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**U.S. FDA Approves AKEEGA™ (Niraparib and Abiraterone Acetate), the First-And-Only Dual Action Tablet for the Treatment of Patients with BRCA-Positive Metastatic Castration-Resistant Prostate Cancer**

*Approval is based on the Phase 3 MAGNITUDE study, a prospectively designed precision medicine study including the largest population of BRCA-positive patients in combination trials to date with metastatic castration-resistant prostate cancer (mCRPC)*

*AKEEGA™ plus prednisone significantly improved radiographic progression-free survival compared to abiraterone acetate plus prednisone (AAP) in patients with BRCA-positive mCRPC*

**HORSHAM, Pa., August 11, 2023** – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced that the U.S. Food & Drug Administration (FDA) has approved AKEEGA™ (niraparib and abiraterone acetate), the first-and-only dual action tablet combining a PARP inhibitor with abiraterone acetate, given with prednisone, for the treatment of adult patients with deleterious or suspected deleterious BRCA-positive mCRPC, as detected by an FDA-approved test.<sup>1</sup>

“As a physician, identifying patients with a worse prognosis is a priority, especially those whose cancers have a BRCA mutation,” said Kim Chi, M.D.\*, Medical Oncologist at BC Cancer – Vancouver and principal investigator of the Phase 3 MAGNITUDE study. “We prospectively designed the MAGNITUDE study to identify the subset of patients most likely to benefit from targeted treatment with AKEEGA and to help us understand how we can potentially achieve better health outcomes for patients.”

Prostate cancer is one of the most common cancers in the U.S., with an estimated 288,300 new cases and nearly 35,000 deaths expected in 2023.<sup>2</sup> Approximately 10 to 15 percent of patients with mCRPC have *BRCA* gene alterations. Patients with *BRCA*-positive mCRPC are more likely to have aggressive disease and may experience poor outcomes and a shorter survival time.<sup>3,4,5,6,7</sup>

“The approval of AKEEGA brings an important treatment option to patients with prostate cancer as they consider their road ahead, and it also highlights the importance of genetic testing and precision medicine for this disease,” said Shelby Moneer, MS, CHES\*\*, Vice President of Patient Programs and Education, ZERO Prostate Cancer. “All individuals diagnosed with prostate cancer should consider genetic testing, especially those from racial and ethnic minority groups who tend to have worse cancer outcomes. This is imperative to close the racial and ethnic disparities in prostate cancer health outcomes.”

The FDA approval is based on positive results from the randomized, double-blind, placebo-controlled multi-center Phase 3 MAGNITUDE study. In *BRCA*-positive patients treated with the combination AKEEGA™ plus prednisone, a statistically significant 47 percent risk reduction was observed for radiographic progression-free survival (rPFS) (Hazard ratio [HR], 0.53; p=0.001). At the second interim analysis (IA2), with median follow-up at 24.8 months in the *BRCA*-positive subgroup, rPFS by central review demonstrated a consistent trend favoring AKEEGA™ plus prednisone, with a median rPFS of 19.5 months compared with 10.9 months for placebo and AAP (HR, 0.55 [95 percent confidence interval (CI), 0.39-0.78]). Additionally, there was an observed improvement in the secondary endpoints of time to symptomatic progression (TSP) (HR, 0.54 [95 percent CI, 0.35-0.85]) and time to initiation of cytotoxic chemotherapy (TCC) (HR, 0.56 [95 percent CI, 0.35-0.90]) for AKEEGA™ plus prednisone compared with AAP alone, supported by a trend towards improvement in overall survival (OS) (HR, 0.88 [95 percent CI, 0.58-1.34]).

The observed safety profile of the combination of AKEEGA™ plus prednisone was consistent with the known safety profile of each FDA-approved monotherapy. Of the patients in the MAGNITUDE study with a *BRCA* gene alteration, 41 percent who received AKEEGA™ experienced a serious adverse event (AE). The most common AEs occurring in 20 percent or more of patients who received AKEEGA™ plus prednisone versus patients who received placebo and AAP were musculoskeletal pain (44 percent vs. 42 percent, respectively), fatigue (43 percent vs. 30 percent), constipation (34 percent vs. 20 percent), hypertension (33 percent vs. 27 percent) and nausea (33 percent vs. 21 percent). Permanent discontinuation of any component of AKEEGA™ due to an adverse reaction occurred in 15 percent of patients.

“Janssen’s legacy of advancing the science of prostate cancer has contributed to the evolution of transformational treatment approaches for more than a decade,” said Kiran Patel, M.D., Vice President, Clinical Development, Solid Tumors, Janssen Research & Development, LLC. “This milestone, which marks the approval of Janssen’s third prostate cancer treatment, highlights the importance of advancing precision medicine approaches and genetic testing for the treatment of patients with *BRCA*-positive mCRPC.”

### **About AKEEGA™**

AKEEGA™ (niraparib and abiraterone acetate) is the first-and-only orally administered, once daily dual action tablet (DAT) of niraparib, a highly selective poly (ADP-ribose) polymerase (PARP) inhibitor, and abiraterone acetate, an androgen biosynthesis inhibitor. The novel DAT combination therapy targets two oncogenic drivers in patients with mCRPC and HRR gene alterations. AKEEGA™ is indicated with prednisone for the treatment of adults with mCRPC and *BRCA*-positive mutations. The recommended starting dose is 200 mg niraparib/1,000 mg abiraterone acetate (two tablets). The 100 mg niraparib/1,000 mg abiraterone acetate dose option (two tablets) is available for dose reduction.

In April 2016, Janssen Biotech, Inc. entered a worldwide (except Japan) collaboration and license agreement with TESARO, Inc. (acquired by GlaxoSmithKline [GSK] in 2019) for exclusive rights to niraparib in prostate cancer.

### **About Metastatic Castration-Resistant Prostate Cancer**

Metastatic castration-resistant prostate cancer characterizes cancer that no longer responds to androgen deprivation therapy and has spread to other parts of the body. The most common metastatic sites are bones, followed by lungs and liver. Prostate cancer is the second most common cancer in men worldwide, behind lung cancer. More than one million patients around the world are diagnosed with prostate cancer each year. Patients with mCRPC and HRR gene alterations, of which *BRCA* mutations are the most common, are more likely to have aggressive disease, poor outcomes and a shorter survival time.

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### **About MAGNITUDE**

MAGNITUDE ([NCT03748641](#)) is a Phase 3, randomized, double-blind, placebo-controlled, multi-center clinical study evaluating the safety and efficacy of the combination of AKEEGA™ plus prednisone for patients with mCRPC, with or without certain HRR gene alterations, and who have not received prior therapy for mCRPC except for up to four months of AAP.

The study included patients with (HRR biomarker [BM] positive; *ATM*, *BRCA1*, *BRCA2*, *BRIP1*, *CDK12*, *CHEK2*, *FANCA*, *HDAC2*, *PALB2*) and without specified gene alterations (HRR BM negative), who were randomized 1:1 to receive niraparib 200 mg once daily plus AAP or placebo plus AAP.<sup>8</sup> A total of 423 patients with HRR gene alterations were enrolled, 225 (53.2 percent) of whom had *BRCA* mutations.<sup>9,10,11</sup> The primary endpoint of the MAGNITUDE trial was rPFS assessed by blinded independent central review.<sup>12</sup> Secondary endpoints included TCC, TSP and OS. Analysis of the group of patients with *BRCA* alterations was alpha controlled for rPFS and prespecified for other endpoints.

### **Access to AKEEGA™ (niraparib and abiraterone acetate)**

Once a patient and their doctor have decided that AKEEGA™ is right for the patient, Janssen can help find the resources patients may need to get started and stay on therapy. Janssen offers support navigating the payer processes to assist patients in gaining access to AKEEGA™. We can provide information on insurance coverage and potential out-of-pocket costs and identify options that may help make AKEEGA™ more affordable. If patients have commercial or private health insurance and need help paying for AKEEGA™, the Janssen CarePath Savings Program may be able to help. To learn more about access and affordability support visit [JanssenCarePath.com](http://JanssenCarePath.com) or call 1-877-CarePath (1-877-227-3728). We also offer personalized support for patients that provides one-on-one guidance, information, and educational resources, which includes helping them explore cost support options. Patients can get connected to dedicated support from our Care Navigators by calling *Janssen Compass*® directly at 844-628-1234 or by visiting [JanssenCompass.com](http://JanssenCompass.com) and requesting an introductory call. *Janssen Compass*® is limited to education for patients about their Janssen therapy, its administration, and/or their disease. It is intended to supplement a patient's understanding of their therapy and is not intended to provide medical advice, replace a treatment plan from the patient's doctor or nurse, provide case management services, or serve as a reason to prescribe a Janssen medication.

### **IMPORTANT SAFETY INFORMATION FOR AKEEGA™**

#### **WARNINGS AND PRECAUTIONS**

The safety population described in the WARNINGS and PRECAUTIONS reflect exposure to AKEEGA™ in combination with prednisone in *BRCAm* patients in Cohort 1 (N=113) of MAGNITUDE.

#### **Myelodysplastic Syndrome/Acute Myeloid Leukemia**

AKEEGA™ may cause myelodysplastic syndrome/acute myeloid leukemia (MDS/AML).

MDS/AML, including cases with fatal outcome, has been observed in patients treated with niraparib, a component of AKEEGA™.

All patients treated with niraparib who developed secondary MDS/cancer-therapy-related AML had received previous chemotherapy with platinum agents and/or other DNA-damaging agents, including radiotherapy.

For suspected MDS/AML or prolonged hematological toxicities, refer the patient to a hematologist for further evaluation. Discontinue AKEEGA™ if MDS/AML is confirmed.

### **Myelosuppression**

AKEEGA™ may cause myelosuppression (anemia, thrombocytopenia, or neutropenia).

In MAGNITUDE Cohort 1, Grade 3-4 anemia, thrombocytopenia, and neutropenia were reported, respectively in 28%, 8%, and 7% of patients receiving AKEEGA™. Overall, 27% of patients required a red blood cell transfusion, including 11% who required multiple transfusions. Discontinuation due to anemia occurred in 3% of patients.

Monitor complete blood counts weekly during the first month of AKEEGA™ treatment, every two weeks for the next two months, monthly for the remainder of the first year and then every other month, and as clinically indicated. Do not start AKEEGA™ until patients have adequately recovered from hematologic toxicity caused by previous therapy. If hematologic toxicities do not resolve within 28 days following interruption, discontinue AKEEGA™ and refer the patient to a hematologist for further investigations, including bone marrow analysis and blood sample for cytogenetics.

### **Hypokalemia, Fluid Retention, and Cardiovascular Adverse Reactions**

AKEEGA™ may cause hypokalemia and fluid retention as a consequence of increased mineralocorticoid levels resulting from CYP17 inhibition [see Clinical Pharmacology (12.1)]. In post-marketing experience, QT prolongation and Torsades de Pointes have been observed in patients who develop hypokalemia while taking abiraterone acetate, a component of AKEEGA™. Hypertension and hypertensive crisis have also been reported in patients treated with niraparib, a component of AKEEGA™.

In MAGNITUDE Cohort 1, which used prednisone 10 mg daily in combination with AKEEGA™, Grades 3-4 hypokalemia was detected in 2.7% of patients on the AKEEGA™ arm and Grades 3-4 hypertension were observed in 14% of patients on the AKEEGA™ arm.

The safety of AKEEGA™ in patients with New York Heart Association (NYHA) Class II to IV heart failure has not been established because these patients were excluded from MAGNITUDE.

Monitor patients for hypertension, hypokalemia, and fluid retention at least weekly for the first two months, then once a month. Closely monitor patients whose underlying medical conditions might be compromised by increases in blood pressure, hypokalemia, or fluid retention, such as those with heart failure, recent myocardial infarction, cardiovascular disease, or ventricular arrhythmia. Control hypertension and correct hypokalemia before and during treatment with AKEEGA™.

Discontinue AKEEGA™ in patients who develop hypertensive crisis or other severe cardiovascular adverse reactions.

### **Hepatotoxicity**

AKEEGA™ may cause hepatotoxicity.

Hepatotoxicity in patients receiving abiraterone acetate, a component of AKEEGA™, has been reported in clinical trials. In post-marketing experience, there have been abiraterone acetate-associated severe hepatic toxicity, including fulminant hepatitis, acute liver failure, and deaths.

In MAGNITUDE Cohort 1, Grade 3-4 ALT or AST increases (at least 5 x ULN) were reported in 1.8% of patients. The safety of AKEEGA™ in patients with moderate or severe hepatic impairment has not been established as these patients were excluded from MAGNITUDE.

Measure serum transaminases (ALT and AST) and bilirubin levels prior to starting treatment with AKEEGA™, every two weeks for the first three months of treatment and monthly thereafter. Promptly measure serum total bilirubin, AST, and ALT if clinical symptoms or signs suggestive of hepatotoxicity develop. Elevations of AST, ALT, or bilirubin from the patient's baseline should prompt more frequent monitoring and may require dosage modifications.

Permanently discontinue AKEEGA™ for patients who develop a concurrent elevation of ALT greater than 3 x ULN and total bilirubin greater than 2 x ULN in the absence of biliary obstruction or other causes responsible for the concurrent elevation, or in patients who develop ALT or AST  $\geq 20$  x ULN at any time after receiving AKEEGA™.

### **Adrenocortical Insufficiency**

AKEEGA™ may cause adrenal insufficiency.

Adrenocortical insufficiency has been reported in clinical trials in patients receiving abiraterone acetate, a component of AKEEGA™, in combination with prednisone, following interruption of daily steroids and/or with concurrent infection or stress. Monitor patients for symptoms and signs of adrenocortical insufficiency, particularly if patients are withdrawn from prednisone, have prednisone dose reductions, or experience unusual stress. Symptoms and signs of adrenocortical insufficiency may be masked by adverse reactions associated with mineralocorticoid excess seen in patients treated with abiraterone acetate. If clinically indicated, perform appropriate tests to confirm the diagnosis of adrenocortical insufficiency. Increased doses of corticosteroids may be indicated before, during, and after stressful situations.

### **Hypoglycemia**

AKEEGA™ may cause hypoglycemia in patients being treated with other medications for diabetes.

Severe hypoglycemia has been reported when abiraterone acetate, a component of AKEEGA™, was administered to patients receiving medications containing thiazolidinediones (including pioglitazone) or repaglinide.

Monitor blood glucose in patients with diabetes during and after discontinuation of treatment with AKEEGA™. Assess if antidiabetic drug dosage needs to be adjusted to minimize the risk of hypoglycemia.

### **Increased Fractures and Mortality in Combination with Radium 223 Dichloride**

AKEEGA™ with prednisone is not recommended for use in combination with Ra-223 dichloride outside of clinical trials.

The clinical efficacy and safety of concurrent initiation of abiraterone acetate plus prednisone/prednisolone and radium Ra 223 dichloride was assessed in a randomized,

placebo-controlled multicenter study (ERA-223 trial) in 806 patients with asymptomatic or mildly symptomatic castration-resistant prostate cancer with bone metastases. The study was unblinded early based on an Independent Data Monitoring Committee recommendation.

At the primary analysis, increased incidences of fractures (29% vs 11%) and deaths (39% vs 36%) have been observed in patients who received abiraterone acetate plus prednisone/prednisolone in combination with radium Ra 223 dichloride compared to patients who received placebo in combination with abiraterone acetate plus prednisone.

It is recommended that subsequent treatment with Ra-223 not be initiated for at least five days after the last administration of AKEEGA™, in combination with prednisone.

### **Posterior Reversible Encephalopathy Syndrome**

AKEEGA™ may cause Posterior Reversible Encephalopathy Syndrome (PRES).

PRES has been observed in patients treated with niraparib as a single agent at higher than the recommended dose of niraparib included in AKEEGA™.

Monitor all patients treated with AKEEGA™ for signs and symptoms of PRES. If PRES is suspected, promptly discontinue AKEEGA™ and administer appropriate treatment. The safety of reinitiating AKEEGA™ in patients previously experiencing PRES is not known.

### **Embryo-Fetal Toxicity**

The safety and efficacy of AKEEGA™ have not been established in females. Based on animal reproductive studies and mechanism of action, AKEEGA™ can cause fetal harm and loss of pregnancy when administered to a pregnant female.

Niraparib has the potential to cause teratogenicity and/or embryo-fetal death since niraparib is genotoxic and targets actively dividing cells in animals and patients (e.g., bone marrow).

In animal reproduction studies, oral administration of abiraterone acetate to pregnant rats during organogenesis caused adverse developmental effects at maternal exposures approximately  $\geq 0.03$  times the human exposure (AUC) at the recommended dose.

Advise males with female partners of reproductive potential to use effective contraception during treatment and for 4 months after the last dose of AKEEGA™. Females who are or may become pregnant should handle AKEEGA™ with protection, e.g., gloves.



Based on animal studies, AKEEGA™ may impair fertility in males of reproductive potential.

## **ADVERSE REACTIONS**

The safety of AKEEGA™ in patients with *BRCAm* mCRPC was evaluated in Cohort 1 of MAGNITUDE.

The most common adverse reactions ( $\geq 10\%$ ), including laboratory abnormalities, are decreased hemoglobin, decreased lymphocytes, decreased white blood cells, musculoskeletal pain, fatigue, decreased platelets, increased alkaline phosphatase, constipation, hypertension, nausea, decreased neutrophils, increased creatinine, increased potassium, decreased potassium, increased AST, increased ALT, edema, dyspnea, decreased appetite, vomiting, dizziness, COVID-19, headache, abdominal pain, hemorrhage, urinary tract infection, cough, insomnia, increased bilirubin, weight decreased, arrhythmia, fall, and pyrexia.

Serious adverse reactions reported in  $>2\%$  of patients included COVID-19 (7%), anemia (4.4%), pneumonia (3.5%), and hemorrhage (3.5%). Fatal adverse reactions occurred in 9% of patients who received AKEEGA™, including COVID-19 (5%), cardiopulmonary arrest (1%), dyspnea (1%), pneumonia (1%), and septic shock (1%).

## **DRUG INTERACTIONS**

### **Effect of Other Drugs on AKEEGA™**

Avoid coadministration with strong CYP3A4 inducers.

Abiraterone is a substrate of CYP3A4. Strong CYP3A4 inducers may decrease abiraterone concentrations, which may reduce the effectiveness of abiraterone.

### **Effects of AKEEGA™ on Other Drugs**

Avoid coadministration unless otherwise recommended in the Prescribing Information for CYP2D6 substrates for which minimal changes in concentration may lead to serious toxicities. If alternative treatments cannot be used, consider a dose reduction of the concomitant CYP2D6 substrate drug.

Abiraterone is a CYP2D6 moderate inhibitor. AKEEGA™ increases the concentration of CYP2D6 substrates, which may increase the risk of adverse reactions related to these substrates.

Monitor patients for signs of toxicity related to a CYP2C8 substrate for which a minimal change in plasma concentration may lead to serious or life-threatening adverse reactions.

Abiraterone is a CYP2C8 inhibitor. AKEEGA™ increases the concentration of CYP2C8 substrates, which may increase the risk of adverse reactions related to these substrates.

Please see the full [Prescribing Information](#) for AKEEGA™.

\*Dr. Chi has been a paid consultant to Janssen; Dr. Chi has not been paid for any media work.

\*\*Ms. Moneer has not been paid for any media work.

### **About the Janssen Pharmaceutical Companies of Johnson & Johnson**

At Janssen, we're creating a future where disease is a thing of the past. We're the Pharmaceutical Companies of Johnson & Johnson, working tirelessly to make that future a reality for patients everywhere by fighting sickness with science, improving access with ingenuity, and healing hopelessness with heart. We focus on areas of medicine where we can make the biggest difference: Cardiovascular, Metabolism & Retina; Immunology; Infectious Diseases & Vaccines; Neuroscience; Oncology; and Pulmonary Hypertension.

Learn more at [www.janssen.com](http://www.janssen.com). Follow us at [@JanssenGlobal](#) and [@JanssenUS](#). Janssen Biotech, Inc. and Janssen Research & Development, LLC are part of the Janssen Pharmaceutical Companies of Johnson & Johnson.

### **Cautions Concerning Forward-Looking Statements**

*This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding product development and the potential benefits and treatment impact of AKEEGA™. The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Janssen Research & Development, LLC; Janssen Biotech, Inc., and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges and uncertainties inherent in product research and development, including the uncertainty of clinical success and of obtaining regulatory approvals; uncertainty of commercial success; competition, including*

technological advances, new products and patents attained by competitors; challenges to patents; changes in behavior and spending patterns of purchasers of health care products and services; changes to applicable laws and regulations, including global health care reforms; and trends toward health care cost containment. A further list and descriptions of these risks, uncertainties and other factors can be found in Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended January 1, 2023, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in Johnson & Johnson's subsequent Quarterly Reports on Form 10-Q and other filings with the Securities and Exchange Commission. Copies of these filings are available online at [www.sec.gov](http://www.sec.gov), [www.jnj.com](http://www.jnj.com) or on request from Johnson & Johnson. None of Janssen Research & Development, LLC, Janssen Biotech, Inc., the Janssen Pharmaceutical Companies nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

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<sup>1</sup> AKEEGA™ Prescribing Information. Horsham, PA: Janssen Biotech, Inc.

<sup>2</sup> American Cancer Society. Cancer Facts & Figures 2023. Accessed May 11, 2023.

<https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2023/2023-cancer-facts-and-figures.pdf>

<sup>3</sup> Scott RJ, Mehta A, Macedo GS, Borisov PS, Kanavaran R, El Metnawy W. Genetic testing for homologous recombination repair (HRR) in metastatic castration-resistant prostate cancer (mCRPC): challenges and solutions. *Oncotarget*. 2021 Aug 3;12(16):1600-1614. doi: 10.18632/oncotarget.28015. PMID: 34381565; PMCID: PMC8351605. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8351605/>

<sup>4</sup> Castro E, Romero-Laorden N, Del Pozo A, et al. PROREPAIR-B: A prospective cohort study of the impact of germline DNA repair mutations on the outcomes of patients with metastatic castration-resistant prostate cancer. *J Clin Oncol*. 2019;37(6):490-503. doi:10.1200/JCO.18.00358.

<sup>5</sup> Cavanagh, H., & Rogers, K. M. (2015). The role of BRCA1 and BRCA2 mutations in prostate, pancreatic and stomach cancers. *Hereditary cancer in clinical practice*, 13(1), 16. <https://doi.org/10.1186/s13053-015-0038-x>

<sup>6</sup> Messina, C., Cattrini, C., Soldato, D., et al (2020). BRCA mutations in prostate cancer: Prognostic and predictive Implications. *J Oncol.*, 2020, 4986365. <https://doi.org/10.1155/2020/4986365>

<sup>7</sup> Na, R., Zheng, S. L., Han, M., et al (2017). Germline mutations in ATM and BRCA1/2 distinguish risk for lethal and indolent prostate cancer and are associated with early age at death. *European Urology*, 71(5), 740–747. <https://doi.org/10.1016/j.eururo.2016.11.033>

<sup>8</sup> Chi et al. Phase 3 MAGNITUDE study: First results of niraparib (NIRA) with abiraterone acetate and prednisone (AAP) as first-line therapy in patients (pts) with metastatic castration-resistant prostate cancer (mCRPC) with and without homologous recombination repair (HRR) gene alterations. Oral presentation, 2022 ASCO GU Annual Meeting.

<sup>9</sup> AKEEGA™ Prescribing Information. Horsham, PA: Janssen Biotech, Inc.

<sup>10</sup> Efsthathiou E, et al. Niraparib With Abiraterone Acetate and Prednisone in Patients With Metastatic Castration-Resistant Prostate Cancer and Homologous Recombination Repair Gene Alterations: Second Interim Analysis of MAGNITUDE. Poster presentation, 2023 ASCO GU Annual Meeting. February 16, 2023.

<sup>11</sup> AKEEGA™ Prescribing Information. Horsham, PA: Janssen Biotech, Inc.

<sup>12</sup> AKEEGA™ Prescribing Information. Horsham, PA: Janssen Biotech, Inc.