MERCK
INVENTING FOR LIFE

Merck Announces HIV Collaboration with Gilead

March 15, 2021

Forward-looking statement of Merck & Co., Inc., Kenilworth, N.J., USA

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Risks and uncertainties include but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of the global outbreak of novel coronavirus disease (COVID-19); the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; global trends toward health care cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; the company’s ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of the company’s patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions.

The company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in the company’s 2020 Annual Report on Form 10-K and the company’s other filings with the Securities and Exchange Commission (SEC) available at the SEC’s Internet site (www.sec.gov).

Merck continues to execute on clear strategic priorities through new HIV collaboration

Our dedication to HIV continues

1980s

1983
HIV is discovered

1989
Role of protease published – AZT launches

1990s

1996
CRIXIVAN

1998
Once Daily STOCRIN (efavirenz)

2000s

2000
ACHAP Partnership with Botswana and Bill and Melinda Gates Foundation

2007
ISENTRESS raltegravir film-coated tablets 400 mg

2010s

2017
Isentress HD raltegravir film-coated tablets 600 mg

2018
Pifeltro doravirine

Delstrigo doravirine/lamivudine/tenofovir disoproxil fumarate

2020+

2020
Collaboration with Bill and Melinda Gates Foundation in PrEP

2021
Collaboration with GILD for investigational combination of islatravir + lenacapavir

Continuing to innovate …

Significant unmet need remains in HIV

In 2019, there were ~1.7M new global HIV infections[1]

Treatment

- Options that reduce stigma, provide simplicity and improve adherence
- Ability to improve HIV status anonymity and quality of life
- Need for continued antiviral suppression even after late or missed doses
- Treatments with reduced toxicity

Prevention

- Current uptake of daily PrEP options is suboptimal
- High unmet need in women due to high rates of new infections and limited prevention options
- Longer-acting formulations have potential to improve uptake by providing additional options

1. WORLD HEALTH ORGANIZATION, NOV. 2020

Unmet need in HIV drives Merck's efforts

Unmet need		islatravir
Extended dosing	Options that address daily-dosing pill fatigue	Broad development program studying investigational islatravir in combination treatment regimens, including with investigational lenacapavir, and as a single agent in prevention
Acceptable toxicity profiles	Anonymity to help avoid HIV-related stigma	

Islatravir and lenacapavir are both potentially first-in-class late-stage assets with potent virologic activity against HIV

Merck's islatravir

- Islatravir is a novel investigational nucleoside reverse transcriptase translocation inhibitor (NRTTI)
- Islatravir inhibits HIV through multiple mechanisms, based on Phase 1 data, contributing to an expected high barrier to resistance
- In Phase 2 study of QD oral treatment, doravirine + islatravir maintained virologic suppression in treatment naive adults with HIV-1; regimen now in Phase 3
- Current data supports several long-acting formulations in both treatment and prevention

Gilead's lenacapavir

- Lenacapavir is a novel investigational capsid inhibitor
- In vitro studies show lenacapavir to interfere with both assembly and disassembly of the capsid
- Phase 1 data support subcutaneous Q6M administration
- Met primary endpoint in Phase 2/3 trial

Combinations of islatravir and lenacapavir have potential to create efficacious and well-tolerated long-acting regimens

Characteristics of investigational lenacapavir make it a promising potential partner in long-acting HIV treatment regimens

Mechanism with activity against wild-type and drug-resistant virus[1]

Long half-life and potential suitability for long-acting regimens[2] – currently under evaluation as Q6M regimen

Ability to develop in both long-acting oral and injectable formulations[2]

1. BASED ON IN VITRO AND PHASE 2/3 HTE DATA; 2. BASED ON PHASE 1 DATA

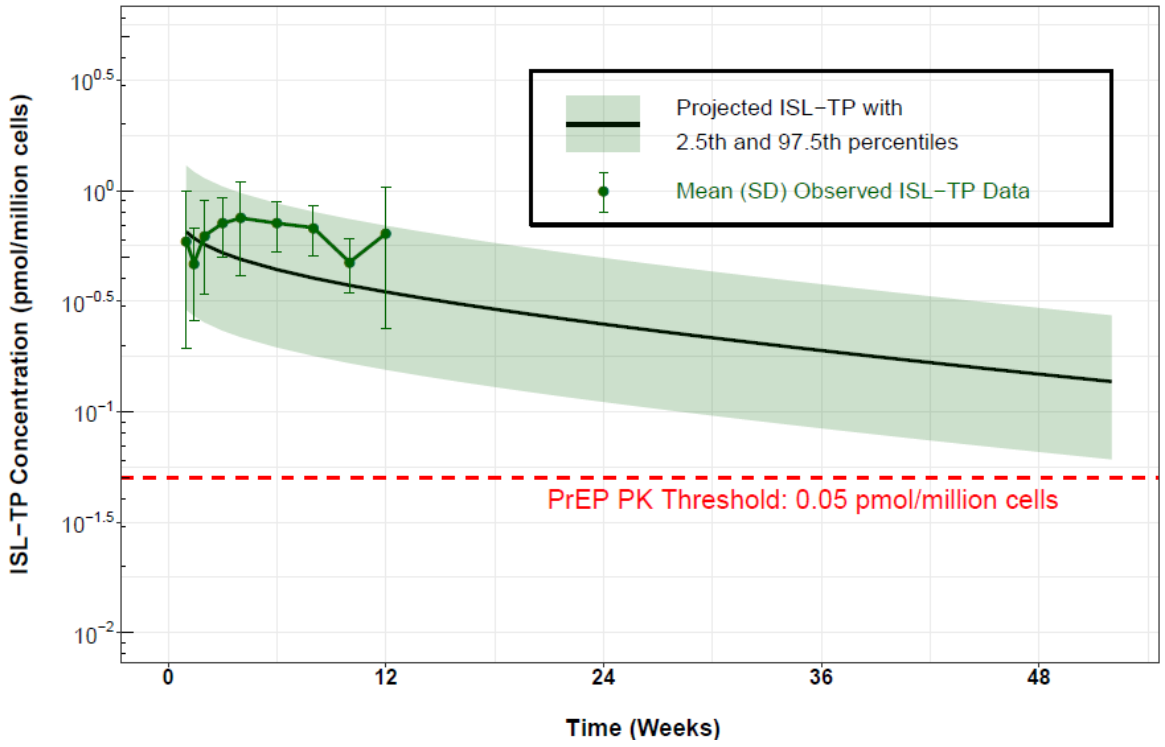
Merck is progressing a broad internal islatravir development program across treatment and prevention

Treatment		Prevention	
Daily Oral (QD) **islatravir** + doravirine *Phase 3*	Weekly Oral (QW) **islatravir** + MK-8507 *Entering Phase 2*	Monthly Oral (QM) **islatravir** *Phase 3*	Yearly Implant **islatravir** *Entering Phase 2*

Investigational islatravir has the potential to be the foundation of future Merck HIV treatment and prevention regimens

Presented encouraging islatravir data across treatment and prevention at CROI 2021

Once-yearly implant data



Phase 1 data from PrEP implant support the potential to provide drug concentrations above the target PK threshold for at least one year.

Data from broad HIV development program across treatment and PrEP highlighted at CROI 2021:

Prevention:

- Phase 1 once-yearly implant data, projecting ability to provide yearly HIV prophylaxis
- Once-monthly oral PK threshold and phase 3 dose selection data

Treatment:

- In vitro MK-8507 resistance profile data demonstrating suitability as weekly treatment partner to islatravir
- Model-informed dose selection data of MK-8507 and islatravir as once weekly oral
- 96-week viral blip data from Phase 2b study of doravirine and islatravir

1. MATTHEWS ET. AL; CROI 2021

Combination of islatravir and lenacapavir has the potential to build upon Merck's long-acting HIV treatment strategy for benefit of people living with HIV

Treatment			
Daily Oral (QD)	Weekly Oral (QW)	Long-Acting Oral	Long-Acting Injectable
islatravir + doravirine	islatravir + MK-8507	islatravir + lenacapavir	islatravir + lenacapavir

First oral therapy clinical trial studying the combination of islatravir + lenacapavir expected to begin in the second half of 2021

Terms of the collaboration

Deal Terms	
Terms	• Gilead and Merck will work as partners, sharing operational responsibilities, necessary intellectual property and know-how, as well as development, commercialization and marketing costs, and any future revenues
Focus	• Long-acting oral and injectable formulations of islatravir + lenacapavir, with other formulations added to the collaboration as mutually agreed
Revenue Split	• Merck and Gilead will share global product revenues on islatravir + lenacapavir combinations equally until product revenues surpass certain pre-agreed per formulation revenue tiers • Oral combination products: upon passing $2B a year in sales, revenue split will adjust to 65% Gilead and 35% Merck for any revenues above the threshold • Injectable combination products: upon passing $3.5B a year in sales, revenue split will adjust to 65% Gilead and 35% Merck for any revenues above the threshold
Development and Commercialization	• Merck and Gilead will share global development and commercialization costs 40%/60%, respectively • Oral combination products: Merck will lead commercialization in EU and rest of the world; Gilead will lead in the U.S. • Injectable combination products: Merck will lead commercialization in the U.S.; Gilead will lead in the EU and rest of the world • Both companies will co-promote islatravir + lenacapavir combinations in the U.S. and certain other major markets
Options	• Both companies will have the option to license the other's investigational oral integrase inhibitors to develop in combination with either islatravir or lenacapavir • The option can be exercised following the completion of the first Phase 1 clinical trial of that integrase inhibitor • Upon exercise of option, the companies will split profits and costs on the combination unless the non-exercising company opts out

Significant potential benefits of collaboration to Merck and people living with HIV

- Collaboration allows for the possibility for innovation that otherwise would not occur by combining two potentially first-in-class assets to be evaluated as long-acting HIV treatment regimens
- Gilead represents a strong partner in HIV given its expertise, presence and commitment in HIV
- Together, Merck and Gilead will have the opportunity to explore providing people living with HIV with new, long-acting oral and injectable treatment options
- Long-acting regimens have potential to address certain remaining unmet needs

Opportunity to establish the combination of islatravir + lenacapavir as an innovative long-acting HIV treatment regimen

Commercial opportunity in treatment and prevention for Merck

Treatment

- Global HIV market is expected to grow to $30.6B in 2024[1]
- Long-acting treatment options will emerge to help address unmet needs
- Physicians want multiple treatment choices to customize therapies for people living with HIV

Prevention

- PrEP market is expected to more than triple by 2029, reaching $9.7B[2]
- In the U.S., 50% of at-risk individuals could be on PrEP regimens by 2026
- PrEP is a key component of UNAIDS goal of reducing new infections from ~1.7M to <200,000 by 2030
- Long-acting PrEP options will emerge as an innovative, convenient option

1. EVALUATE PHARMA., MAY 2019; 2. INFORMA PHARMA INTELLIGENCE, DEC. 2020

Building a broad HIV development program with the goal of maximizing benefits for people living with HIV

Long-Acting Oral
islatravir + lenacapavir

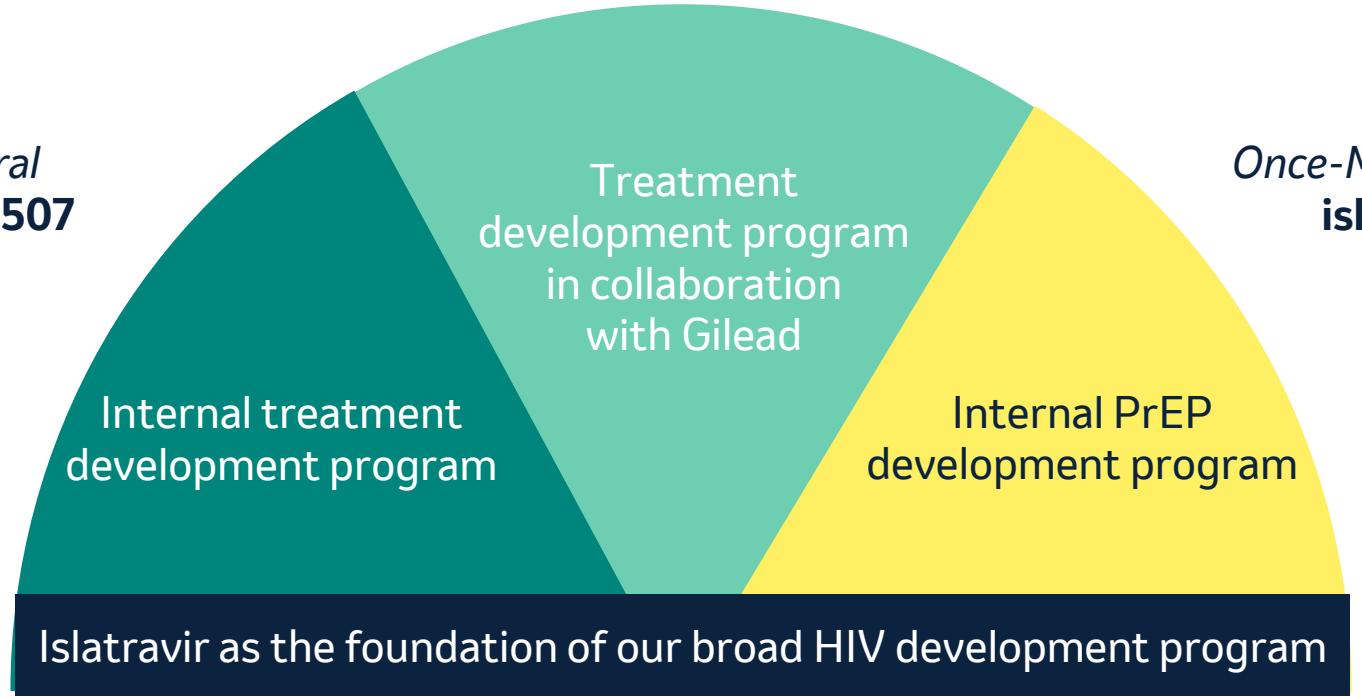
Long-Acting Injectable
islatravir + lenacapavir

Once-Weekly Oral
islatravir + MK-8507

Once-Monthly Oral
islatravir

Once-Daily Oral
islatravir + doravirine

Once-Yearly Implant
islatravir



Appendix: islatravir development program