapy alone. In people receiving Avastin plus chemotherapy, adverse events were consistent with those seen in previous trials of Avastin across tumor types for approved indications.

## STUDY ADVERSE EVENTS IN STAGE III OR IV OVARIAN CANCER

In a stage III or IV ovarian cancer study, the most common severe to life-threatening side effects that increased by 2% or more in people who received Avastin plus chemotherapy followed by Avastin alone or Avastin plus chemotherapy compared to those who received chemotherapy alone were fatigue (9%, 6%, 6%, respectively), high blood pressure (hypertension; 10%, 6%, 2%), decreased platelet count (21%, 20%, 15%) and decreased white blood cell count (51%, 53%, 50%).

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# Important Safety Information (continued)



If you have any questions about your condition or treatment, talk to your doctor.

You may report side effects to the FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch). You may also report side effects to Genentech at 1-888-835-2555.

**Visit Genentech Access Solutions ([www.GenentechAccessSolutions.com](http://www.GenentechAccessSolutions.com)) for coverage and reimbursement support, patient assistance, and information resources.**

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## References

1. Avastin Patient Site. <http://www.avastin.com/patient>.
2. Genentech. Avastin Full Prescribing Information. 2018.
3. Avastin Healthcare Professional Site. <http://www.avastin-hcp.com>.