Evaluate Vantage

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Gilead to spend more time in the Tropics

Jacob Plieth

Radius/Menarini's hit with elacestrant could have major implications for others targeting relapsed ER-positive/Her2-negative breast cancer. Already a direct competitor, Sanofi's amcenestrant, has suffered a protracted delay, and yesterday readout from a second key trial, Gilead's Tropics-02, slipped into January/February 2022. Tropics-02 tests the anti-Trop2 drug Trodelvy rather than a Serd like elacestrant or amcenestrant, and is a third-line study. But there are important parallels between the delays, and both Sanofi and Gilead will now be able to review Radius's full data at the San Antonio Breast Cancer Symposium before unveiling their own trials. There is no suggestion that Ameera-3 and/or Tropics-02 data are already in house, and that analysis is being deliberately delayed, of course. Perhaps all patients, including those in the control arm, are progressing more slowly than expected, though Tropics-02 allows neither a PI3K nor a second CDK4/6 inhibitor within study; both are important new options. Gilead told analysts yesterday that event-driven trials were "inherently variable", and that it still hoped to see a clinically meaningful two-month PFS benefit over control. Those conscious that Gilead spent $21bn to buy Trodelvy's originator, Immunomedics, will note nervously that Tropics-02 had already earlier been enlarged – not a sign of confidence.

Selected studies in ER-positive/Her2-negative breast cancer

Trial	Project (company)	Design	Comparator	Result
Emerald	Elacestrant (Radius)	2nd/3rd-line, post endocrine therapy + CDK4/6 inhibitor combo	Faslodex, Arimidex, Femara or Aromasin	Toplined positive for PFS in all-comers & ESR1mut; full data at SABCS, Dec 2021
Ameera-3	Amcenestrant (Sanofi)	≥2nd-line, post endocrine therapy + CDK4/6 inhibitor*	Faslodex, Arimidex, Femara, Aromasin or Nolvadex	Readout delayed from Q2 2021 to Q1 2022
Tropics-02	Trodelvy (Gilead)	3rd-line, post endocrine therapy and a CDK4/6 inhibitor	Xeloda, Navelbine, Gemzar or Halaven	Trial upsized and changed to sole PFS primary endpoint; readout delayed from Q4 2021 to Q1 2022

*Source: study schema. Note: *CDK4/6 inhibitor only "if approved and available", and mandatory in at least 80% of patients.*