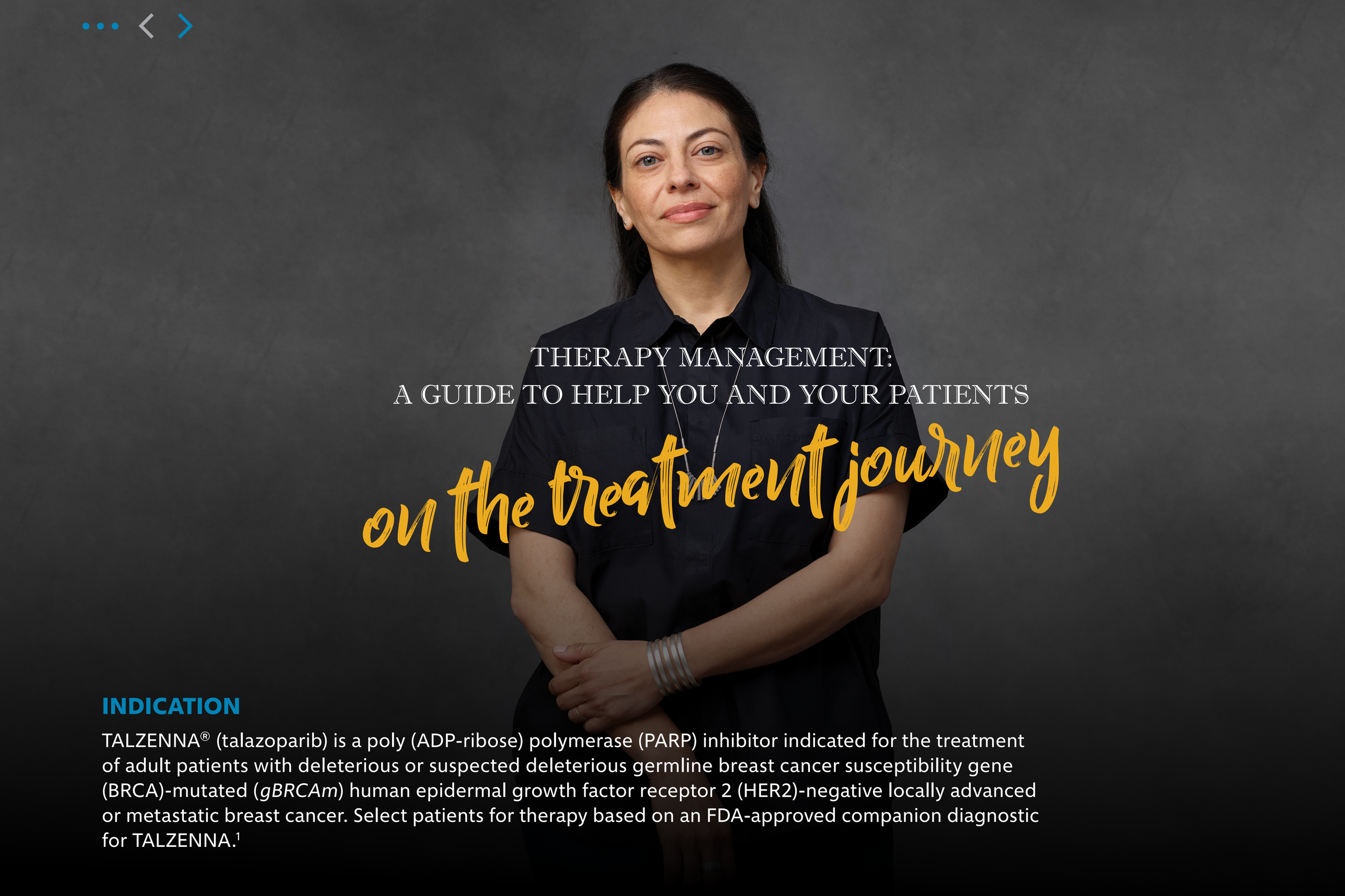

THERAPY MANAGEMENT: A GUIDE TO HELP YOU AND YOUR PATIENTS *on the treatment journey*

INDICATION

TALZENNA® (talazoparib) is a poly (ADP-ribose) polymerase (PARP) inhibitor indicated for the treatment of adult patients with deleterious or suspected deleterious germline breast cancer susceptibility gene (BRCA)-mutated (*gBRCAm*) human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer. Select patients for therapy based on an FDA-approved companion diagnostic for TALZENNA.[1]

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EMBRACA: the largest Phase 3, open-label study of PARP inhibitor monotherapy in g*BRCA*-mutated HER2- locally advanced or metastatic breast cancer[1-3]

- **Patients were randomized** 2:1 to receive TALZENNA 1 mg capsules once daily or physician's choice of chemotherapy* at standard doses (N=431)[1,3]
- **Primary endpoint** was progression-free survival (PFS) per RECIST v1.1, as assessed by BICR; secondary endpoints included objective response rate (ORR), overall survival (OS), and safety; exploratory endpoints included duration of response (DoR) for objective responders[4]

Baseline characteristics (ITT population)[3]

	TALZENNA (n=287)	Chemotherapy (n=144)
Demographics		
Age, median (range), y[1]	46 (28.0-84.0)	51 (24.0-89.0)
<50 y, No. (%)	182 (63.4)	67 (46.5)
Female, (%)	98.6	97.9
Clinical status		
Stage of breast cancer (BC)		
Locally advanced, No. (%)	15 (5.2)	9 (6.2)
Metastatic, No. (%)	271 (94.4)	135 (93.8)
ECOG PS 0/1/2, (%)	53.3/44.3/2.1	58.3/39.6/1.4
Measurable disease by investigator, No. (%)	219 (76.3)	114 (79.2)
History of CNS metastases, No. (%)	43 (15.0)	20 (13.9)
Visceral disease, No. (%)	200 (69.7)	103 (71.5)
Disease-free interval (initial diagnosis to ABC) <12 months, No. (%)	108 (37.6)	42 (29.2)
Hormone receptor status, No. (%)		
TNBC	130 (45.3)	60 (41.7)
HR+	157 (54.7)	84 (58.3)
***BRCA* status, No. (%)**[†]		
***BRCA*1+**	133 (46.3)	63 (43.8)
***BRCA*2+**	154 (53.7)	81 (56.2)
Prior treatment		
Prior adjuvant/neoadjuvant therapy, No. (%)	238 (82.9)	121 (84.0)
No. of previous hormone-therapy–based regimens for HR+ BC in the TALZENNA group (n=157) and the standard-therapy group (n=84), Median (range)	2.0 (0-6)	2.0 (0-6)
Prior platinum therapy, No. (%)	46 (16.0)	30 (20.8)
Prior cytotoxic regimens for ABC, No. (%)		
0	111 (38.7)	54 (37.5)
1	107 (37.3)	54 (37.5)
2	57 (19.9)	28 (19.4)
3	12 (4.2)	8 (5.6)

*Capecitabine, eribulin, gemcitabine, or vinorelbine.
[†]Only 10 patients (6 and 4 patients in the TALZENNA and standard-therapy groups, respectively) were identified as having a suspected deleterious mutation. The remainder who underwent central testing with BRACAnalysis CDx® had a known pathogenic variant.

TALZENNA was superior to chemotherapy in delaying disease progression[1]

TALZENNA significantly outperformed chemotherapy in PFS[1]

8.6 months (95% CI: 7.2-9.3) median PFS with TALZENNA

vs

HR=0.54 (95% CI: 0.41-0.71); *P*<0.0001

5.6 months (95% CI: 4.2-6.7) median PFS with chemotherapy

- **Confirmed ORR[‡§] more than doubled** with TALZENNA compared with chemotherapy: 50.2% (95% CI: 43.4-57.0) vs 18.4% (95% CI: 11.8-26.8)[1,3]
- **Median DoR[‡‖] was longer with TALZENNA vs chemotherapy:** 6.4 months (95% CI: 5.4-9.5) vs 3.9 months (95% CI: 3.0-7.6)[1,3]
- **Final OS analysis did not reach statistical significance:** median OS 19.3 months (95% CI: 16.6-22.5) with TALZENNA vs 19.5 months (95% CI: 17.4-22.4) with chemotherapy (HR=0.85 [95% CI: 0.67-1.07]; *P*=0.17)[1]

ABC=advanced breast cancer; BICR=blinded independent central review; *BRCA*=breast cancer susceptibility gene; CI=confidence interval; CNS=central nervous system; ECOG PS=Eastern Cooperative Oncology Group performance status; HR=hazard ratio; HR+=hormone receptor-positive; ITT=intent-to-treat; RECIST=Response Evaluation Criteria in Solid Tumors; TNBC=triple-negative breast cancer.

[‡]Response rate based on confirmed responses. Confirmed response: best overall response of partial response or complete response, confirmed by a subsequent tumor assessment (at least 4 weeks later) by investigator assessment.
[§]Conducted in the ITT population with measurable disease at baseline.
[‖]Analyzed in the ITT patients who experienced an objective response as assessed by the investigator.

SELECTED SAFETY INFORMATION

Myelodysplastic Syndrome/Acute Myeloid Leukemia (MDS/AML) have been reported in patients who received TALZENNA. Overall, MDS/AML has been reported in <1% (3 out of 787, 0.4%) of solid tumor patients treated with TALZENNA in clinical studies. The duration of TALZENNA treatment in these three patients prior to developing MDS/AML was 4 months, 24 months, and 60 months respectively. These patients had received previous chemotherapy with platinum agents and/or other DNA damaging agents including radiotherapy.

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1 DOSE | **1** TIME A DAY WITH OR WITHOUT FOOD[1]

1 mg capsule[1]

Recommended starting dose is 1 mg taken orally once daily, with or without food[1]

0.25 mg, 0.5 mg, and 0.75 mg capsules[1]

Available for dose reduction[1]

Capsules not actual size.

Flexible once-daily dosing options for patients requiring dose modification[1]

Recommended starting dose	First dose reduction	Second dose reduction	Third dose reduction
1 mg **once daily**	0.75 mg **once daily**	0.5 mg **once daily**	0.25 mg **once daily**

- Treatment with TALZENNA should be discontinued if more than 3 dose reductions are required

Administration considerations[1]

- Patients should be treated until disease progression or unacceptable toxicity occurs
- The hard capsules should be swallowed whole and must not be opened or dissolved
- If the patient vomits or misses a dose, an additional dose should not be taken. The next prescribed dose should be taken at the usual time

Some adverse reactions may require dose modification

- **Monitor complete blood count (CBC)** monthly and as clinically indicated[1]

Type of Adverse Reactions	Adverse Reactions	Withhold TALZENNA Until Levels Resolve to	Resume TALZENNA
Hematologic	Hemoglobin <8 g/dL	≥9 g/dL	Resume TALZENNA at a reduced dose
	Platelet count <50,000/µL	≥75,000/µL	
	Neutrophil count <1,000/µL	≥1,500/µL	
Non-hematologic	Grade 3 or Grade 4	≤Grade 1	Consider resuming TALZENNA at a reduced dose or discontinue

- Most adverse reactions were managed with dose interruptions, dose reductions, or standard supportive medical therapy[3,5]

DOSE INTERRUPTIONS due to adverse reaction of any grade: **65%** of TALZENNA patients vs 50% of chemotherapy patients[1]

DOSE REDUCTIONS due to any cause: **53%** of TALZENNA patients vs 40% of chemotherapy patients[1]

PERMANENT DISCONTINUATION due to adverse reaction: **5%** of TALZENNA patients vs 6% of chemotherapy patients[1]

Some patients may require dose modifications[1]

Reduce recommended dose to 0.75 mg once daily	Reduce recommended dose to 0.5 mg once daily
• Moderate renal impairment (CLcr 30-59 mL/min) • Coadministration with certain P-gp inhibitors*	Severe renal impairment (CLcr 15-29 mL/min)

- If P-gp inhibitor is discontinued, increase TALZENNA dose (after 3-5 half-lives of P-gp inhibitor) to dose used prior to initiation of P-gp inhibitor[1]
- Coadministration with BCRP inhibitors may increase talazoparib exposure; if coadministration cannot be avoided, monitor patients for potential increased adverse reactions[1]

BCRP=breast cancer resistance protein; CLcr=creatinine clearance; P-gp=P-glycoprotein.
*In clinical studies, coadministration with P-gp inhibitors including amiodarone, carvedilol, clarithromycin, itraconazole, and verapamil resulted in an approximate 45% increase in TALZENNA exposure and an increased rate of TALZENNA dose reduction.

SELECTED SAFETY INFORMATION

Myelosuppression consisting of anemia, leukopenia/neutropenia, and/or thrombocytopenia have been reported in patients treated with TALZENNA. Grade ≥3 anemia, neutropenia, and thrombocytopenia were reported, respectively, in 39%, 21%, and 15% of patients receiving TALZENNA. Discontinuation due to anemia, neutropenia, and thrombocytopenia occurred, respectively, in 0.7%, 0.3%, and 0.3% of patients.

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Adverse Reactions* (in ≥20% of Patients Receiving TALZENNA) in EMBRACA[1]

Adverse Reactions	TALZENNA n=286 (%)			Chemotherapy† n=126 (%)		
	Grades 1-4	Grade 3	Grade 4	Grades 1-4	Grade 3	Grade 4
Blood and lymphatic system disorders						
Anemia‡	53	38	1	18	4	1
Neutropenia§	35	18	3	43	20	16
Thrombocytopenia‖	27	11	4	7	2	0
Metabolism and nutrition disorders						
Decreased appetite	21	<1	0	22	1	0
Nervous system disorders						
Headache	33	2	0	22	1	0
Gastrointestinal disorders						
Nausea	49	<1	0	47	2	0
Vomiting	25	2	0	23	2	0
Diarrhea	22	1	0	26	6	0
Skin and subcutaneous tissue disorders						
Alopecia	25	0	0	28	0	0
General disorders and administration site conditions						
Fatigue¶	62	3	0	50	5	0

CTCAE=Common Terminology Criteria for Adverse Events; NCI=National Cancer Institute.
*Graded according to NCI CTCAE 4.03.
†Capecitabine, eribulin, gemcitabine, or vinorelbine.
‡Includes anemia, hematocrit decreased, hemoglobin decreased, and red blood cell count decreased.
§Includes febrile neutropenia, neutropenia, and neutrophil count decreased.
‖Includes thrombocytopenia and platelet count decreased.
¶Includes fatigue and asthenia.

SELECTED SAFETY INFORMATION

The **most common lab abnormalities (≥25%)** for TALZENNA vs chemotherapy were decreases in hemoglobin (90% vs 77%), leukocytes (84% vs 73%), lymphocytes (76% vs 53%), neutrophils (68% vs 70%), platelets (55% vs 29%), and calcium (28% vs 16%) and increases in glucose (54% vs 51%), aspartate aminotransferase (37% vs 48%), alkaline phosphatase (36% vs 34%), and alanine aminotransferase (33% vs 37%).

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Myelosuppression consisting of anemia, leukopenia/neutropenia, and/or thrombocytopenia have been reported in patients treated with TALZENNA. Grade ≥3 anemia, neutropenia, and thrombocytopenia were reported, respectively, in 39%, 21%, and 15% of patients receiving TALZENNA. Discontinuation due to anemia, neutropenia, and thrombocytopenia occurred, respectively, in 0.7%, 0.3%, and 0.3% of patients.[1]

Monitor complete blood counts for cytopenia at baseline and monthly thereafter. Do not start TALZENNA until patients have adequately recovered from hematological toxicity caused by previous therapy. If hematological toxicity occurs, dose modifications (dosing interruption with or without dose reduction) are recommended. **With respect to MDS/AML**, for prolonged hematological toxicities, interrupt TALZENNA and monitor blood counts weekly until recovery. If the levels have not recovered after 4 weeks, refer the patient to a hematologist for further investigations. If MDS/AML is confirmed, discontinue TALZENNA.[1]

Embryo-fetal toxicity

Based on its mechanism of action and findings from animal data, TALZENNA can cause fetal harm when administered to a pregnant woman.[1]

- Apprise pregnant women and females of reproductive potential of the potential risk to a fetus[1]
- Advise females of reproductive potential to use effective contraception during treatment and for at least 7 months following the last dose of TALZENNA[1]
- Based on findings from genetic toxicity and animal reproduction studies, advise male patients with female partners of reproductive potential or who are pregnant to use effective contraception during treatment and for at least 4 months following the last dose of TALZENNA[1]

Please see full Important Safety Information on page 11. Click for full Prescribing Information or visit TalzennaHCP.com.

EMBRACA STUDY | STARTING PATIENTS | PROVEN SAFETY | WARNINGS AND PRECAUTIONS | HEMATOLOGIC ADVERSE REACTIONS | NONHEMATOLOGIC ADVERSE REACTIONS | BROAD ACCESS FOR PATIENTS | IMPORTANT SAFETY INFORMATION

TALZENNA® talazoparib 1 mg capsules

Select **hematologic** adverse reactions in EMBRACA

*In prespecified and post hoc exploratory analyses**

- **Most common hematologic adverse reactions were transient**[5]
- Most adverse reactions were managed with dose interruptions, dose reductions, or standard supportive medical therapy[3,5]

Anemia†

Incidence: TALZENNA[1]
Grades 1-4: 53%
Grade 3: 38%
Grade 4: 1%

83 days — **Median time to first episode** of Grade ≥3 anemia vs 137 days with chemotherapy[5,6]

7 days — **Median duration** of Grade ≥3 anemia vs 7 days with chemotherapy[5]

8 days — **Median time to recovery** from any anemia vs 8 days with chemotherapy[5]

› **14%** of TALZENNA patients with anemia experienced subsequent‡ fatigue vs 4% of chemotherapy patients[5]

Neutropenia§

Incidence: TALZENNA[1]
Grades 1-4: 35%
Grade 3: 18%
Grade 4: 3%

50 days — **Median time to first episode** of Grade ≥3 neutropenia vs 22 days with chemotherapy[5,6]

7 days — **Median duration** of Grade ≥3 neutropenia vs 8 days with chemotherapy[5]

9 days — **Median time to recovery** from any neutropenia vs 9 days with chemotherapy[5]

› **1 case** of febrile neutropenia was reported with TALZENNA and chemotherapy[5]

› **4%** of TALZENNA patients with neutropenia experienced subsequent‡ infections vs 10% of chemotherapy patients[5]

*NOTE: Prespecified analysis included adverse event incidence rates, while post hoc exploratory analysis included median time to first episode, duration, and time to recovery in EMBRACA. Post hoc exploratory analyses were conducted in the safety population with a data cutoff date of September 15, 2017.[5,7]

† Anemia includes preferred terms: anemia, decreased hemoglobin, decreased hematocrit.
‡ The start date of the second adverse event had to occur on or within the start and end dates of the first adverse event.
§ Neutropenia includes preferred terms: neutropenia, decreased neutrophil count.

SELECTED SAFETY INFORMATION

Monitor complete blood counts for cytopenia at baseline and monthly thereafter. Do not start TALZENNA until patients have adequately recovered from hematological toxicity caused by previous therapy. If hematological toxicity occurs, dose modifications (dosing interruption with or without dose reduction) are recommended. **With respect to MDS/AML**, for prolonged hematological toxicities, interrupt TALZENNA and monitor blood counts weekly until recovery. If the levels have not recovered after 4 weeks, refer the patient to a hematologist for further investigations. If MDS/AML is confirmed, discontinue TALZENNA.

Some counseling tips for patients on managing adverse reactions

Anemia

- Delay activity until anemia is better, or limit activities to those that are important[8,9]
- Get plenty of rest, and try to sleep at least 8 hours each night. Try to take 1 to 2 short naps (1 hour or less) during the day[8,9]
- Accept help when offered[8,9]
- Eat a well-balanced diet that contains all the calories, iron, and protein that the body needs[8,10]
- Stand up slowly, as dizziness may occur when standing up too fast. When getting up from lying down, sit for a minute before standing[8,10]
- Hydrate and maintain electrolyte balance[11]

› Discuss potential use of supportive therapy for anemia (eg, iron therapy, transfusion)[11]
› Remind your patients to call you if usual activities are not doable or if feelings of dizziness or faintness occur[8]
› Remind your patients to call you if shortness of breath occurs or if their heart is pounding or beating very fast[8]

Neutropenia

- Avoid adults and children who are sick with colds or fevers. Avoid public gyms, pools, and other public places until white blood cell count returns to a safe level[8,9,12,13]
- Wash hands often with soap and water, and use sanitizing wipes to clean surfaces and items that have been touched. Carry hand sanitizer for times when soap and water aren't available[8,13]
- Be gentle and thorough when wiping after bowel movements[8]
- Take good care of skin, and be careful not to get cuts or nicks; clean cuts right away; use electric shaver instead of razor[8,13]
- Maintain good oral care[8,13]
- Wash raw vegetables and fruits well before eating; keep hot foods hot and cold foods cold; do not eat raw or undercooked fish, seafood, meat, chicken, or eggs[8,13]

› Discuss potential use of supportive therapy for neutropenia (eg, growth factor support)[11]
› Remind your patients to call you right away if signs of infection occur or if chills, sweats, or fever occurs[8,13]

Remind your patients to report any adverse reactions

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Select **hematologic** adverse reactions in EMBRACA

*In prespecified and post hoc exploratory analyses**

Thrombocytopenia†

Incidence: TALZENNA[1]

Grades 1-4: 27%

Grade 3: 11%

Grade 4: 4%

36 days

Median time to first episode of Grade ≥3 thrombocytopenia vs 184 days with chemotherapy[5,6]

8 days

Median duration of Grade ≥3 thrombocytopenia vs 18 days with chemotherapy[5]

9 days

Median time to recovery from any thrombocytopenia vs N/A with chemotherapy[5]

- **98%** of TALZENNA patients with thrombocytopenia did **not** experience a subsequent‡ bleeding event vs 99% of chemotherapy patients[5]

- Overlapping Grade 3/4 hematologic events with TALZENNA: anemia + neutropenia, 5.9%; anemia + thrombocytopenia, 3.1%; and neutropenia + thrombocytopenia, 4.9%[5]

*NOTE: Prespecified analysis included adverse event incidence rates, while post hoc exploratory analysis included median time to first episode, duration, and time to recovery in EMBRACA. Post hoc exploratory analyses were conducted in the safety population with a data cutoff date of September 15, 2017.[5,7]

† Thrombocytopenia includes preferred terms: thrombocytopenia, platelet count decreased.

‡ The start date of the second adverse event had to occur on or within the start and end dates of the first adverse event.

Some counseling tips for patients on managing adverse reactions

Thrombocytopenia

- Brush teeth with a very soft (foam) toothbrush, and use water flosser to clean gums (not floss or toothpick)[8,9]
- Blow nose gently[8]
- Be careful when using scissors, knives, or sharp objects[8]
- Use electric shaver instead of a razor[8]
- Apply gentle but firm pressure to any cuts until bleeding stops[8]
- Wear shoes all the time, even inside the house or hospital[8]
- Do not play sports or do other potentially harmful activities[8]
- Do not use tampons, enemas, suppositories, or rectal thermometers[8]
- Do not wear tight clothes, wristbands, or waistbands[8]

- Discuss potential use of supportive therapy for thrombocytopenia (eg, transfusion)[11]
- Remind your patients to call you if they experience excessive bruising or significant bleeding[8,12]

Remind your patients to report any adverse reactions

SELECTED SAFETY INFORMATION

TALZENNA can cause **fetal harm** when administered to pregnant women. Advise women of reproductive potential to use effective contraception during treatment and for at least 7 months following the last dose. A pregnancy test is recommended for females of reproductive potential prior to initiating TALZENNA treatment. Advise male patients with female partners of reproductive potential or who are pregnant to use effective contraception during treatment with TALZENNA and for at least 4 months after receiving the last dose. Based on animal studies, TALZENNA may impair fertility in males of reproductive potential. Advise women not to breastfeed while taking TALZENNA and for at least 1 month after receiving the last dose because of the potential for serious adverse reactions in nursing infants.

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Select **nonhematologic** adverse reactions in EMBRACA

*In prespecified and post hoc exploratory analyses**

- **The majority of nonhematologic adverse reactions in the TALZENNA group were Grade 1 in severity**[3,5]
- Most adverse reactions were managed with dose interruptions, dose reductions, or standard supportive medical therapy[3,5]

Fatigue

Incidence: TALZENNA[1]

Grades 1-4: 62%
Grade 3: 3%
Grade 4: 0%

54 days

Median time to first episode of Grade ≥2 fatigue vs 29 days with chemotherapy[5,6]

35 days

Median duration of Grade ≥2 fatigue vs 22 days with chemotherapy[5]

Nausea and vomiting

Nausea incidence: TALZENNA[1]

Grades 1-4: 49%
Grade 3: <1%
Grade 4: 0%

30 days

Median time to first episode of Grade ≥2 nausea vs 9 days with chemotherapy[5,6]

14 days

Median duration of Grade ≥2 nausea vs 14 days with chemotherapy[5]

Vomiting incidence: TALZENNA[1]

Grades 1-4: 25%
Grade 3: 2%
Grade 4: 0%

46 days

Median time to first episode of Grade ≥2 vomiting vs 16 days with chemotherapy[5,6]

6 days

Median duration of Grade ≥2 vomiting vs 3 days with chemotherapy[5]

*NOTE: Prespecified analysis included adverse event incidence rates, while post hoc exploratory analysis included median time to first episode and duration in EMBRACA. Post hoc exploratory analyses were conducted in the safety population with a data cutoff date of September 15, 2017.[5,7]

Some counseling tips for patients on managing adverse reactions

Fatigue

- Relax by doing yoga, meditating, and/or listening to guided imagery to decrease stress[8]
- Eat 5 to 6 small meals and/or snacks a day[8]
- Drink plenty of fluids[8]
- Rest, take naps, try not to do too much, and sleep at least 8 hours each night[8,12]
- When feeling up to it, be active by taking a 15-minute walk or riding an exercise bike[8,12]
- Plan a reasonable work schedule[8,12]
- Keep a diary of physical and emotional effects and let your healthcare provider know if you notice changes in your energy level[8]
- Let family and friends help with tasks[8,12]
- Practice good nutrition[11]

Nausea and vomiting

- Eat foods that are bland and easy to digest[8]
- Eat smaller, more frequent meals when you are able[8,14]
- Reduce food aromas and other stimuli with strong odors, and eat food at room temperature to lessen odor[8,9]
- Suck on small bits of popsicles, fruit ices, sugar-free mints, or tart candies[8,9]
- Use distractions such as soft music, a favorite television program, quiet hobbies, meditation, or the company of others[8]
- Stay at home and get plenty of rest[8,14]
- It is important to drink fluids as tolerated to avoid dehydration[11]

› Remind your patients to call you if nausea and vomiting do not resolve, and consider antiemetic medication[8,11]

Remind your patients to report any adverse reactions

SELECTED SAFETY INFORMATION

The **most common adverse reactions (≥20%)** of any grade for TALZENNA vs chemotherapy were fatigue (62% vs 50%), anemia (53% vs 18%), nausea (49% vs 47%), neutropenia (35% vs 43%), headache (33% vs 22%), thrombocytopenia (27% vs 7%), vomiting (25% vs 23%), alopecia (25% vs 28%), diarrhea (22% vs 26%), and decreased appetite (21% vs 22%).

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Select **nonhematologic** adverse reactions in EMBRACA

*In prespecified and post hoc exploratory analyses**

Alopecia

Incidence: TALZENNA[1]

Grades 1-4: 25% Grade 3: 0% Grade 4: 0%

- 22.7% was Grade 1† (hair loss of <50% of normal) and 2.4% was Grade 2‡ (hair loss of ≥50% of normal) vs 19.8% Grade 1 and 7.9% Grade 2 for patients who received chemotherapy[1,4,15]

*NOTE: Prespecified analysis included adverse event incidence rates, while post hoc exploratory analysis included median time to first episode and duration in EMBRACA. Post hoc exploratory analyses were conducted in the safety population with a data cutoff date of September 15, 2017.[5,7]

†Grade 1 defined as hair loss of <50% of normal for that individual that is not obvious from a distance but only on close inspection. A different hairstyle may be required to cover the hair loss, but it does not require a wig or hairpiece to camouflage.[15]

‡Grade 2 defined as hair loss of ≥50% of normal for that individual that is readily apparent to others. A wig or hairpiece is necessary if the patient desires to completely camouflage the hair loss.[15]

Some counseling tips for patients on managing adverse reactions

Alopecia

- Avoid products that can hurt the scalp (eg, hairsprays, hair dyes, curlers, brush rollers, straightening or curling irons, electric hair dryers, hair bands and clips, and perm or relaxer products)[8]
- Be gentle when washing hair[8]
- If hair loss occurs[8]:
  - Protect the scalp by wearing head coverings when outside
  - Avoid very hot or very cold places; stay warm
  - Sleep on satin pillowcase
  - Talk about your feelings to a healthcare provider, friend, family member, or someone else with cancer

Remind your patients to report any adverse reactions

SELECTED SAFETY INFORMATION

The **most frequently reported Grade ≥3 adverse reactions (≥10%)** for TALZENNA vs chemotherapy were anemia (39% vs 5%), neutropenia (21% vs 35%), and thrombocytopenia (15% vs 2%).

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TALZENNA is covered for[7]:

96% of the commercially insured population*

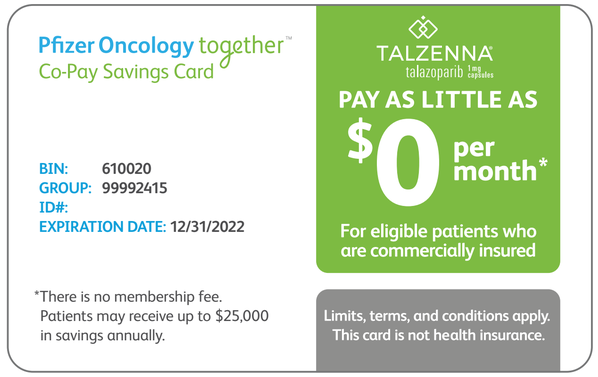
100% of the Medicare Part D-insured population*

*TALZENNA is included on formulary/plan policies. Additional requirements may apply. Formulary data are current as of 11/2021.

Commercially Insured

Resources for eligible patients with commercial, private, employer, or state health insurance marketplace coverage:

- Co-pay assistance: Eligible, commercially insured patients **may pay as little as $0 per month for TALZENNA.** Limits, terms, and conditions apply.† There are no income requirements, forms, or faxing to enroll



†Patients are not eligible to use this card if they are enrolled in a state or federally funded insurance program, including but not limited to Medicare, Medicaid, TRICARE, Veterans Affairs health care, a state prescription drug assistance program, or the Government Health Insurance Plan available in Puerto Rico. Patients may receive up to $25,000 in savings annually. **The offer will be accepted only at participating pharmacies. This offer is not health insurance.** No membership fees apply. Pfizer reserves the right to rescind, revoke, or amend this offer without notice. For full Terms and Conditions, please see PfizerOncologyTogether.com/terms. For any questions, please call 1-877-744-5675, visit PfizerOncologyTogether.com/terms or write: Pfizer Oncology Together Co-Pay Savings Program, 2250 Perimeter Park Drive, Suite 300, Morrisville, NC 27560.

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Call **1-877-744-5675** (Monday–Friday 8 AM–8 PM ET)

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Myelodysplastic Syndrome/Acute Myeloid Leukemia (MDS/AML) have been reported in patients who received TALZENNA. Overall, MDS/AML has been reported in <1% (3 out of 787, 0.4%) of solid tumor patients treated with TALZENNA in clinical studies. The duration of TALZENNA treatment in these three patients prior to developing MDS/AML was 4 months, 24 months, and 60 months respectively. These patients had received previous chemotherapy with platinum agents and/or other DNA damaging agents including radiotherapy.

Myelosuppression consisting of anemia, leukopenia/neutropenia, and/or thrombocytopenia have been reported in patients treated with TALZENNA. Grade ≥3 anemia, neutropenia, and thrombocytopenia were reported, respectively, in 39%, 21%, and 15% of patients receiving TALZENNA. Discontinuation due to anemia, neutropenia, and thrombocytopenia occurred, respectively, in 0.7%, 0.3%, and 0.3% of patients.

Monitor complete blood counts for cytopenia at baseline and monthly thereafter. Do not start TALZENNA until patients have adequately recovered from hematological toxicity caused by previous therapy. If hematological toxicity occurs, dose modifications (dosing interruption with or without dose reduction) are recommended. **With respect to MDS/AML**, for prolonged hematological toxicities, interrupt TALZENNA and monitor blood counts weekly until recovery. If the levels have not recovered after 4 weeks, refer the patient to a hematologist for further investigations. If MDS/AML is confirmed, discontinue TALZENNA.

TALZENNA can cause **fetal harm** when administered to pregnant women. Advise women of reproductive potential to use effective contraception during treatment and for at least 7 months following the last dose. A pregnancy test is recommended for females of reproductive potential prior to initiating TALZENNA treatment. Advise male patients with female partners of reproductive potential or who are pregnant to use effective contraception during treatment with TALZENNA and for at least 4 months after receiving the last dose. Based on animal studies, TALZENNA may impair fertility in males of reproductive potential. Advise women not to breastfeed while taking TALZENNA and for at least 1 month after receiving the last dose because of the potential for serious adverse reactions in nursing infants.

The **most common adverse reactions (≥20%)** of any grade for TALZENNA vs chemotherapy were fatigue (62% vs 50%), anemia (53% vs 18%), nausea (49% vs 47%), neutropenia (35% vs 43%), headache (33% vs 22%), thrombocytopenia (27% vs 7%), vomiting (25% vs 23%), alopecia (25% vs 28%), diarrhea (22% vs 26%), and decreased appetite (21% vs 22%).

The **most frequently reported Grade ≥3 adverse reactions (≥10%)** for TALZENNA vs chemotherapy were anemia (39% vs 5%), neutropenia (21% vs 35%), and thrombocytopenia (15% vs 2%).

The **most common lab abnormalities (≥25%)** for TALZENNA vs chemotherapy were decreases in hemoglobin (90% vs 77%), leukocytes (84% vs 73%), lymphocytes (76% vs 53%), neutrophils (68% vs 70%), platelets (55% vs 29%), and calcium (28% vs 16%) and increases in glucose (54% vs 51%), aspartate aminotransferase (37% vs 48%), alkaline phosphatase (36% vs 34%), and alanine aminotransferase (33% vs 37%).

Coadministration with P-gp inhibitors or **BCRP inhibitors** may increase TALZENNA exposure. If coadministering with the P-gp inhibitors amiodarone, carvedilol, clarithromycin, itraconazole, or verapamil is unavoidable, reduce the TALZENNA dose to 0.75 mg once daily. When the P-gp inhibitor is discontinued, increase the TALZENNA dose (after 3–5 half-lives of the P-gp inhibitor) to the dose used prior to the initiation of the P-gp inhibitor. When coadministering TALZENNA with other known P-gp inhibitors or BCRP inhibitors, monitor patients for potential increased adverse reactions.

For patients with moderate **renal impairment**, the recommended dose of TALZENNA is 0.75 mg once daily. For patients with severe renal impairment, the recommended dose of TALZENNA is 0.5 mg once daily. No dose adjustment is required for patients with mild renal impairment. TALZENNA has not been studied in patients requiring hemodialysis.

Click for full Prescribing Information or visit TalzennaHCP.com.

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