

## JP Morgan Healthcare Conference

Daniel O'Day Chairman and Chief Executive Officer

January 11<sup>th</sup>, 2021



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## // CILEAD



Building on our legacy to create new possibilities...

To meet significant patient need in virology, oncology, and inflammation

# Maintaining the highest bar for innovation, combining entrepreneurial biotech spirit with global scale and disciplined focus



Transformative Therapies



Employer & Partner of Choice



Shareholder Value



## 2020: Building for Growth

#### 2020 Strategy Execution Highlights



Completed
significant BD
activity to enhance
commercial portfolio
and clinical pipeline



Increased pipeline size by 50% overall<sup>1</sup> with notable opt-in opportunities



Re-prioritized programs and created new governance for the portfolio

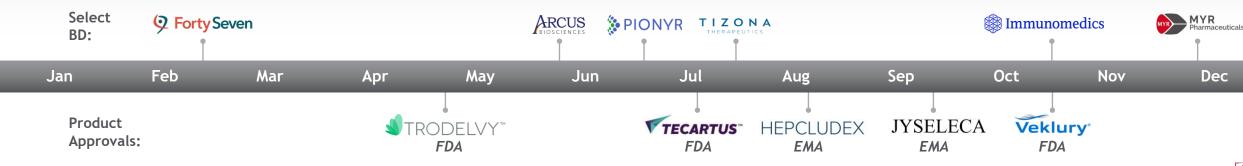


Five new product approvals<sup>2</sup>, including COVID-19 treatment, Veklury



Recruited key talent (research, clinical development, data science, commercial strategy) with significant build in oncology

#### 2020 Select Milestones





## Full Year 2020 Guidance

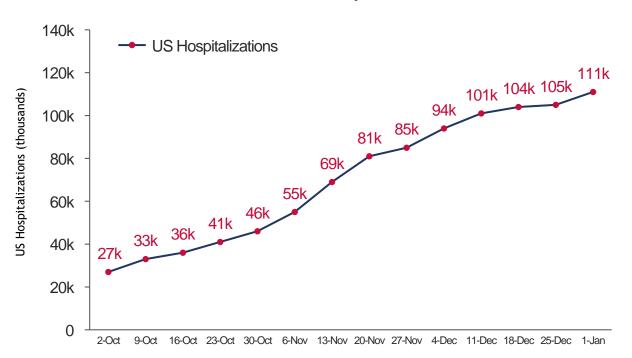
in millions, except percentages and per share amounts  October 28, 20		Updated January 11, 2021	Comments				
Product Sales	\$23,000 - \$23,500	\$24,300 - \$24,350					
Product Sales excluding Veklury		\$21,500 - \$21,525	Reflects strong performance in-line with prior expectations				
Veklury		\$2,800 - \$2,825	Reflects increased hospitalization rates and utilization during the most recent COVID surge				
Non-GAAP							
Product Gross Margin	86% - 87%	~86.5%					
R&D Expense <sup>1</sup>	Mid-teens percentage growth	~20% growth	<ul> <li>Reflects expense for obligations under the previously disclosed new commercialization and development agreement for Jyseleca® (filgotinib) with Galapagos NV</li> </ul>				
SG&A Expense <sup>2</sup>	Low double-digit percentage growth	~10% growth	In-line with prior expectations				
Operating Income	\$10,700 - \$11,200	\$11,650 - \$11,750					
Effective Tax Rate	~20%	~19% - 19.5%					
Diluted EPS	\$6.25 - \$6.60	\$6.98 - \$7.08					
GAAP Diluted Earnings (Loss) Per Share	\$(0.25) - \$0.10	\$(0.08) - \$0.02					



## Role of Veklury (remdesivir) More Critical Than Ever

#### US COVID-19 Hospitalizations increased 4x in Q4

Q4 2020 US Hospitalizations<sup>1</sup>



Only FDA Approved Antiviral for COVID-19



~1 in 2

Patients hospitalized in the US treated with Veklury<sup>2</sup>

~1M

US Patients treated with Veklury<sup>2</sup>

40+

Interventional or observational studies<sup>3</sup>

<sup>1.</sup> Source: Johns Hopkins University COVID-19 Tracker, COVID Tracking Project, IntegriChain 852 and 867 and HHS admissions; 2. Patients treated and utilization estimates based on volume donated and shipped for distribution within the US, assumed average treatment course of 6.25 vials/patient); 3. Interventional or observational studies registered on clinicaltrials.gov either completed, underway or planned evaluating the use of remdesivir alone; as background therapy; or in combination with other agents in patients with COVID-19



## Clear Path to Near and Long-Term Growth

**Excluding Veklury (remdesivir)** 

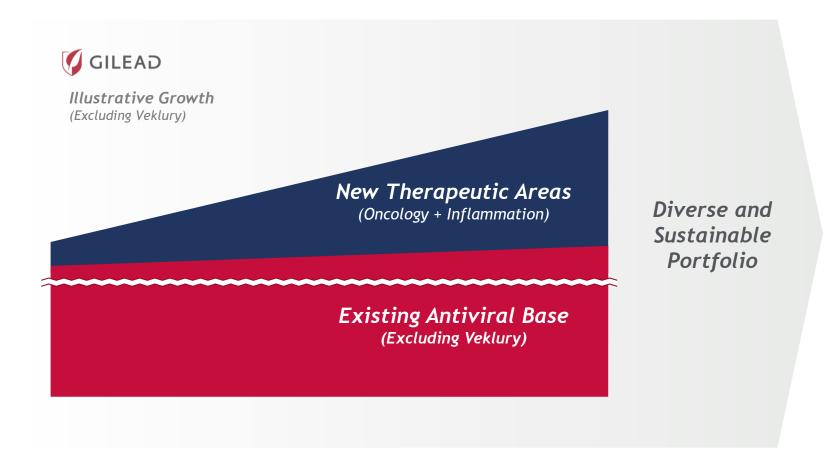
Deliver on Opportunities in New Therapeutic Areas



Continue Leadership in Antivirals



Prioritize and Execute
Across Portfolio





## Growth Driven by Internal and External Innovation

#### Near- to Mid-term Growth<sup>1</sup>

#### Mid- to Long-term Growth<sup>1</sup>





magrolimab



lenacapavir



Internal assets + Opt-ins:

ARCUS PIONYR TIZONA
THERAPPHYTICS



Cell Therapy

Internal assets + Galápagos
Opt-in Opportunities



*Inflammation* 

Oncology

Antivirals (Excluding Veklury)

2021



2030+

## Clear Path to Near and Long-Term Growth

**Excluding Veklury (remdesivir)** 

Deliver on Opportunities in New Therapeutic Areas



Continue Leadership in Antivirals



Prioritize and Execute
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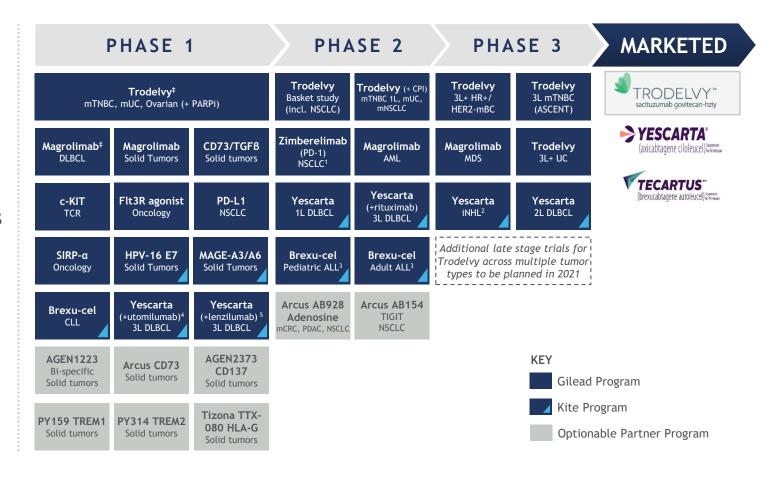




## Oncology Now an Important New Pillar of Growth

#### **Key Oncology Portfolio Features**

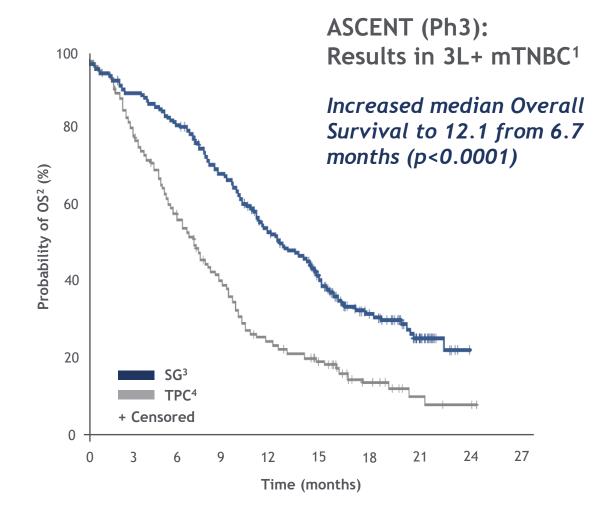
- Multiple new, high-quality therapies across all stages of development and with diverse MOAs
- Approved transformational medicines provide benefit in hematology and solid tumors
- Enhanced oncology expertise through acquisitions supplement Gilead's capability and improve ability to execute for growth





# Trodelvy<sup>TM</sup> as a Cornerstone With Immediate Benefits and Long-Term Potential

- TRODELYY™ sacituzumab govitecan-hziy is a foundational therapy offering immediate transformational benefits in 3L+ mTNBC
- sBLAs filed with FDA for full approval in 3L mTNBC and accelerated approval in mUC 3L
- EMA MAA filing in 3L+ mTNBC expected Q1'21
- PFS data readout in 2H 2021 for TROPiCS-02 Phase 3 trial in 3L+ HR+/HER2- mBC (OS data in 2023)





# Expansion Plans Across Multiple Tumor Types and Lines of Therapy



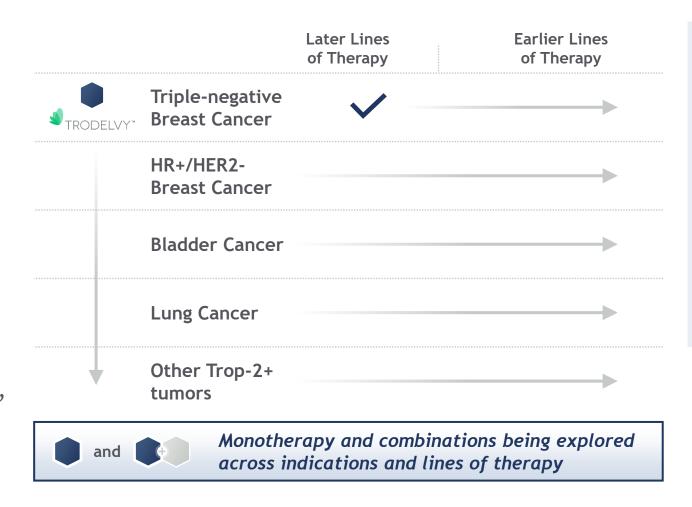
#### **Broad Applicability**

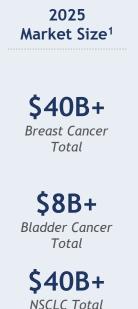
Trodelvy targets Trop-2 which is expressed in multiple cancers suggesting broad applicability



#### **Combination Potential**

Opportunity to combine with checkpoint inhibitors, targeted agents, and/or chemotherapy







## Clear Path to Near and Long-Term Growth

**Excluding Veklury (remdesivir)** 

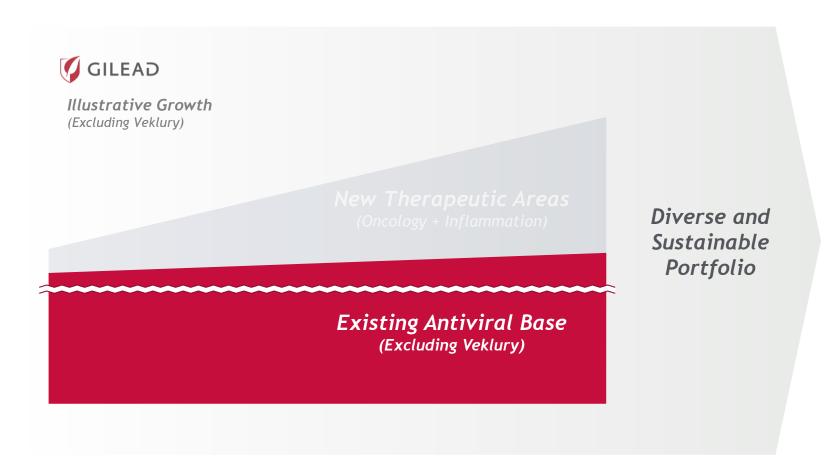
Deliver on Opportunities in New Therapeutic Areas



Continue Leadership in Antivirals



Prioritize and Execute
Across Portfolio





## Pioneering in HIV: Past, Present, and Future

#### Once-a-Day Oral

Legacy Single-Tablet Regimens















Current Single-Tablet Regimens







#### Long-Acting

Investigational Long-Acting Agent

## Lenacapavir 6-month dosing

Being studied for treatment and prevention





## Confident in Biktarvy Near- and Mid-Term Growth



#1

Prescribed Regimen in US and Other Regions<sup>1</sup>

64%

y/y Revenue Growth O3'20 vs. O3'19

Consensus Projected Peak Sales<sup>2</sup> of

\$>10B

US Market Exclusivity Through

2033



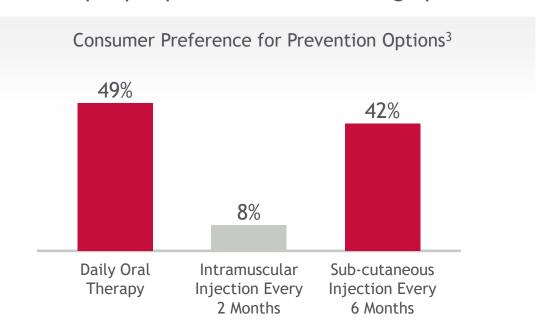
## Lenacapavir Could Be A Long-Acting Game-Changer

#### Lenacapavir Profile Highlights

- Potential first-in-class HIV capsid inhibitor
- **Highly potent** investigational agent, dosing as infrequently as **every 6 months**
- Significantly reduced viral load in proof-ofconcept Phase 2/3 hTE<sup>1</sup> trial ©copello
  - Anticipate FDA submission in 2H 2021
- FDA Breakthrough Designation<sup>2</sup>

#### 6-month Dosing Unlocks Significant Potential

 Assuming equal safety, efficacy, and cost, more people prefer 6-month dosing option





# Accelerating Development of Lenacapavir in HIV Long-Acting Treatment and Prevention

#### **Treatment**

- 6-month data in treatment naïve population expected 2H 2021 Calibrate
- Exploring internal and external partners for optimal combination regimens
  - Flexible dosing profile (oral and parenteral) supports possibility of multiple long-acting duration options
  - Potential combination regimen(s) expected to enter clinic in next 12-18 months

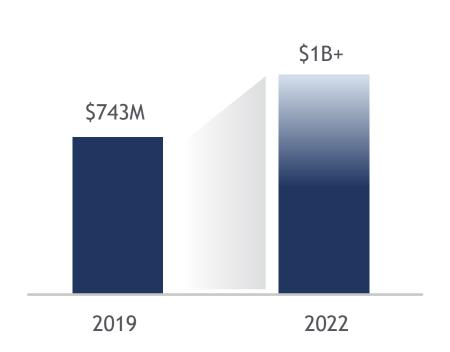
#### **Prevention**

- Monotherapy may be sufficient
- 6-month dosing could meet significant unmet need, materially increasing market size
- Studies to initiate in 2021:
  - Cisgender men, transgender women, transgender men, and gender non-binary people who have sex with men 1H 2021
  - Adolescent girls and young women 2H 2021



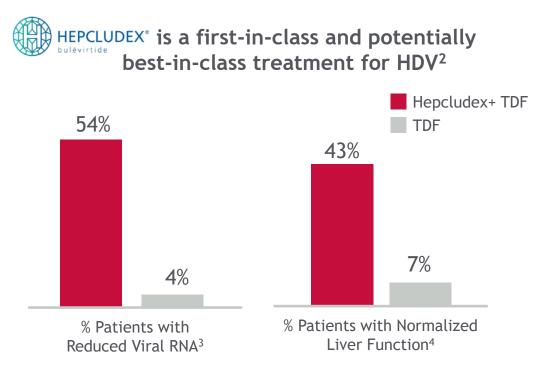
## Progress in Viral Hepatitis Further Strengthens Core Antiviral Business

#### Expected HBV Sales of \$1B+ by 2022<sup>1</sup>



Continuing to lead in *HBV Cure*: Ph2 combination studies to initiate this year

#### Novel HDV Therapy, Synergies with HBV



US BLA submission expected in 2H 2021; more approvals, including in Asia, expected in 2023+



## Clear Path to Near and Long-Term Growth

**Excluding Veklury (remdesivir)** 

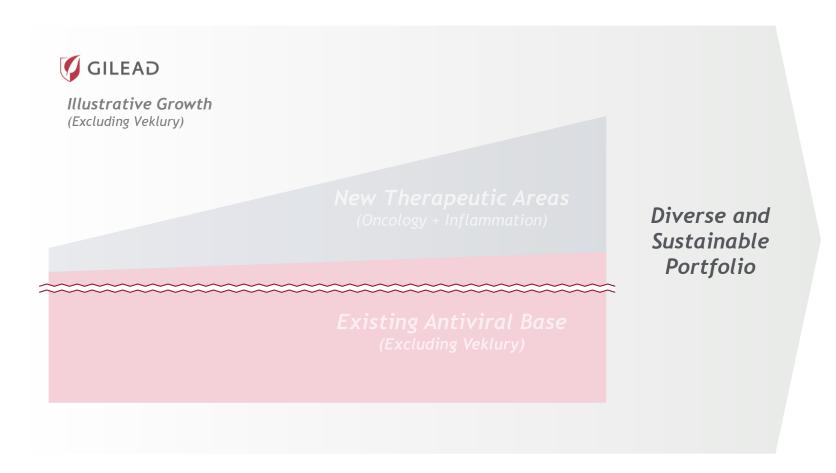
Deliver on Opportunities in New Therapeutic Areas



Continue Leadership in Antivirals



Prioritize and Execute
Across Portfolio





## Sustainable, More Diverse Portfolio

#### **Key Features of Transformed Portfolio**



Growth drivers have high probability of success from on-market status (e.g. Trodelvy) or compelling data (e.g. lenacapavir)



Smart deal structures de-risk investments, providing opt-in rights after proof-of-concept data is in hand

#### Prioritization to Drive Value



>50% expansion of pipeline<sup>1</sup> with higher value programs provides opportunity to **re-prioritize** programs of less value

#### Select **re-prioritization** examples:

- Filgotinib: stopped clinical trials in psoriatic arthritis, ankylosing spondylitis, and non-infectious uveitis
- NASH: not pursuing pivotal trial in favor of Phase 2b
- Outlicensing of SYK inhibitor



### Select 2021 Milestones

#### Lenacapavir capsid inhibitor Phase 3 initiation for PrEP Hepcludex<sup>1</sup> (Bulevirtide) Phase 3 data readout in HDV Trodelvy (Sacituzumab govitecan-hziy) MAA filing in 3L mTNBC Trodelvy (Sacituzumab govitecan-hziy) Anticipated sBLA full approval in 3L mTNBC Trodelvy (Sacituzumab govitecan-hziy) Anticipated sBLA approval in 3L mUC Magrolimab Phase 3 initiation in AML Yescarta (Axi-cel) Phase 3 data read out in 2L DLBCL Yescarta (Axi-cel) Anticipated MAA filing in iNHL Yescarta (Axi-cel) Anticipated sBLA approval in iNHL Tecartus (Brexu-cel) Anticipated sBLA/MAA submission in adult ALL Domvanilimab (TIGIT) Phase 2 interim read out in NSCLC (ARC-7) Ziritaxestat ATX inhibitor Phase 3 futility analysis data read out in IPF



COVID-19 Impact: Some clinical trials continue to be impacted by the pandemic, which may result in delays in achieving milestones.

Viral Diseases Inflammatory Diseases Oncology Regulatory approval or pivotal readout
Lenacapavir capsid inhibitor Anticipated NDA submission in heavily treatment experienced population
Lenacapavir capsid inhibitor Phase 2 data read out for virologically suppressed population
Hepcludex <sup>1</sup> (Bulevirtide) Anticipated BLA submission for HDV
Trodelvy (Sacituzumab govitecan-hziy) Anticipated MAA approval in 3L mTNBC
Trodelvy (Sacituzumab govitecan-hziy) Phase 3 data read out in HR+/HER2- mBC
Magrolimab Phase 1b data read out in MDS
Magrolimab Potential BLA/MAA submission for accelerated approval in MDS
Magrolimab + rituximab Phase 1b/2 interim data read out in 3L+ DLBCL
Yescarta (Axi-cel) Phase 2 data read out in 1L DLBCL

1H 2021

2H 2021



## 2021 Strategic Business Development

2020

18

Strategic Partnerships & Acquisitions<sup>1</sup>

**12** Gilead Molecules<sup>2</sup>

**14+** Opt-in Molecules<sup>2</sup>



Continued focus on transformative science

2021



Execute on opportunities from recent BD activity



Pursue bolt-ons with very high bar, remain opportunistic re: exceptional medicines



## 2021 Capital Allocation

## Guiding Principles

We will:

Continue to invest in our business and R&D pipeline while managing expenses

Grow our dividend and pay down at least \$4B of debt

Repurchase shares



## Summary



Clear path to growth (excluding Veklury) through strategic transformation of our portfolio



Important new pillar of growth in oncology with Trodelvy as cornerstone



Strong antiviral foundation with continued leadership in HIV



Sustainable growth will be driven by continued internal and external innovation

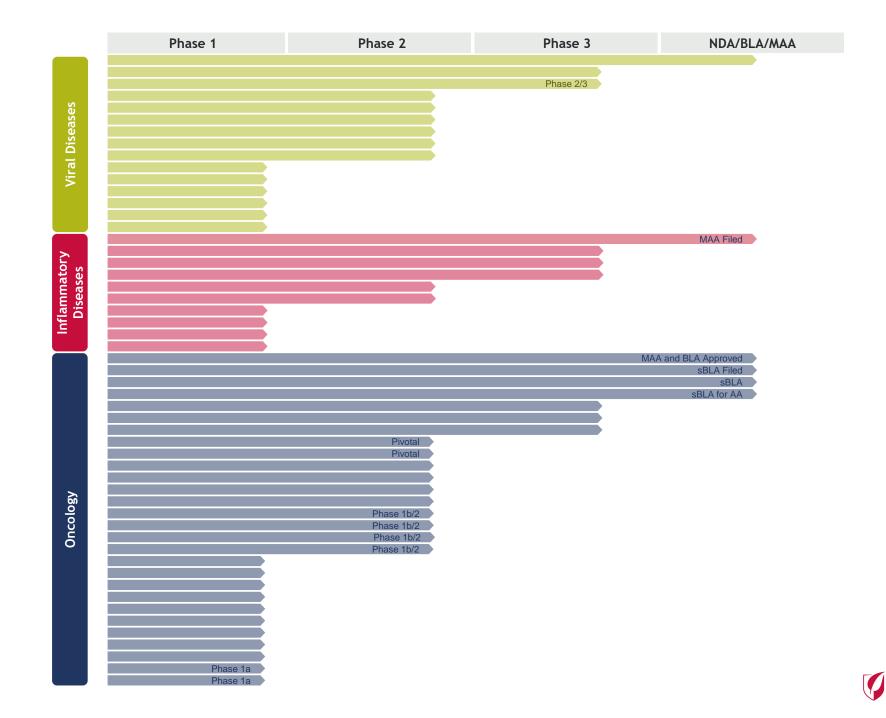
- Financial strength and flexibility to continue strategic BD investments





# Overview of Clinical Pipeline Today

- Clinical stage programs<sup>1</sup>
  18 through BD since Jan '19
- NDA/BLA/MAA filings, P3 and Registrational P2 trials
- Clinical stage NMEs via in-licensing, and acquisitions accounting for 23 programs
- Breakthrough Therapy
  Designations





## Viral Disease Pipeline

			Pre-Cl	inical	Phase 1	Phase 2	Phase 3	Filed	Updates since Q3'20
	Veklury® (remdesivir for injection)	Outpatient COVID-19							Expanded indication
$\geq$	Remdesivir inhaled form (GS-5794)	Outpatient COVID-19							
	Remdesivir sub cutaneous form (GS-5794)	COVID-19							
	Lenacapavir capsid inhibitor (GS-6207)	HIV LA HTE					Phase 2/3		
	Lenacapavir capsid inhibitor (GS-6207)	HIV LA VS					•		
	bNAb combination (GS-5423, GS-2872) <sup>1</sup>	HIV Cure					•		
	Lefitolimod TLR-9 agonist (GS-1703) <sup>1</sup>	HIV Cure					<b>•</b>		
	Vesatolimod TLR-7 agonist (GS-9620)	HIV Cure					•		
>	Elipovimab bNAb (GS-9722)	HIV Cure							
¥	Effector IgG #2 (GS-9723)	HIV Cure							PC → P1
	Unboosted protease inhibitor (GS-1156)	HIV Treatment							
	Long acting bictegravir (GS-9883)	HIV LA							
	Long acting oral combination	HIV LA							
	Lenacapavir capsid inhibitor (GS-6207)	HIV PrEP							
	Hookipa HIV vaccine	HIV Cure							
	Hepcludex® (bulevirtide) <sup>2</sup>	HDV	*				MAA A	Approved	Acquired from MYR <sup>2</sup>
무	Hepcludex® (bulevirtide) <sup>2</sup> + PEG-INF	HDV	*				•		Acquired from MYR <sup>2</sup>
표	Selgantolimod TLR-8 agonist (GS-9688)	HBV Cure					<b>&gt;</b>		
HBV	Oral PD-L1 small molecule (GS-4224)	HBV Cure							
	Hookipa HBV vaccine (GS-6779)	HBV Cure							







## Inflammatory Disease Pipeline

		<b>Pre-Clinical</b>	Phase 1	Phase 2	Phase 3	Filed	Updates since Q3'20
Filgotinib JAK-1 inhibitor (GS-6034)	Ulcerative colitis				M	AA Filed	MAA filed
Filgotinib JAK-1 inhibitor (GS-6034)	Crohn's Disease						
Filgotinib JAK-1 inhibitor (GS-6034)	Psoriatic arthritis						Removed from pipeline
Filgotinib JAK-1 inhibitor (GS-6034)	Ankylosing spondylitis						Removed from pipeline
Filgotinib JAK-1 inhibitor (GS-6034) Filgotinib JAK-1 inhibitor (GS-6034) TPL2 inhibitor (GS-4875)	Uveitis						Removed from pipeline
TPL2 inhibitor (GS-4875)	Ulcerative colitis						Removed from pipeline
TPL2 inhibitor (GS-5290)	Inflammatory Bowel Disease	*					New
IRAK4 inhibitor (GS-5718)	Inflammatory Bowel Disease						
TPL2 inhibitor (GS-5290) IRAK4 inhibitor (GS-5718) IRAK4 inhibitor (GS-5718) Tirabrutintib BTK inhibitor (GS-4059)	Lupus	*					New
Tirabrutintib BTK inhibitor (GS-4059)	CSU	*					New
α4β7 inhibitor (GS-1427)	Inflammatory Bowel Disease						
Small molecule inhibitor (neutrophil target)	Inflammatory Diseases						
Small molecule inhibitor (innate immunity target)	Inflammatory Diseases						
Cilofexor FXR agonist (GS-9674)	PSC						
Ziritaxestat ATX inhibitor (GLPG-1690)	IPF						
Ziritaxestat ATX inhibitor (GLPG-1690) Cilofexor / firsocostat combination Selonsertib ASK1 inhibitor (GS-4997)	NASH						
Selonsertib ASK1 inhibitor (GS-4997)	DKD						
Ziritaxestat ATX inhibitor (GLPG-1690)	Systemic Sclerosis						Removed from pipeline
Galapagos	Inflammatory and Fibrosis Diseases	8 clinical stage	programs				
Galapagos Galapagos	Inflammatory and Fibrosis Diseases	Multiple pre-cl	inical stage p	rograms			





## Oncology Cell Therapy Pipeline

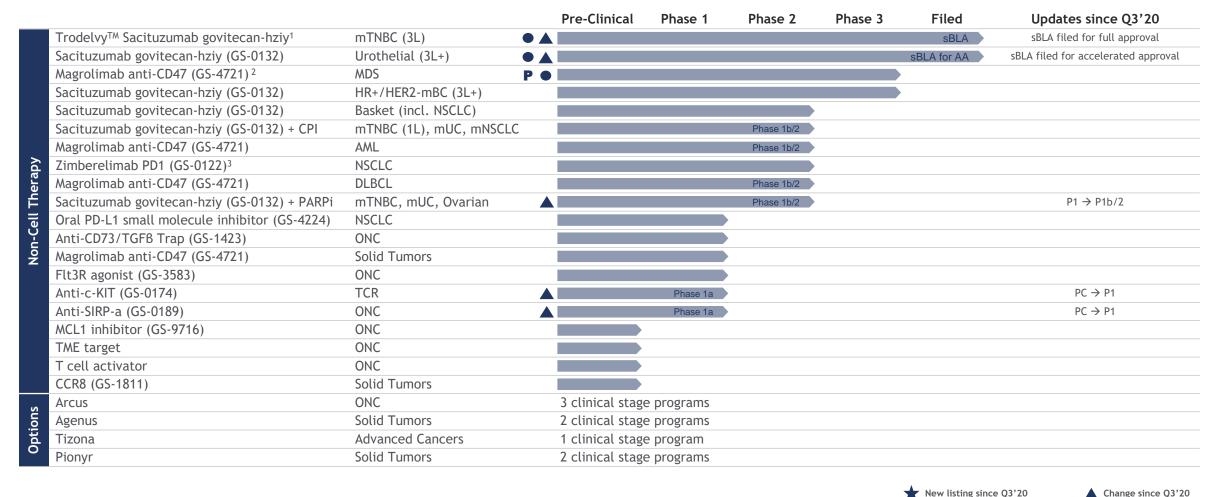
		Pre-Clinical	Phase 1	Phase 2	Phase 3	Filed	Updates since Q3'20
Tecartus™ (Brexu-cel)¹	MCL				MAA and BLA A	Approved	MAA approved
Axi-cel	iNHL	•			sE	BLA Filed	
Yescarta® (Axi-cel)	2L DLBCL						
Yescarta® (Axi-cel)	1L DLBCL						
Brexu-cel	Adult ALL	•		Pivotal			
Brexu-cel	Pediatric ALL	•		Pivotal			
Yescarta® (Axi-cel) <sup>2</sup>	3L DLBCL (+rituximab)						
Yescarta® (Axi-cel)³	3L DLBCL (+lenzilumab)			•			
Yescarta® (Axi-cel) <sup>4</sup>	3L DLBCL (+utomilumab)			•			
KITE-718 (MAGE-A3/A6) <sup>5</sup>	Solid Tumor			•			
KITE-439 (HPV-16 E7) <sup>5</sup>	Solid Tumor			<b>)</b>			
Brexu-cel	CLL			•			
KITE-037 (Allo-HD CD19)6	R/R DLBCL						
KITE-222 (CLL-1)	AML						
KITE-363 (Dual targeting)	R/R DLBCL						

<sup>&</sup>lt;sup>1</sup> Conditional approvals. <sup>2</sup> Clinical collaboration with Genentech. <sup>3</sup> Clinical collaboration with Humanigen. <sup>4</sup> Clinical collaboration with Pfizer, <sup>5</sup> Collaboration with NIH. <sup>6</sup> Partnership with Sangamo. ALL - Acute lymphocytic leukemia. AML - Acute myeloid leukemia. Axi-cel - Axicabtagene Ciloleucel. Brexu-cel - Brexucabtagene autoleucel. CLL- Chronic lymphocytic leukemia. DLBCL - Diffuse large B cell lymphoma. iNHL - indolent non-Hodgkin's lymphoma. MCL - Mantle cell lymphoma. R/R - relapsed / refractory. Pipeline shown above as of end of Q4'20.



New listing since Q3'20 ▲ Change since Q3'20 Breakthrough Therapy Designation

## Oncology Non-Cell Therapy Pipeline



Breakthrough Therapy Designation

P PRIME Designation

<sup>&</sup>lt;sup>1</sup> Accelerated FDA approval granted. <sup>2</sup> Breakthrough and PRIME designation. <sup>3</sup> Non-Gilead sponsored trial(s) ongoing.

AML – Acute myeloid leukemia. CPI – Checkpoint inhibitor. DLBCL – Diffuse large B cell lymphoma. HR+/HER2- mBC – Hormone Receptor positive, human epidermal growth factor receptor 2 negative metastatic breast cancer. MDS – Myelodysplastic syndrome.

mTNBC – Metastatic triple-negative breast cancer. mUC - metastatic urothelial cancer. mNSCLC - metastatic non-small cell lung cancer. NSCLC – Non small cell lung cancer. PARP inhibitor. TCR – Transplant conditioning regimen. TME – Tumor microenvironment. Pipeline shown above as of end of Q4'20.

