

## Q123 Financial Results

April 27, 2023



### Forward-Looking Statements

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### Contents

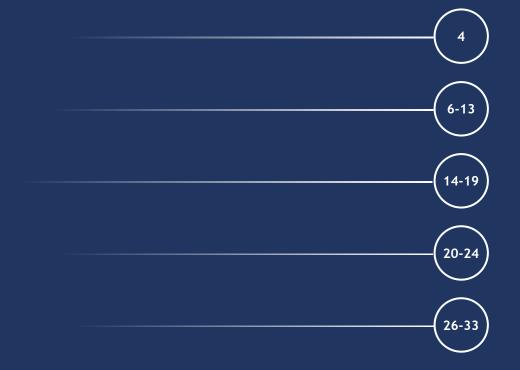
Q123 Key Takeaways

Commercial Results

**CMO Updates** 

**Financial Results** 

**Appendix** 





### Gilead Q123 Key Takeaways

#### Financial Results

- Total Product Sales, excl. Veklury, +15% YoY to \$5.7B, with strong HIV and Oncology growth
- Total HIV +13% YoY strong growth amid seasonal dynamics, with Biktarvy +24% YoY to \$2.7B
- Oncology +59% YoY to \$670M driven by Cell Therapy and Trodelvy
- Operating expenses driven by higher clinical trial activities, including 22 Phase 3 trials<sup>1</sup>

#### **Regulatory Activity**

- Trodelvy approved in U.S. for pre-treated HR+/HER2- mBC
- Continue to expect MAA decision on Trodelvy for pre-treated HR+/HER2- mBC in 2H23

#### Pipeline Execution

- Positive Phase 3 ZUMA-7 overall survival data shared for Yescarta
- Positive Phase 1b data for lenacapavir plus bNAbs at CROI
- Positive Phase 1 data for obeldesivir (GS-5245) shared at ECCMID
- 10 trials achieved FPI, including OAKTREE for obeldesivir and ZUMA-23 for 1L LBCL
- Completed Tmunity acquisition, adding solid tumor programs, manufacturing & technology platform



### 2023 Focus: Select Key Catalysts Across Portfolio

1H23

$\sim$	Completed	
	completed	

0	On	Track
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Program	Trial	Indication	Update	Status	Program	Trial	Indication	Update	Status
	TROPiCS-02	HR+/HER2- mBC	sBLA decision	$\bigcirc$	Vacanta	ZUMA-23	1L HR LBCL	Phase 3 FPI	
Trodelvy	EVOKE-03	1L NSCLC	Phase 3 FPI	•	Yescarta	ZUMA-24	2L LBCL OPT	Interim phase 2 update	0
	ASCENT-05	Adjuvant TNBC	Phase 3 FPI	•	Obeldesivir	OAKTREE	COVID-19 standard risk	Phase 3 FPI	<b>②</b>
Domvanalimab	ARC-7	1L NSCLC	Phase 2 update	0	Len / isl oral	NCT05052996	HIV LA VS	Phase 2 FPI (restart)	•

### 2H23

Program	Trial	Indication	Update	Status	Program	Trial	Indication	Update	Status
Trodelvy	TROPiCS-02	HR+/HER2- mBC	MAA decision	0	Len / bic oral	ARTISTRY-1	HIV VS TE	Phase 2 update	0
Trodelvy	ASCENT-07	HR+/HER2- chemo-naïve mBC	Phase 3 FPI	0	Lenacapavir	PURPOSE 3	HIV PrEP	Phase 2 FPI	0
Etrumadenant	ARC-6	mCRPC	Interim phase 2 update	0	Lenacapavir	PURPOSE 4	HIV PrEP	Phase 2 FPI	0
Etrumadenant	ARC-9	mCRC	Interim phase 2 update Bulevirtide	Bulevirtide	MYR204	HDV Finite Tx	Phase 2 update	0	
Magrolimab	ENHANCE	1L HR MDS	Interim phase 3 update	0	Tilpisertib fosmecarbil	PALEKONA	Ulcerative Colitis	Phase 2 FPI	0





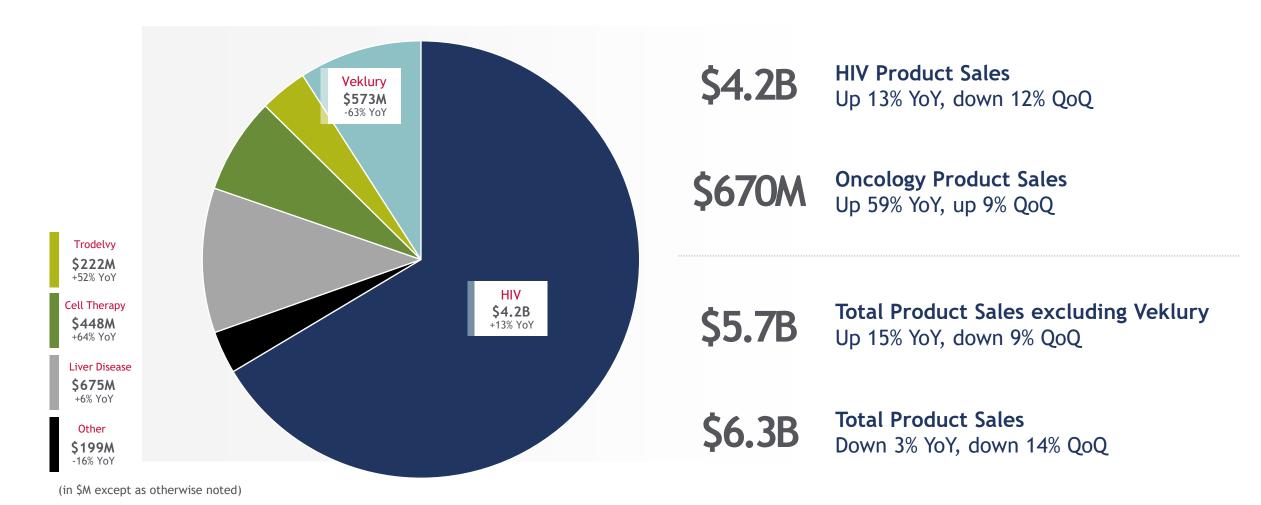
## Commercial Results & Market Dynamics



Johanna Mercier
Chief Commercial Officer



### Robust HIV and Oncology Growth YoY in Q123





### HIV: Strong Demand Amid Seasonal Dynamics

#### Product Sales (\$M)



#### Solid Q123 Growth of +13% YoY

- YoY due to favorable pricing dynamics, higher demand and lower inventory draw-down
- QoQ decline due to seasonal inventory and pricing dynamics, offset by higher demand
- Sunlenca for HTE now available in the U.S. and Europe

#### Market Growth Continues YoY

- U.S. treatment market up ~2% with Europe up ~4%
- U.S. PrEP market up ~19%



### Leadership Across HIV Treatment & PrEP





Q123 sales: \$2.7B; +24% YoY, -8% QoQ

>46%

3%

U.S. Treatment Market Share

U.S. Market Share Gain YoY

+24% YoY due to higher demand and favorable pricing and inventory dynamics

**-8% QoQ** due to seasonal inventory and pricing dynamics, offset by higher demand

Q123 sales: \$449M; +20% YoY, -16% QoQ

>40%

+14%

U.S. PrEP Market Share U.S. Descovy for PrEP Demand Growth YoY

+20% YoY due to higher demand and favorable pricing

-16% QoQ due to seasonal pricing and inventory dynamics, offset by higher demand



### Liver Disease: Maintaining Position in Viral Hepatitis

#### Product Sales (\$M)















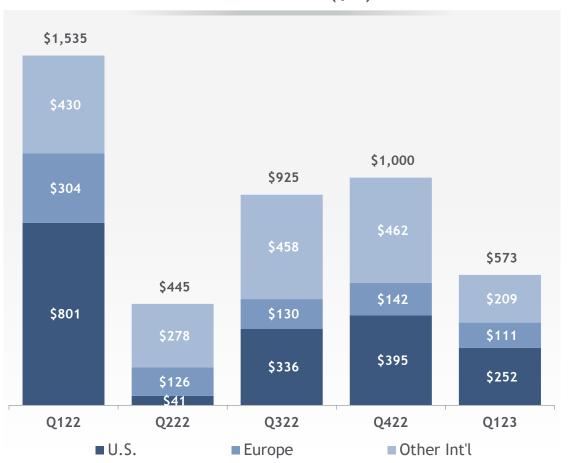
Q123 sales +6% YoY; -3% QoQ

- +6% YoY primarily due to higher demand and timing of DOC HCV purchases in the U.S.
- -3% QoQ primarily due to lower HBV-related channel inventory in the U.S., partially offset by timing of HCV orders in Europe



### Veklury: Solid Share Despite Lower Hospitalizations

#### Product Sales (\$M)





>50%

~13M

U.S. hospitalized patients treated for COVID<sup>1</sup>

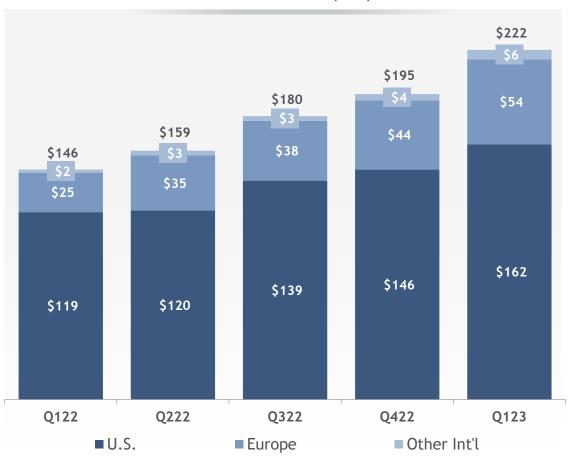
People treated with remdesivir to date<sup>2</sup>

 Obeldesivir<sup>3</sup> Phase 3 trials underway in non-hospitalized patients with COVID-19 who are deemed high-risk or standard-risk



### Trodelvy: Expanding Breast Cancer Options

#### Product Sales (\$M)





\$222M

+52%

+14%

Sales in Q123

YoY Growth

QoQ Growth

- Solid U.S. demand, up 7% QoQ
- FDA approval received for pre-treated HR+/HER2- mBC in February 2023
- EC decision expected in 2H23



### Cell Therapy: Demand Drives YoY Growth

#### Product Sales (\$M)





#### Q123 sales +70% YoY; Up 6% QoQ

 YoY growth driven by higher demand across 2L and 3L R/R large B-cell lymphoma, as well as favorable pricing dynamics in Europe



#### Q123 sales +40% YoY; +8% QoQ

 YoY growth driven by higher demand for R/R mantle cell lymphoma and R/R adult acute lymphoblastic leukemia





## **CMO Updates**



Merdad Parsey, MD, PhD
Chief Medical Officer

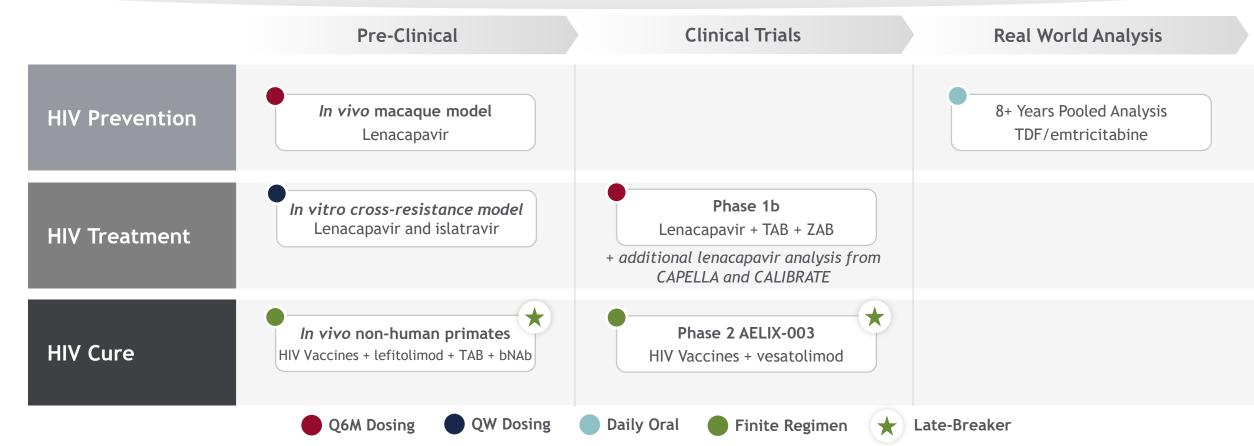


### Gilead Demonstrates Leadership in HIV at CROI

Wirology Abstracts at CROI 2023<sup>1</sup>

HIV Oral Presentations at CROI 2023

Clinical Programs in HIV





### Committed to Continued Efforts in COVID-19



#### **Real World Analyses**

- Reduced 30-day hospital readmission across variants<sup>1</sup>
- Improves 14-day and 28-day survival, including in immunocompromised patients<sup>2</sup>

### **Obeldesivir**

(GS-5245)







High-Risk

~45%

Diagnosed patients with COVID-19 at high-risk<sup>3</sup>

~55%

Diagnosed patients with COVID-19 at standard-risk4

2 ongoing registrational Phase 3 studies **OAKTREE FPI in Q123** 



Study Dosing: Obeldesivir one tablet, twice-daily for 5 days



### Trodelvy: Cornerstone of Solid Tumor Portfolio



#### **Breast Cancer**



- FDA Approval in Pre-treated HR+/HER2- mBC and EC Decision Expected 2H23
- Now Approved in 47 Markets for mTNBC

Ongoing Phase 3 **Trials** 

#### **NSCLC**

#### **Expanding** ∠ ✓ NSCLC Program¹

- EVOKE-01 (2-3L) Data in 2024
- EVOKE-03 (1L) FPI

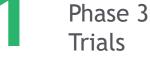
Ongoing Phase 3 Trials

#### Bladder Cancer



- TROPHY Cohort 1 Data Update
- TROPHY Cohort 2-3 Primary Analysis

Ongoing Phase 3 Trials





### Cell Therapy Portfolio Continues to Expand

#### **Key Updates:**



- Investment in Rapid Manufacturing & Novel CAR T Technology

  TMUNITY Transaction Closed Feb 2023
- ZUMA-7: 2L LBCL Yescarta Shows 5-Year OS Benefit
- ZUMA-24: 2L LBCL OPT
  Interim Phase 2 Update Expected in Q223

#### Hematological Cancers Acute Acute Large B-cell Follicular Mantle Cell Myeloid Lymphocytic Lymphoma Lymphoma Lymphoma Leukemia Leukemia Multiple Rare B-cell Myeloma<sup>1</sup> **Malignancies Solid Tumors** Triple-Non-small negative **Pancreatic** Hepatocellular **Ovarian** Cell Lung Cancer<sup>2</sup> Cancer<sup>2</sup> Carcinoma Breast Cancer<sup>2</sup> Cancer<sup>2</sup> Approved or Accelerated Approval Clinical Programs Potential Diseases



### 2023 Focus: Select Key Catalysts Across Portfolio

1H23





Program	Trial	Indication	Update	Status	Program	Trial	Indication	Update	Status
	TROPiCS-02	HR+/HER2- mBC	sBLA decision	$\bigcirc$	Vacanta	ZUMA-23	1L HR LBCL	Phase 3 FPI	
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### 2H23

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Tradalyy	TROPiCS-02	HR+/HER2- mBC	MAA decision	0	Len / bic oral	ARTISTRY-1	HIV VS TE	Phase 2 update	0
Trodelvy	ASCENT-07	HR+/HER2- chemo-naïve mBC	Phase 3 FPI	0	Lenacapavir	PURPOSE 3	HIV PrEP	Phase 2 FPI	0
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Magrolimab	ENHANCE	1L HR MDS	Interim phase 3 update	0	Tilpisertib fosmecarbil	PALEKONA	Ulcerative Colitis	Phase 2 FPI	0





## Financial Results



Andrew Dickinson
Chief Financial Officer



### Q123 Strong Base Sales Growth of 15% YoY

#### Product Sales (\$M)



#### Total Product Sales down 3% YoY

- Veklury decline partially offset by base business growth
- Net of hedges, FX negatively impacted Total Product Sales by ~\$106M YoY, or ~2%

#### Product Sales excl. Veklury up 15% YoY

- Double-digit growth in HIV and Oncology
- Excluding FX headwind of ~\$81M, Product Sales excluding Veklury was up 16% YoY



### First Quarter Non-GAAP Data

In millions, except percentages and per share amounts	Q122	Q123	YoY Change
COGS	825	871	-
Product Gross Margin	87%	86%	-
R&D <sup>1</sup>	1,150	1,439	+25%
Acquired IPR&D1	8	481	N/M
SG&A	1,083	1,318	+22%
Non-GAAP Costs and Expenses	\$3,066	\$4,109	34%
Non-GAAP Operating Income	\$3,524	\$2,243	-36%
Operating Margin	53%	35%	
Effective Tax Rate	18%	19%	
Non-GAAP Net Income	\$2,676	\$1,725	-36%
Non-GAAP Diluted EPS	\$2.12	\$1.37	-35%
Shares used in per share calculation-diluted	1,262	1,261	

#### **Expenses**

- R&D primarily driven by increased clinical activities
- Acquired IPR&D in Q123 includes expenses associated with Tmunity, Arcellx and Nurix transactions
- SG&A primarily driven by Oncology commercial expansion and investments, higher BPD fee and corporate activities

#### Operating Margin & EPS

 Decreases reflect higher operating expenses and lower revenues, primarily due to Veklury



### 2023 Guidance

	2 February 2023	27 April 2023
Total Product Sales	\$26.0B - \$26.5B	No change
Product Sales ex-Veklury	\$24.0B - \$24.5B	No change
Veklury Sales	~\$2.0B	No change
Non-GAAP		
Product Gross Margin	86%	No change
R&D Expense	High single-digit % growth	Low double-digit % growth
Acquired IPR&D	\$0.7B	No change
SG&A Expense	Low single-digit % decline	No change
Operating Income	\$11.0B - \$11.6B	No change
Effective Tax Rate	~20%	No change
Diluted EPS	\$6.60 - \$7.00	No change
GAAP Diluted EPS	\$5.30 - \$5.70	\$4.75 - \$5.15

#### **Product Sales Guidance Unchanged**

Base business growth of 4% to 6% YoY

#### **Non-GAAP Operating Expenses**

Increased investment R&D to reflect greater clinical trial activities

#### **GAAP Diluted EPS**

 Update from last quarter reflects additional intangible asset amortization following approval of Trodelvy for pre-treated HR+/HER2- mBC and changes in the fair value of equity investments



### Capital Priorities Unchanged: Returned ~\$1.4B in Q1

\$969M

Dividends Paid in Q123

\$400M

Shares Repurchased in Q123 4.9M shares at average \$82.29

- Ontinue to invest in our business and R&D pipeline while managing expenses
- Continue ordinary course partnerships and business development transactions
- Grow our dividend
- Repurchase shares to offset dilution and opportunistically reduce share count





## **Q&A**



Daniel O'Day

Chairman and
Chief Executive Officer



Andrew Dickinson
Chief Financial Officer



Johanna Mercier
Chief Commercial Officer



Merdad Parsey, MD, PhD
Chief Medical Officer





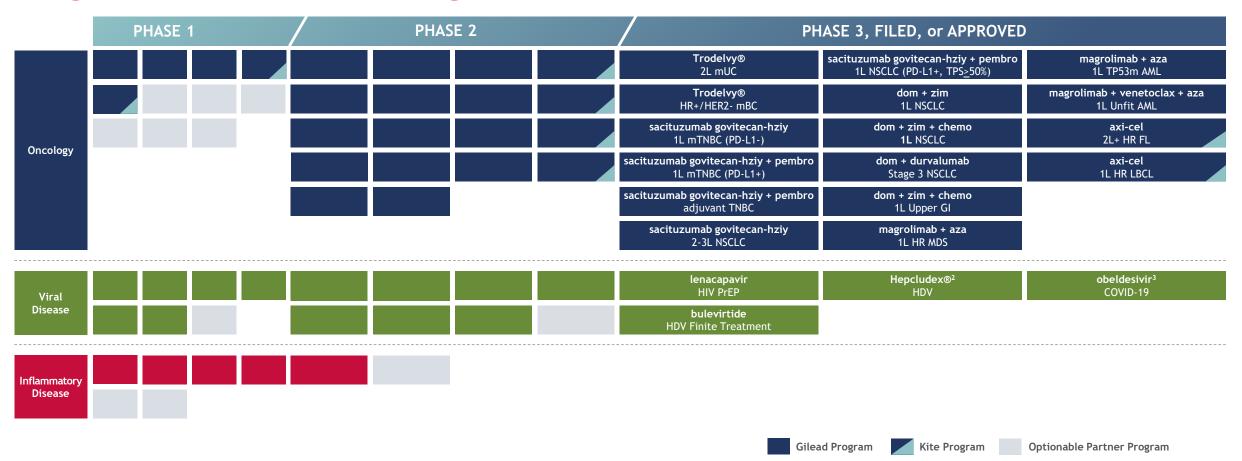
## Appendix

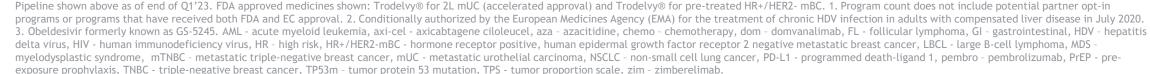


### Robust Pipeline with Upcoming Catalysts

61 Clinical stage programs<sup>1</sup>

11 Potential clinical stage opt-in assets







### **Oncology Cell Therapy Pipeline**

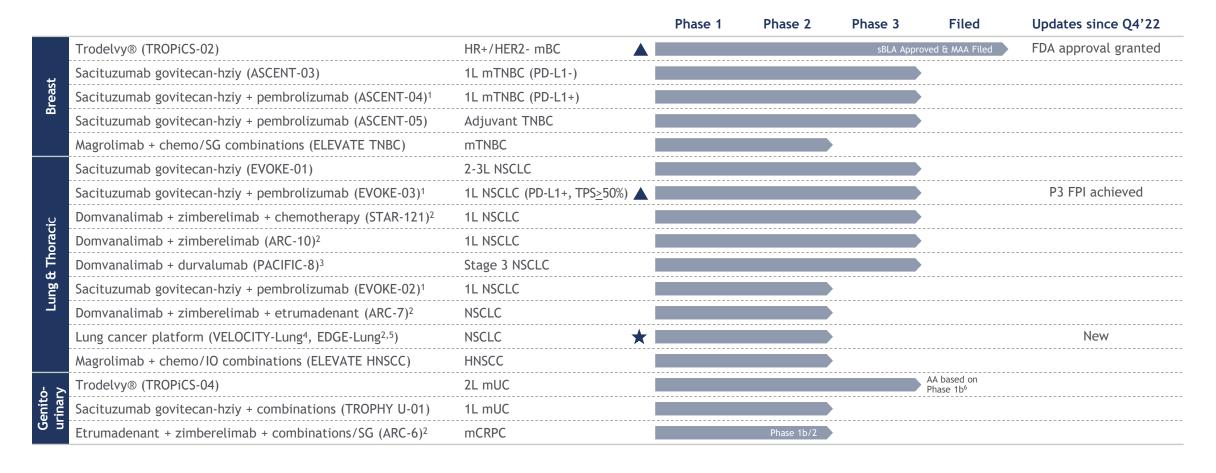


			Phase 1	Phase 2	Phase 3	Filed	Updates since Q4'22
	Axicabtagene ciloleucel (ZUMA-22)	2L+ HR FL				·	
	Axicabtagene ciloleucel (ZUMA-23)	1L HR LBCL				·	P3 FPI achieved
ару	Axicabtagene ciloleucel (ZUMA-24)	2L LBCL Outpatient					
hera	Brexucabtagene autoleucel (ZUMA-4)	Pediatric ALL			>		
ell T	Brexucabtagene autoleucel (ZUMA-25)	Basket (Rare B-cell Malignancies)					
ဗီ	CAR-T ddBCMA (KITE-772) (iMMagine-1)¹	R/R MM			<b>&gt;</b>		
	CLL-1 (KITE-222)	R/R AML		<b>•</b>			
	CD19/20 bicistronic (KITE-363)	3L+ LBCL		•			
Opt- ins	Galapagos	Advanced Cancers	2 clinical stage				



### **Oncology Pipeline 1/2**

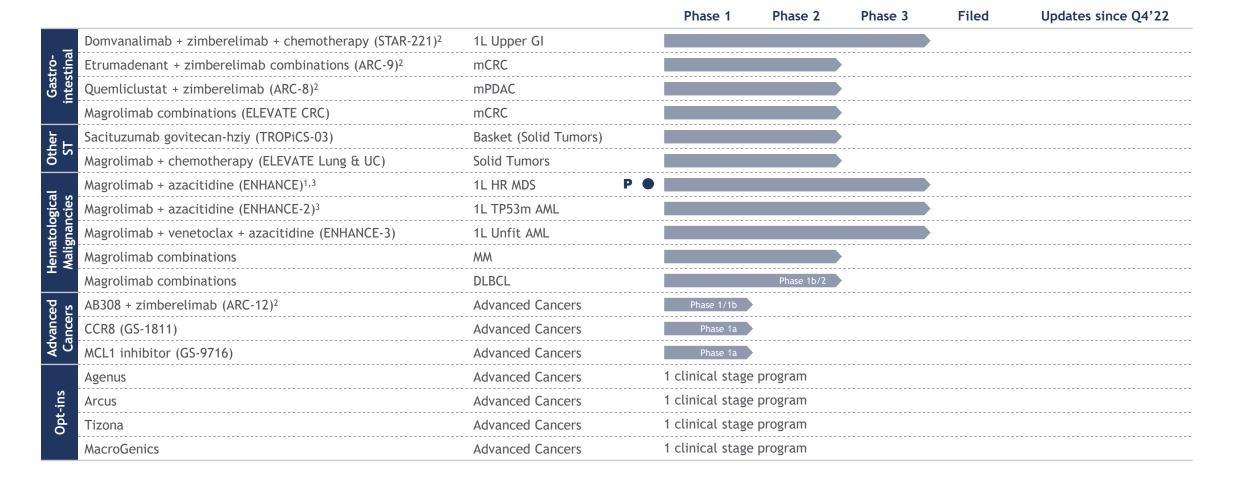




Pipeline shown above as of end of Q1'23. 1. In collaboration with Merck. 2. In collaboration with Arcus Biosciences. 3. In collaboration with Arcus Biosciences and AstraZeneca. 4. VELOCITY-Lung includes combinations of domvanalimab, etrumadenant, zimberelimab, and sacituzumab govitecan-hziy. 5. EDGE-Lung includes immunotherapy-based combinations of quemliclustat, domvanalimab, and zimberelimab. 6. The FDA granted accelerated approval for Trodelvy® in 2L mUC Apr 2021 based on TROPHY U-01 Phase 1b trial. AA - accelerated approval, Chemo - chemotherapy, FPI - first patient in (patient screening + consent), HNSCC - head and neck squamous cell carcinoma, HR+/HER2-mBC - hormone receptor positive, human epidermal growth factor receptor 2 negative metastatic breast cancer, IO - immuno-oncology, MAA - marketing authorization application, mCRPC - metastatic castrate-resistant prostate cancer, mTNBC - metastatic triple-negative breast cancer, mUC - metastatic urothelial carcinoma, NSCLC - non-small cell lung cancer, PD-L1 - programmed death-ligand 1, sBLA - supplemental biologics license application, SG - sacituzumab govitecan-hziy, TNBC - triple-negative breast cancer, TPS - tumor proportion scale.

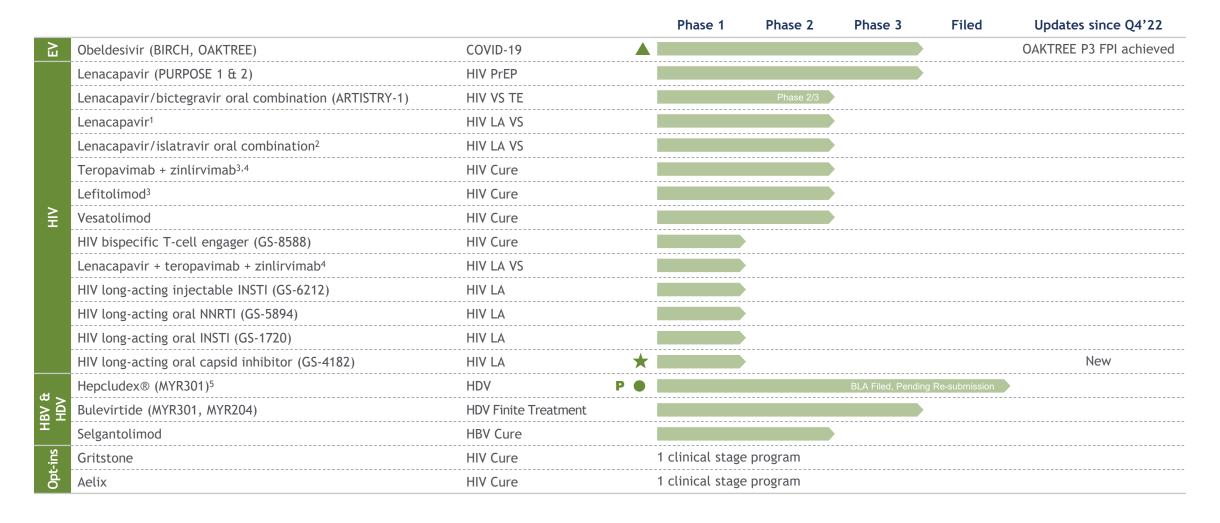


### **Oncology Pipeline 2/2**





### Viral Diseases Pipeline





### Inflammatory Diseases Pipeline

			Phase 1	Phase 2	Phase 3	Filed	Updates since Q4'22
ory	Tilpisertib fosmecarbil	Inflammatory Bowel Disease		<b>&gt;</b>			
nato	Edecesertib	Lupus		·			
lamr Dise	α4β7 inhibitor (GS-1427)	Inflammatory Bowel Disease		·			
<u>lu</u>	BTLA agonist (GS-0272)	Inflammatory Diseases		·			
Fib-	Cilofexor/firsocostat/semaglutide combination <sup>1</sup>	NASH			<b>&gt;</b>		
Opt-	Galapagos	Inflammatory and Fibrotic Diseases	3 clinical stage	programs			



# GAAP to Non-GAAP Reconciliation of Outstanding Adjusted Debt and Adjusted EBITDA

in billions where applicable	Mar 31, 2022	Jun 30, 2022	Sep 30, 2022	Dec 31, 2022	Mar 31, 2023
Total Debt, net	\$26.21	\$26.22	\$25.22	\$25.23	\$25.24
Debt Discounts, Premiums and Issuance Costs	0.17	0.17	0.17	0.16	0.16
Liability related to sale of future royalties <sup>1</sup>	(1.13)	(1.14)	(1.14)	(1.14)	(1.15)
Total Adjusted Debt <sup>1, 2</sup>	\$25.25	\$25.25	\$24.25	\$24.25	\$24.25

#### **Last Twelve Months Ended**

	Mar 31, 2022	Jun 30, 2022	Sep 30, 2022	Dec 31, 2022	Mar 31, 2023
Net Income attributable to Gilead	\$4.52	\$4.14	\$3.33	\$4.59	\$5.58
Add: Interest Expense <sup>3</sup> & Other Income (expense), net	1.35	1.46	1.46	1.52	1.58
Add: Tax	1.37	1.44	1.23	1.25	1.73
Add: Depreciation	0.32	0.32	0.32	0.32	0.34
Add: Amortization <sup>4</sup>	2.18	2.18	2.16	2.08	2.05
Add: Acquired in-process research and development expenses <sup>5</sup>	0.11	0.32	0.71	0.84	1.30
Add: In-process research and development impairment	2.70	2.70	2.70	2.70	0.00
Add: Litigation matters <sup>6</sup>	1.25	1.25	1.25	0.00	0.00
Adjusted EBITDA <sup>7,8</sup>	\$13.80	\$13.80	\$13.17	\$13.30	\$12.58
Adjusted Debt to Adjusted EBITDA ratio <sup>7, 8</sup>	~1.83x	~1.83x	~1.84x	~1.82x	~1.93x

<sup>1</sup> Represents a funding agreement with RPI Finance Trust that was assumed as part of our acquisition of Immunomedics received cash in exchange for perpetual, tiered royalty payments on worldwide sales of Trodelvy. This funding agreement is classified as debt. 2 Adjusted Debt excludes future tax payments related to remaining obligations for the deemed one-time repatriation transition tax from the Tax Cuts and Jobs Act, totaling \$3.5 billion as of March 31, 2023. These future tax payments are expected to be \$0.9 billion in 2023, \$1.2 billion in 2023, \$1.2 billion in 2025, 3 Total interest expenses and amortization of inventory step-up charges beginning in Q4 2020, includes acquisition-related amortization of inventory step-up charges. 5 Beginning in Q4 2022, the Acquired IPR&D expenses line item and the collaboration payments made prior to regulatory approval, which were previously included in R&D expenses line item, as well as initial costs to acquire rights to IPR&D projects with no alternative future use through collaborations were recast to reflect this change. For all periods presented, Adjusted EBITDA excludes only initial costs of externally developed IPR&D projects with no alternative future use, acquired directly in a transaction other than a business combination, including upfront payments related to various collaborations and the initial costs of influences and analysts to assess the overall operating performance in the context of financial leverage.

