



## **TROPiCS-02 Readout Announcement – FAQ**

7 March 2022

### **Q1. Did PFS meet your bar for clinically meaningful?**

- There is a broad range of views on what is “clinically meaningful” in this population. We are evaluating the data and will explore potential pathways with regulatory authorities to bring Trodelvy to this group of patients.

### **Q2. You reference TROPiCS-02 clinical activity consistent with the Phase 1/2 IMMU-132-01 study. What were the results of that study?**

- The Phase 1/2 IMMU-132-01 study evaluated Trodelvy in a subset of HR+/HER2- metastatic breast cancer patients. As published [here](#) (Kalinsky et al, 2020), a PFS of 5.5 months was reported. There was no comparator arm in this study.

### **Q3. What does this mean for HR+/HER2- earlier line patients?**

- We saw statistically significant clinical activity in TROPiCS-02, and there is no change to our plan to move forward with studies for earlier line patients.

### **Q4. What are the next milestones for this trial?**

- The final overall survival data readout is expected in 2024, subject to the timing of events.
- The study allows for a second, interim OS analysis and we will update you on our expectations following review with regulatory authorities.
- In the meantime, patients will continue to be followed and treated per protocol.

### **Q5. Is it reasonable to expect a statistically significant final overall survival readout given the data so far?**

- In the first interim analysis, the study demonstrated a trend in improvement for overall survival which means Trodelvy is showing a numerical improvement that was not statistically significant at the first interim analysis. We will continue to follow patients while the data matures to understand the final overall survival result.

**Q6. How does this impact Gilead's 2022 guidance?**

- We are not changing our 2022 guidance at this time.
- In terms of the 2022 revenue guidance issued on February 1<sup>st</sup>, we did not assume any TROPiCS-02-related launches until late 2022 at the earliest.
- We expect an immaterial impact to Operating Expenses in 2022 with the trial still ongoing and our planned studies on-track.
- We are evaluating the impact to our in-process R&D on the balance sheet, and that could impact our GAAP EPS guidance. We expect to update you on our Q1 call.

**Q7. Is there any change to your goal that 1/3 of Gilead's revenue will derive from oncology products in 2030?**

- We remain confident in that goal.
- The 2030 goal was risk-adjusted and – given the nature of our business – allowed for a range of outcomes across our portfolio.

**Q8. Are there any changes to the Trodelvy program?**

- We are very confident in Trodelvy's activity and pan-tumor potential given ASCENT trial data for mTNBC and TROPiCS-02 for mUC – and the approvals that followed – in addition to TROPiCS-02 which showed statistically significant PFS.
- TROPiCS-02 is ongoing, in addition to a range of other Trodelvy trials, including 1L TNBC and NSCLC in combination with Keytruda, or in our other ongoing later-line trials in bladder cancer and NSCLC. Most of the 20+ oncology trials we plan to initiate this year include Trodelvy.

**Forward-Looking Statements**

This FAQ includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that are subject to risks, uncertainties and other factors, including Gilead's ability to initiate, progress or complete clinical trials involving Trodelvy within currently anticipated timelines or at all; the possibility of unfavorable results from ongoing or additional clinical trials involving Trodelvy; Gilead's ability to submit regulatory applications for new or expanded indications for Trodelvy, including for the treatment of metastatic HR+/HER2- breast cancer, in the currently anticipated timelines or at all; Gilead's ability to receive regulatory approvals in a timely manner or at all, including regulatory approvals of Trodelvy for the treatment of metastatic HR+/HER2- breast cancer and other indications, and the risk that any such approvals may be subject to significant limitations on use; the possibility that Gilead may make a strategic decision to discontinue development of Trodelvy for the treatment of metastatic HR+/HER2- breast cancer and as a result, Trodelvy may never be commercialized for this indication; and any assumptions underlying any of the foregoing. These and other risks, uncertainties and other factors are described in detail in Gilead's Annual Report on Form 10-K for the year ended December 31, 2021, as filed with the U.S. Securities and Exchange Commission. These risks, uncertainties and other factors could cause actual results to differ materially from those referred to in the forward-looking statements. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. The reader is cautioned that any such forward-looking statements are not guarantees of future performance and involve risks and uncertainties, and is cautioned not to place undue reliance on these forward-looking statements. All forward-looking statements are based on information currently available to Gilead, and Gilead assumes no obligation and disclaims any intent to update any such forward-looking statements.