

VERZENIO (abemaciclib): Detailing Script

Conversational answers to speak during the Dr. Raj demo

The DR. RAJ lines are likely prompts. The YOU lines are yours to read aloud, in your own voice. Where an answer describes how a therapy is managed, you're relaying what practices do, not directing patient care yourself.

THE BASICS: WHAT IT IS

DR. RAJ: *What is Verzenio?*

YOU: "So Verzenio, or abemaciclib as the generic, is an oral pill from Lilly that patients take twice a day. It's in a class called CDK4/6 inhibitors, and it's given together with endocrine therapy to treat HR-positive, HER2-negative breast cancer. That's really the core setting for it."

DR. RAJ: *Who makes it?*

YOU: "It's ours, Eli Lilly. It's one of our flagship products in oncology."

DR. RAJ: *What class is it, and what else is in that class?*

YOU: "It's a CDK4/6 inhibitor. There are three on the market: ours, abemaciclib, plus palbociclib, which is Ibrance from Pfizer, and ribociclib, Kisqali from Novartis. Where Verzenio really stands apart is that it's dosed continuously, and it has the strongest data in the early-disease setting. I'll come back to that in a minute."

DR. RAJ: *How is it taken?*

YOU: "It's a tablet, twice a day, about every twelve hours, with or without food, and it's continuous, so there's no built-in week off. When it's paired with endocrine therapy the dose is 150 milligrams twice daily, and if it's used on its own, the monotherapy dose is 200 twice daily."

HOW IT WORKS

DR. RAJ: *How does it work?*

YOU: "The simple version is this. Cancer cells grow by moving through the cell-division cycle, and there are two proteins, CDK4 and CDK6, that act like the engine driving that. Verzenio blocks that engine, so the cells stall out and stop dividing."

DR. RAJ: *Why combine it with endocrine therapy?*

YOU: "Because you're hitting the tumor two different ways at once. In HR-positive disease, estrogen is what's fueling the growth, and endocrine therapy shuts that signal off. Verzenio blocks the cell-cycle engine. Put them together and you're coming at the tumor from two angles, which works better than either one alone."

DR. RAJ: *Can you give me the precise molecular action?*

YOU: "Sure. If you want it in detail, it's an ATP-competitive inhibitor of CDK4 and CDK6. By blocking those kinases it prevents phosphorylation of the retinoblastoma protein, the Rb protein, and that keeps the cell locked in the G1 phase, so it can't move into DNA replication and divide."

DR. RAJ: *What makes abemaciclib different from the other two?*

YOU: "A few things, really. It's more selective for CDK4 over CDK6, which means less bone-marrow suppression, and that's why it can be dosed continuously without a week off. It also crosses the blood-brain barrier and has shown activity in the brain. And it's the only one in the class with an approval and mature data in the adjuvant, early-disease setting."

WHEN TO USE IT & IN WHICH PATIENTS

DR. RAJ: *What's it actually approved for?*

YOU: "Two broad settings, both in HR-positive, HER2-negative disease. One is early breast cancer, the adjuvant or curative-intent setting, for node-positive, high-risk patients, to keep the cancer from coming back. The other is

advanced or metastatic disease, where it's used with an aromatase inhibitor up front, or with fulvestrant after progression, or on its own once endocrine therapy and chemo have been tried.”

DR. RAJ: *Who's the ideal early-breast-cancer patient?*

YOU: “Your high-risk, node-positive HR-positive, HER2-negative early patients, the ones you're genuinely worried about recurrence with. To put a definition on it, high risk means either four or more positive nodes, or one to three positive nodes plus something else that raises the stakes, like grade 3 disease or a tumor five centimeters or larger.”

DR. RAJ: *Do I still need a Ki-67 test to use it?*

YOU: “No, not anymore, and that's actually made it simpler. The original approval back in 2021 required a Ki-67 score of 20 percent or higher. But the label was expanded in 2023 and that requirement came off, so now you're identifying patients purely on nodal status, tumor size, and grade.”

DR. RAJ: *Who's the ideal metastatic patient?*

YOU: “HR-positive, HER2-negative advanced or metastatic disease. You can use it first-line with an aromatase inhibitor, or after progression with fulvestrant. And it's not narrow. First-line use covers pre-, peri-, and postmenopausal patients, with ovarian suppression where that's appropriate, and it's approved for men as well.”

DR. RAJ: *When would you not use it?*

YOU: “It's not for HER2-positive or triple-negative disease. It's really an HR-positive, HER2-negative drug. And I wouldn't point you toward it for a low-risk, node-negative early patient where endocrine therapy alone does the job. The main practical consideration is making sure a patient can manage the diarrhea, which I'll get to.”

HISTORY & APPROVALS

DR. RAJ: *When was it introduced?*

YOU: “It first got FDA approval on September 28th, 2017, in the metastatic setting. And it's expanded pretty steadily since then, moving into earlier lines and then into early breast cancer.”

DR. RAJ: *Walk me through the approval history.*

YOU: “Happy to. It started in 2017 with the metastatic approvals: with fulvestrant after progression, and as monotherapy after endocrine therapy and chemo. In early 2018 it picked up first-line metastatic use with an aromatase inhibitor. Then October 2021 was the big one, the first adjuvant approval for high-risk early disease, though at first it needed that Ki-67 score. And in March 2023 they broadened it and dropped the Ki-67 requirement. The headline is that it's the first and only CDK4/6 inhibitor approved in the adjuvant setting.”

If he wants the dates, the table is here to glance at:

Date	Milestone
Sep 2017	First approval: with fulvestrant after progression, and monotherapy after endocrine therapy plus chemo (metastatic).
Feb 2018	First-line metastatic, with an aromatase inhibitor (based on MONARCH 3).
Oct 2021	First adjuvant approval: high-risk node-positive early disease, Ki-67 of 20% or higher (based on monarchE).
Mar 2023	Adjuvant indication expanded. Ki-67 requirement removed; patients identified by nodes, size, and grade.

THE BENEFIT & THE EVIDENCE

DR. RAJ: *What benefit does it add when it's combined with endocrine therapy?*

YOU: “Both of the things you'd care about, honestly. In the high-risk early setting, it lowers the chance of the cancer coming back. And in metastatic disease, it stretches out the time before the cancer progresses. So it's not one or the other. You're getting both.”

DR. RAJ: *What does the clinical data show?*

YOU: “Big picture, in early high-risk disease it cut the risk of recurrence by about a third, and in metastatic disease it roughly doubled the time before progression. I can give you the specific numbers from each trial if that's useful.”

DR. RAJ: *What trials support it?*

YOU: “The backbone is the MONARCH program in metastatic disease, plus monarchE in early disease. Quick tour: MONARCH 1 was the monotherapy study, MONARCH 2 paired it with fulvestrant in the second line, MONARCH 3 was first-line with an aromatase inhibitor, and monarchE is the big adjuvant trial in early disease.”

Trial	Setting	Result
MONARCH 1	Monotherapy	Single agent in heavily pretreated metastatic disease; response rate about 19.7%.
MONARCH 2	+ fulvestrant	Second-line after progression. Median PFS 16.4 vs 9.3 months; overall survival 46.7 vs 37.3 months.
MONARCH 3	+ aromatase inhibitor	First-line metastatic. Median PFS 29.0 vs 14.8 months, roughly doubled.
monarchE	Adjuvant, early BC	5,637 patients, 2 years of Verzenio plus endocrine therapy. Improved disease-free survival and now overall survival.

DR. RAJ: *Give me the headline numbers from monarchE.*

YOU: “In the early-disease trial, four-year invasive disease-free survival was about 86 percent with Verzenio plus endocrine therapy, versus about 79 percent with endocrine therapy alone. At five years the recurrence risk was down roughly a third, and what's striking is that the benefit kept widening even after the two-year treatment course ended. It's also now shown an overall survival benefit, which makes it the first in the class to do that in early disease.”

DR. RAJ: *And the metastatic numbers?*

YOU: “First-line, in MONARCH 3, median progression-free survival was 29 months with Verzenio plus an aromatase inhibitor, versus about 15 without, so roughly double. Second-line, in MONARCH 2 with fulvestrant, it was about 16 months versus 9, and overall survival came in around 47 months versus 37.”

SAFETY & TOLERABILITY

DR. RAJ: *What are the most common side effects?*

YOU: “Diarrhea is the big one, and that's the one to plan for. You'll also see neutropenia and lower white counts, some fatigue, nausea, anemia, the occasional infection. But diarrhea is the headline. It tends to show up early, usually the first week or two, it's usually low-grade, and it's manageable.”

DR. RAJ: *How is the diarrhea managed?*

YOU: “The way most practices get ahead of it is to set the patient's expectations on day one and make sure they've got loperamide on hand before it even starts. Then if it shows up, the patient starts the loperamide and increases fluids, and if it's more stubborn or higher grade, you'd hold the dose and then bring it down. In practice it tends to settle once that's in place.”

(You're describing how it's handled in practice, not directing care. Keep it as “what we see practices do.”)

DR. RAJ: *My patients worry about staying on the pill when the diarrhea hits early. How do you keep them adherent?*

YOU: “Honestly, it comes down to preparing them up front. When patients know it's coming, know it's usually just that first week or two, and have the loperamide ready, they tend to push through it rather than stop. And we've got patient handouts and support programs on our side to reinforce that. So it's really about setting the expectation early and staying in touch through those first couple of weeks.”

DR. RAJ: *What are the more serious things to watch for?*

YOU: “A handful to keep on your radar. The diarrhea, if it's not managed, can lead to dehydration. There's neutropenia, so you'd monitor blood counts. There's a risk of blood clots, venous thromboembolism, so you'd watch the legs and lungs. Interstitial lung disease, or lung inflammation, is uncommon but worth watching for new respiratory symptoms. And there can be liver enzyme elevations, so you'd keep an eye on liver function.”

DR. RAJ: *What monitoring does a patient need?*

YOU: “Blood counts and liver function tests at baseline and then periodically through treatment. Counsel them on the diarrhea up front, and just keep an eye out for any signs of clots or lung issues as you go.”

PRACTICAL & POSITIONING

DR. RAJ: *How long do patients stay on it?*

YOU: “In early disease, the Verzenio course is two years alongside endocrine therapy, and the endocrine therapy itself runs longer. In metastatic disease, you keep going until the disease progresses or side effects force a change.”

DR. RAJ: *Why Verzenio over the other CDK4/6 inhibitors?*

YOU: “A few reasons. It's the only one approved in the early-disease setting with mature recurrence and survival data. It's dosed continuously, so there's no week off. And it gets into the brain, which matters for some patients.”

DR. RAJ: *How does it fit with what I already prescribe?*

YOU: “It doesn't replace your endocrine therapy, it goes on top of it. For your highest-risk early patients, it's really the piece that closes the recurrence gap that endocrine therapy alone leaves behind.”

DR. RAJ: *Is there patient support for cost and adherence?*

YOU: “Yes, we've got patient support and savings programs. I can get you the current specifics or connect you with our access team, and there are patient-facing resources for the adherence side too.”

Sources: FDA approvals, 2017 through 2023; monarchE (JCO 2020 and 5-yr OS JCO 2024; Lilly); MONARCH 1 through 3 (JCO 2017, Ann Oncol 2024); Verzenio Prescribing Information. Verzenio is HR+/HER2- only. Keep the detail on label.