אפריל 2025

רופא/ה נכבד/ה, רוקח/ת נכבד/ה,

הנדון: Pluvicto, solution for injection/infusion [172-79-37413-99]

חברת נוברטיס ישראל בע"מ מבקשת להודיע על עדכון בעלון לרופא ובעלון לצרכן של התכשיר פלוויקטו.

התווית התכשיר:
PLUVICTO is indicated for the treatment of adult patients with prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor (AR) pathway inhibition and taxane-based chemotherapy or who are not medically suitable for texanes.

חומר פעיל:
Lutetium (^{177}Lu) vipivotide tetraxetan 1000 MBq/mL

בעמודים העוקבים מצויינים סעיפים בהם נעשה שינוי אשר מהווה החמרה או שינוי משמעותי.
למידע נוסף, יש לעיין בעלונים לצרכן ולרופא כפי שפורסמו באתר משרד הבריאות.
העלונים נשלחו לפרסום במאגר התרופות שבאתר משרד הבריאות וניתן לקבלם מודפסים על-ידי פניה לבעל הרישום: נוברטיס ישראל בע"מ. תוצרת הארץ 6, תל אביב.

בברכה,

שירן חן גולדשטיין
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להלן פירוט השינויים העיקריים (טקסט באדום עם קו תחתי מציין טקסט שהתווסף לעלון ואילו טקסט שהושמט מסומן באדום עם קו חוצה. החמרה במידע בטיחותי מודגשת בצהוב)

עלון לרופא:

4.6 Radiation Dosimetry

Dosimetry of lutetium Lu 177 vipivotide tetraxetan was collected in 29 patients in the VISION sub-study, in order to calculate whole body and organ radiation dosimetry. The mean and standard deviation (SD) of the estimated radiation absorbed doses to different organs for adults ~~patients~~ receiving PLUVICTO are shown in Table 2. The organs with the highest radiation absorbed doses are lacrimal glands, salivary glands, large intestine (left and right colon), kidneys, and urinary bladder wall. The maximum penetration of lutetium-177 in tissue is approximately 2 mm and the mean penetration is 0.67 mm.

Table 2: Estimated Radiation Absorbed Dose[a] for PLUVICTO in VISION

	Absorbed dose per unit activity (Gy/GBq) N = 29		Calculated absorbed dose for 7.4 GBq administration (Gy)		Calculated absorbed dose for 6 x 7.4 GBq (44.4 GBq cumulative activity) (Gy)	
Organ*	**Mean**	**SD**	**Mean**	**SD**	**Mean**	**SD**
Adrenals	0.033	0.025	0.24	0.19	1.5	1.1
Brain	0.007	0.005	0.049	0.035	0.30	0.22
Esophagus	0.025	0.026	0.18	0.19	1.1	1.1
Eyes	0.022	0.024	0.16	0.18	0.99	1.1
Gallbladder wall	0.028	0.026	0.20	0.19	1.2	1.1
Heart wall	0.17	0.12	1.2	0.83	7.8	5.2
Kidneys	0.43	0.16	3.1	1.2	19	7.3
Lacrimal glands	2.1	0.47	15	3.4	92	21
Left colon	0.58	0.14	4.1	1.0	26	6.0
Liver	0.090	0.044	0.64	0.32	4.0	2.0
Lungs	0.11	0.11	0.76	0.81	4.7	4.9
Pancreas	0.027	0.026	0.19	0.19	1.2	1.1
Prostate	0.027	0.026	0.19	0.19	1.2	1.1
Rectum	0.56	0.14	4.0	1.1	25	6.2
Right colon	0.32	0.078	2.3	0.58	14	3.4
Salivary glands	0.63	0.36	4.5	2.6	28	16
Small intestine	0.071	0.031	0.50	0.23	3.1	1.4
Spleen	0.067	0.027	0.48	0.20	3.0	1.2
Stomach wall	0.025	0.026	0.18	0.19	1.1	1.1
Testes	0.023	0.025	0.16	0.18	1.0	1.1
Thymus	0.025	0.026	0.18	0.19	1.1	1.1
Thyroid	0.26	0.37	1.8	2.7	11	16
Total body	0.037	0.027	0.27	0.20	1.6	1.2
Urinary bladder wall	0.32	0.025	2.3	0.19	14	1.1

aRadiation absorbed dose estimates were derived using OLINDA v2.2 radiation dosimetry software, using measured time-activity data from patient imaging as input.

*Estimated radiation absorbed dose for bone marrow is not included given the wide expected variability based on location and burden of bone metastases between patients [see Warnings and Precautions (7.2)].

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7 WARNINGS AND PRECAUTIONS

7.1 Risk From Radiation Exposure

PLUVICTO contributes to a patient's overall long-term cumulative radiation exposure. Long-term cumulative radiation exposure is associated with an increased risk for cancer.

Minimize radiation exposure to patients, medical personnel, and ~~household contacts~~others during and after treatment with PLUVICTO consistent with institutional good radiation safety practices, patient treatment procedures, and instructions to the patient for follow-up radiation protection at home.

Ensure patients increase oral fluid intake and advise patients to void as often as possible to reduce bladder radiation.

Before the patient is released, ~~the healthcare provider should explain~~ inform patients about the necessary radioprotection precautions ~~that the patient should~~ to follow to minimize radiation exposure to others.

~~Following~~After each administration of PLUVICTO, advise patients to:

- ~~I~~Limit close contact (less than 1 meter) with others ~~household contacts~~ for 2 days or with children and pregnant women for 7 days.
- ~~Following administration of PLUVICTO, advise patients to r~~Refrain from sexual activity for 7 days.
- ~~Following administration of PLUVICTO, advise patients to s~~Sleep in a separate ~~bed~~room from ~~household contacts~~ others for 3 days, from children for 7 days, or from pregnant women for 15 days.

7.2 Myelosuppression

PLUVICTO can cause severe and life-threatening myelosuppression, including anemia, thrombocytopenia, leukopenia, and neutropenia. In the VISION study, Grade 3 or 4 decreased hemoglobin (15%), decreased platelets (9%), decreased leukocytes (7%), and decreased neutrophils (4.5%) occurred in patients treated with PLUVICTO. Grade ≥ 3 pancytopenia occurred in 1.1% (which includes two fatal events) ~~in~~of patients treated with PLUVICTO. Two deaths (0.4%) occurred due to intracranial hemorrhage and subdural hematoma in association with thrombocytopenia ~~were observed in patients who received PLUVICTO.~~, ~~O~~one death (0.2%) occurred due to sepsis and concurrent neutropenia ~~was observed in patients who received PLUVICTO~~., and one death (0.2%) occurred due to bone marrow failure.

Perform complete blood counts before and during treatment with PLUVICTO. Withhold, reduce dose, or permanently discontinue PLUVICTO ~~and clinically treat patients~~ based on the severity of myelosuppression *[see Dosage and Administration (4.4)]*.

7.3 Renal Toxicity

PLUVICTO can cause severe renal toxicity. In the VISION study, Grade 3 or 4 acute kidney injury (3.4%) ~~and increased creatinine (0.9%)~~ occurred in patients treated with PLUVICTO.

Advise patients to remain well hydrated and to urinate frequently before and after administration of PLUVICTO. Perform kidney function laboratory tests, including serum creatinine and calculated creatinine clearance (CLcr), before and during treatment with PLUVICTO. Withhold, reduce dose, or permanently discontinue PLUVICTO based on the severity of renal toxicity *[see Dosage and Administration (4.4)]*.

7.4 Embryo-Fetal Toxicity

The safety and efficacy of PLUVICTO have not been established in females. Based on its mechanism of action, PLUVICTO can cause fetal harm *[see Clinical Pharmacology (12.1)]*. No animal studies using lutetium Lu 177 vipivotide tetraxetan have been conducted to evaluate its effect on female reproduction and embryo-fetal development; however, ~~all radiopharmaceuticals~~radioactive emissions,

including those from PLUVICTO, ~~have the potential to~~can cause fetal harm. Advise males ~~patients~~ with female partners of reproductive potential to use effective contraception during treatment with PLUVICTO and for 14 weeks after the last dose *[see Use in Specific Populations (9.1, 9.3)]*.

8 ADVERSE REACTIONS

8.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The safety of PLUVICTO was evaluated in the VISION study in patients with progressive, PSMA-positive mCRPC previously treated with ARPI therapy and taxane-based chemotherapy *[see Clinical Studies (14)]*~~. Of the 831 patients randomized, 734 patients received at least one dose of randomized treatment~~. Patients received at least one dose of either PLUVICTO 7.4 GBq (200 mCi) administered every 6 to 10 weeks plus BSoC (N = 529) or BSoC alone (N = 205). The median duration of exposure to ~~randomized treatment was 7.8 months (range, 0.3 to 24.9) for patients who received~~ PLUVICTO plus BSoC was 7.8 months (range, 0.3 to 36.5). Among patients who received PLUVICTO plus BSoC, the median number of doses of PLUVICTO received was 5 (range, 1 to 6). The median cumulative ~~dose~~ administered activity of PLUVICTO was 37.5 GBq (range, 7.0 to 48.3).

~~The median duration of follow-up was 14.8 months for~~Serious adverse reactions occurred in 37% of patients who received~~ing~~ PLUVICTO plus BSoC. Serious adverse reactions ~~occurred~~ in ~~36~~>1% of patients who received PLUVICTO plus BSoC~~. Serious adverse reactions in > 1% of patients who received PLUVICTO plus BSoC~~ included ~~hemorrhage (4%),~~ musculoskeletal pain (~~3.84~~%), hemorrhage (4%), sepsis (3.2%), ~~anemia (2.8%),~~ urinary tract infection (~~2.63~~%), anemia (2.8%), acute kidney injury (1.~~97~~%), pneumonia (1.7%), pyrexia (1.5%), pancytopenia (1.3%), ~~pyrexia (1.3%),~~ spinal cord compression (1.1%), and pulmonary embolism (1.1%).
Fatal adverse reactions occurred in ~~2.83~~% of patients who received PLUVICTO plus BSoC, including sepsis (0.9%), pancytopenia (0.6%), hepatic failure (0.4%), intracranial hemorrhage (0.2%), subdural hematoma (0.2%), ischemic stroke (0.2%), COVID-19 (0.2%), and aspiration pneumonia (0.2%).
…

The most common laboratory abnormalities that worsened from baseline in ≥ 30% of patients who received PLUVICTO plus BSoC were decreased lymphocytes, decreased hemoglobin, ~~decreased leukocytes~~, decreased platelets, decreased calcium, and decreased sodium.

Table 3 and Table 4 summarize the incidence of adverse reactions and laboratory abnormalities, respectively, in VISION.

Table 3: Adverse Reactions (≥ ~~5~~10%) in Patients With PSMA-~~p~~Positive mCRPC Who Received PLUVICTO Plus BSoC in VISION

Adverse reactions	PLUVICTO plus BSoC (N = 529)		BSoC (N = 205)	
	All Grades (%)	Grades 3 ~~to~~or 4 (%)	All Grades (%)	Grades 3 ~~to~~or 4 (%)
General disorders				
Fatigue[a]	4~~8~~3	~~7~~6	2~~9~~3	~~1.5~~2.4
Decreased appetite	21	1.9	15	0.5
Weight decreased	11	0.4	~~9~~10	0.5
Peripheral edema[a]	10	0.4	7	1~~0.5~~
~~Pyrexia~~	~~7~~	~~0.4~~	~~3.4~~	~~0~~
Gastrointestinal disorders				
Dry mouth[ab]	39	0	1~~0.5~~	0

Adverse reactions	PLUVICTO plus BSoC (N = 529)		BSoC (N = 205)	
	All Grades (%)	Grades 3 ~~to~~or 4 (%)	All Grades (%)	Grades 3 ~~to~~or 4 (%)
Nausea	3~~6~~5	1.3	17	0.5
Constipation	20	1.1	11	0.5
Vomiting[~~ae~~]	19	0.9	6	0.5
Diarrhea	19	0.8	2.9	0.5
Abdominal pain[~~da~~]	12~~1~~	1.3~~1~~	6	0.5
~~**Blood and lymphatic system**~~ **Musculoskeletal and connective tissue disorders**				
Back pain	24	3.6	15	3.9
Arthralgia~~Anemia~~	~~32~~22	~~13~~1.1	13	~~4.9~~0.5
Bone pain~~Thrombocytopenia~~	~~17~~11	~~8~~2.5	~~4.4~~8	~~1~~2.4
Renal and urinary disorders				
Urinary tract infection[~~ea~~]	12	3.8	1	0.5
~~Acute kidney injury[f]~~	~~9~~	~~3.2~~	~~6~~	~~2.9~~
~~**Nervous system disorders**~~				
~~Dizziness~~	~~8~~	~~0.9~~	~~4.4~~	~~0~~
~~Headache~~	~~7~~	~~0.8~~	~~2~~	~~0~~
~~Dysgeusia[g]~~	~~7~~	~~0~~	~~1.5~~	~~0~~

Abbreviation: BSoC, best standard of care.

~~[a]Peripheral edema includes peripheral edema, fluid retention, and fluid overload.~~

~~[b]Dry mouth includes dry mouth, aptyalism, and dry throat.~~

~~[e]Vomiting includes vomiting and retching.~~

~~[d]Abdominal pain includes abdominal pain, abdominal pain upper, abdominal discomfort, abdominal pain lower, abdominal tenderness, and gastrointestinal pain.~~

~~[e]Urinary tract infection includes urinary tract infection, cystitis, and cystitis bacterial.~~

~~[f]Acute kidney injury includes blood creatinine increased, acute kidney injury, renal failure, and blood urea increased.~~

~~[g]Dysgeusia includes dysgeusia and taste disorder.~~

[a] Includes multiple similar terms

Clinically relevant adverse reactions in < ~~5~~10% of patients who received PLUVICTO plus BSoC included acute kidney injury, dizziness, dysgeusia, headache, pyrexia, dry eye, oral fungal infection, vertigo, ~~and~~gastroesophageal reflux disease, stomatitis, ~~and~~ pancytopenia ~~(including bicytopenia)~~, dry skin, dysphagia, esophagitis, and bone marrow failure.

Table 4: Select Laboratory Abnormalities (≥ 10%) That Worsened ~~f~~From Baseline in Patients With PSMA-~~p~~Positive mCRPC Who Received PLUVICTO Plus BSoC (Between Arm Difference of ≥ 5% All Grades) in VISION

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Laboratory abnormalities	PLUVICTO plus BSoC[a]		BSoC[b]	
	All Grades (%)	Grades 3 ~~to~~or 4 (%)	All Grades (%)	Grades 3 ~~to~~ or 4 (%)
Hematology				
Decreased lymphocytes	85	47	51	18
Decreased hemoglobin	64	15[c]	34	7[c]
Decreased platelets	45	9	20	2.5
Decreased neutrophils	28	4.7	9	0.5
Chemistry				
Decreased estimated glomerular filtration rate (eGFR)~~calcium~~	~~39~~43	~~2.5~~3.6	28	~~3~~2.5
Decreased sodium	3~~4~~3	0.6[c]	23	1
Decreased calcium	34	1.9	18	1.5
Increased aspartate aminotransferase (AST)	2~~9~~8	1.1	18	1[c]
~~Increased creatinine~~	~~24~~	~~0.9[e]~~	~~14~~	~~0.5[e]~~
Increased potassium	24	0.6	18	0.5[c]
Increased sodium	11	0[c]	5	0[c]
~~Hematology~~				
~~Decreased lymphocytes~~	~~85~~	~~47~~	~~51~~	~~18~~
~~Decreased hemoglobin~~	~~63~~	~~15[e]~~	~~34~~	~~7[e]~~
~~Decreased leukocytes~~	~~56~~	~~7~~	~~22~~	~~2~~
~~Decreased platelets~~	~~45~~	~~9~~	~~20~~	~~2.5~~
~~Decreased neutrophils~~	~~28~~	~~4.5~~	~~9~~	~~0.5~~

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9 USE IN SPECIFIC POPULATIONS

9.1 Pregnancy

Risk Summary

The safety and efficacy of PLUVICTO have not been established in females. Based on its mechanism of action, PLUVICTO can cause fetal harm *[see Clinical Pharmacology (12.1)]*. There are no available data on PLUVICTO use in pregnant females. No animal studies using lutetium Lu 177 vipivotide tetraxetan have been conducted to evaluate its effect on female reproduction and embryo-fetal development; however, all ~~radiopharmaceuticals~~ radioactive emissions, including those from PLUVICTO, ~~have the potential to~~can cause fetal harm.

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9.3 Females and Males of Reproductive Potential

Contraception

Males

~~Based on its mechanism of action, a~~Advise male~~s patients~~ with female partners of reproductive potential to use effective contraception during treatment with PLUVICTO and for 14 weeks after the last dose *[see Clinical Pharmacology (12.1), Nonclinical Toxicology (13.1)]*.

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9.5 Geriatric Use

Of the 529 patients who received at least one dose of PLUVICTO plus BSoC in the VISION study, 387 patients (73%) were 65 years of age or older and 143 patients (27%) were 75 years of age or older. No overall differences in effectiveness were observed between patients ≥ 75 years of age and younger patients. Serious adverse reactions occurred in ~~11~~41% of patients ≥ 75 years of age and in ~~11~~35% of younger patients. Grade ≥ 3 adverse reactions occurred in ~~40~~56% of patients ≥ 75 years of age and in ~~31~~53% of younger patients.

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12 CLINICAL PHARMACOLOGY

Pharmacotherapeutic group: Therapeutic radiopharmaceuticals, Other therapeutic radiopharmaceuticals, ATC code: V10XX05

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12.3 Pharmacokinetics

Metabolism

Lutetium Lu 177 vipivotide tetraxetan does not undergo hepatic or renal metabolism.

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14 CLINICAL STUDIES

The efficacy of PLUVICTO was evaluated in VISION (NCT03511664), a randomized (2:1), multicenter, open-label trial ~~that evaluated~~of PLUVICTO plus BSoC (N = 551) ~~or~~versus BSoC alone (N = 280) in ~~men~~ patients with progressive, PSMA-positive mCRPC. Randomization was stratified by baseline lactase dehydrogenase (LDH≤ 260 IU/L vs. > 260 IU/L), presence of liver metastases (yes vs. no), ECOG PS score (0 or 1 vs. 2), and inclusion of an AR pathway inhibitor as part of BSoC (yes vs. no) at the time of randomization. ~~All patients received a GnRH analog or had prior bilateral~~ Patients were required to have a castrate level of serum/plasma testosterone by either medical castration or prior orchiectomy at study entry. Patients were required to have received at least one ARPI ~~pathway inhibitor~~, and 1 or 2 prior taxane-based chemotherapy regimens. Eligible patients were required to have PSMA-positive mCRPC defined as having at least one tumor lesion (soft tissue or bone) with gallium Ga 68 gozetotide uptake greater than in normal liver. Patients were considered ineligible ~~excluded~~ if any one lesion~~s exceeding~~ larger than size criteria ~~in short axis~~ [organs ≥ 1 cm in short axis, lymph nodes ≥ 2.5 cm in short axis, bones (soft tissue component) ≥ 1 cm in short axis] had gallium Ga 68 gozetotide uptake less than or equal to uptake in normal liver.

Patients received PLUVICTO 7.4 GBq (200 mCi) every 6 weeks for up to a total of 6 doses plus BSoC or BSoC alone. BSoC administered at the investigator's discretion included ketoconazole; radiation therapy to localized prostate cancer targets; bone-targeted agents; ~~androgen-reducing agents; AR pathway inhibitors~~ ADT; ARPIs. Patients continued treatment for up to 4-6 doses, or until disease progression or unacceptable toxicity. Patients with stable disease or partial response after 4 doses of PLUVICTO plus BSoC received up to 2 additional doses per investigator's discretion.

~~The following patient demographics and baseline disease characteristics were balanced between the arms.~~ The median age was 71 years (range, 40 to 94 years); 87% White; 7% Black or African American; 2.4% Asian; 1.7% were Hispanic or Latino; 92% had ECOG PS0-1; 8% had ECOG PS2. All patients had received at least one prior taxane-based chemotherapy regimen and 41% of patients received two. One prior ARPI ~~pathway inhibitor~~ had been administered to 51% of patients, 41% of patients had received 2, and 8% of patients had received 3 or more. During the treatment period, 53% of patients in the PLUVICTO plus BSoC arm and 68% of patients in the BSoC alone arm received at least one ARPI ~~pathway inhibitor~~.

The major efficacy outcome measures were overall survival (OS) and radiographic progression-free survival (rPFS) by blinded independent central review (BICR) per Prostate Cancer Working Group 3 (PCWG3)--modified RECIST v1.1 criteria. An additional efficacy outcome measure ~~included~~ was overall response rate (ORR) ~~by BICR per Response Evaluation Criteria in Solid Tumors (RECIST) v1.1~~.

VISION demonstrated a statistically significant improvement in both major efficacy outcome measures of OS and rPFS by BICR with PLUVICTO plus BSoC compared to treatment with BSoC alone. Interpretation of the magnitude of the rPFS effect was limited due to a high degree of censoring from early drop out in the control arm.

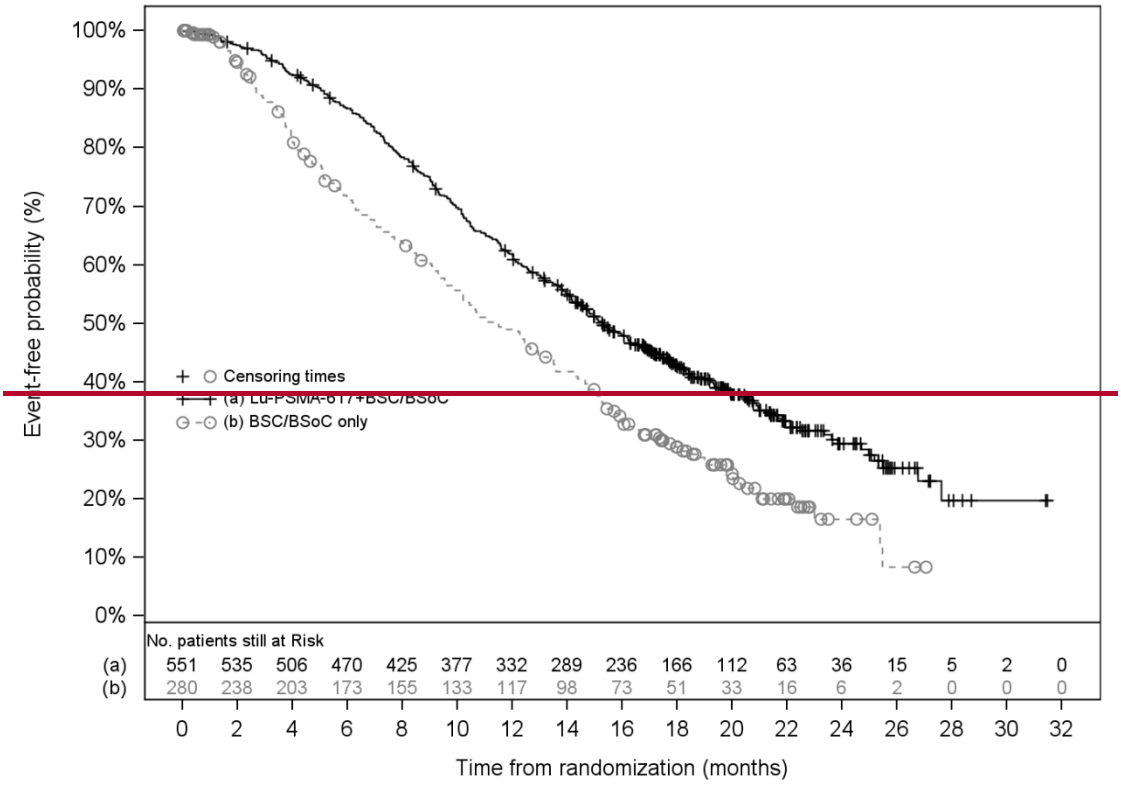
Efficacy results for VISION are presented in Table 7 and Figure 1.

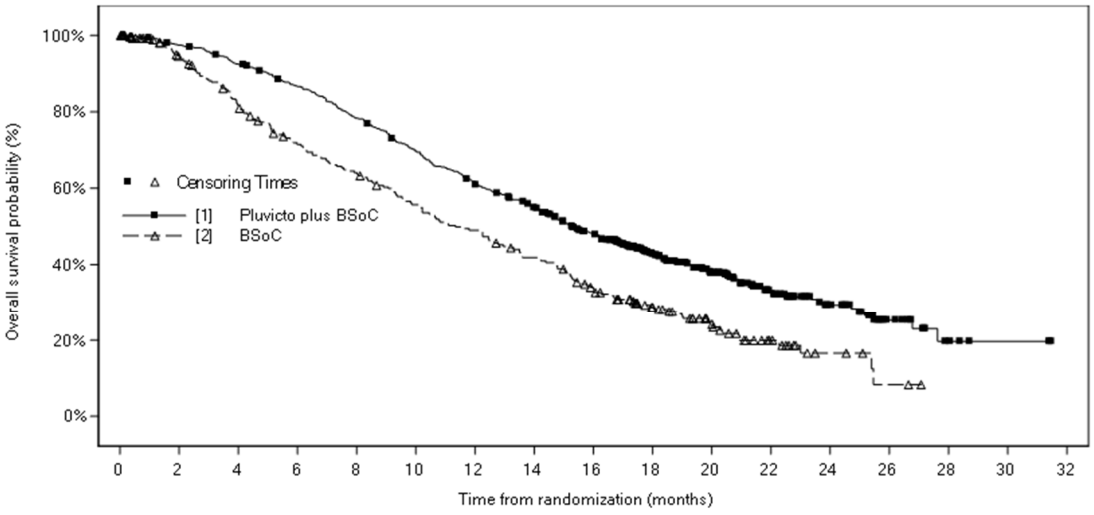
Table 7: Efficacy Results in VISION

	PLUVICTO plus BSoC	**BSoC**
Overall survival (OS)	N = 551	N = 280
Deaths, n (%)	343 (62~~%~~)	187 (67~~%~~)
Median, months (95% CI)[a]	15.3 (14.2, 16.9)	11.3 (9.8, 13.5)
Hazard ratio (95% CI)[b]	0.62 (0.52, 0.74)	
P-value[c]	< 0.001	
Overall response rate (ORR)~~[d,e]~~		
Patients with measurable ~~evaluable~~ disease at baseline	N = ~~319~~184	N = ~~120~~64
ORR (CR + PR), n (%) (95% CI)	~~95 (30%)~~ ~~(25%, 35%)~~ 91 (49) (42, 57)	~~2 (2%)~~ ~~(0%, 6%)~~ 1 (1.6) (0, 8)
Complete response (CR), n (%)	17 (9)~~18 (6%)~~	0 (0~~%~~)
Partial response (PR), n (%)	74 (40)~~77 (24%)~~	1 (1.6)~~2 (2%)~~
P-value[df]	< 0.001	

[a]Based on Kaplan-Meier estimate.
[b]Hazard ratio based on the stratified Cox PH model.
[c]Stratified log-rank test two-sided p-value.
[d]Responses are based on soft tissue and bone lesion assessment.
[e]By BICR per PCWG3-modified RECIST v1.1 criteria.
[f]Stratified Wald's Chi-square test two-sided p-value.

Figure 1. Kaplan-Meier Plot of Overall Survival in VISION





No. of subjects still at risk

[1]	551	535	506	470	425	377	332	289	236	166	112	63	36	15	5	2	0
[2]	280	238	203	173	155	133	117	98	73	51	33	16	6	2	0	0	0

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עלון לצרכן

2. לפני השימוש בתרופה

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אזהרות מיוחדות הנוגעות לשימוש בתרופה
לפני תחילת הטיפול בפלוויקטו, ספר לרופא שלך, ולצוות הרפואי שמטפל בך, לגבי כל מצב רפואי שלך, כולל אם:

- יש לך ספירת תאי דם נמוכה (תאי דם אדומים, המוגלובין, ~~ספירת~~ תאי דם לבנים, ספירת נויטרופילים מוחלטת, ~~ספירת~~ טסיות).
- יש לך או סבלת בעבר מעייפות, חולשה, עור חיוור, קוצר נשימה, דימום או חבורות בקלות מהרגיל או קושי לעצירת דימום, או זיהומים תדירים עם סימנים כגון חום, צמרמורות, כאבי גרון או כיבים בפה (סימנים אפשריים של דיכוי מוח העצם).
- סבלת ~~בעבר~~ או סובל כיום מבעיות בכליות.

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היריון, הנקה ופוריות
היריון
התרופה אינה מיועדת לנשים. בטיחות ויעילות פלוויקטו לא הוכחה בקרב נשים. פלוויקטו עלולה לגרום לפגיעה בעובר.
אם יש לך בת זוג אשר מסוגלת להרות, עלייך להשתמש באמצעי מניעה מתאימים בעת קיום יחסי מין במהלך הטיפול עם פלוויקטו ולמשך 14 שבועות לאחר המנה האחרונה. יידע את הרופא שלך מייד במקרה של היריון במהלך תקופה זו.

...

נהיגה ושימוש במכונות:
לא סביר שפלוויקטו תשפיע על היכולת שלך לנהוג או להשתמש במכונות.

...

3. כיצד תשתמש בתרופה?

...

לאחר הטיפול עם פלוויקטו עליך

- לשתות הרבה ולהטיל שתן בתדירות גבוהה על מנת לסלק את התכשיר מגופך.
- להגביל מגע קרוב (פחות מ-1 מטר) עם אנשים אחרים ~~במשק הבית שלך~~ למשך יומיים, או עם ילדים ונשים הרות למשך 7 ימים.
- להמנע מפעילות מינית למשך 7 ימים.
- לישון בחדר ~~שינה~~ נפרד מאחרים ~~במשק הבית שלך~~ למשך 3 ימים, מילדים למשך 7 ימים או מנשים הרות למשך 15 ימים.

הרופא שלך והצוות הרפואי שמטפל בך, ~~יודיעו לך אם עליך לנקוט~~ יתנו לך הנחיות ברורות בנוגע ~~ל~~כל אמצעי הזהירות המיוחדים שעלייך לנקוט לאחר קבלת תרופה זו. זה עשוי לכלול אמצעי זהירות מיוחדים עבורך או עבור המטפל שלך בכל הקשור לשימוש בשירותים, מקלחת, כביסה, פינוי פסולת, סיוע רפואי חירום, אשפוז לא מתוכנן או נסיעות. פנה לרופא שלך או לצוות המטפל אם יש לך שאלות כלשהן.

...

4. תופעות לוואי

...

תופעות לוואי שכיחות מאוד (very common) תופעות שמופיעות ביותר ממשתמש אחד מעשרה משתמשים:

- עייפות
- יובש בפה
- בחילה

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- ספירת תאי דם אדומים נמוכה (אנמיה)
- כאב גב
- כאב מפרקים
- ~~אובדן~~ ירידה בתאבון
- עצירות
- הקאות
- שלשול
- ~~ספירת טסיות דם נמוכה (תרומבוציטופניה)~~
- דלקת בדרכי השתן
- כאבי בטן
- אובדן משקל
- ~~כאבי בטן~~כאב בעצמות
- נפיחות בכפות הידיים, הקרסוליים או בכפות הרגליים (בצקת היקפית)

תוצאות מעבדה חריגות

המטולוגיה

- ירידה בתאי דם ממערכת החיסון (לימפוציטים, ~~לויקוציטים,~~ נוטרופילים), ירידת ~~ה~~טסיות), ירידת המוגלובין.

ביוכימיה

- ירידה במדד לתפקודי כליות
- ~~הפחתת~~ ירידה ברמות סידן ונתרן
- עלי~~ה~~ת ברמות אספרטט אמינוטרנספרז (AST), ~~קריאטנין,~~ אשלגן ונתרן

תופעות לוואי שכיחות (common) תופעות שמופיעות ב 1-10 משתמשים מתוך 100 משתמשים:

- ~~נפיחות בידיים, קרסוליים או כפות רגליים (בצקת היקפית)~~
- מתן שתן בתדירות נמוכה יותר מהרגיל או מתן כמויות הרבה יותר קטנות של שתן מהרגיל (סימנים אפשריים של בעיות בכליות [פגיעה כלייתית חריפה])
- סחרחורת
- שינוי בחוש הטעם
- כאב ראש
- ~~שינוי בחוש הטעם~~
- חום
- יובש בעיניים
- זיהום פטרייתי בפה
- ורטיגו
- ריפלוקס קיבתי-ושטי
- ~~ירידה בספירת תאי דם (פנציטופניה)~~
- פצעים בפה (סטומטיטיס)
- עייפות, חולשה, עור חיוור, קוצר נשימה, דימום או חבורות בקלות מהרגיל או דימום ממושך מהרגיל או זיהומים תכופים עם סימנים כמו חום, צמרמורות, כאבי גרון או כיבים מהפה (סימנים אפשריים לרמות נמוכות ~~ירידה בספירת~~ של תאי דם [פנציטופניה])
- יובש בעור
- קשיים בבליעה ו/או צרבות (הפרעות בושט)
- דלקת הוושט
- כשל מח עצם

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