HIV Long-Acting Therapy Collaboration with Merck

15 March 2021

Q. What was announced?

- A collaboration to accelerate the next wave of HIV Therapy: an investigational, long-acting formulation that has the potential to free people living with HIV from a daily regimen, with less frequent dosing for both oral and injectable formulations.

- Collaboration pairs Gilead's lenacapavir, an investigational capsid inhibitor, with Merck's islatravir, an investigational nucleoside reverse transcriptase translocation inhibitor (NRTTI), to potentially deliver our shortest path to regulatory approval for a long-acting therapy for people living with HIV.

- Builds on the two companies' decades-long commitment to innovative therapies for people living with HIV, with long-acting therapies expected to offer the next wave of growth starting in the mid-2020s. The collaboration includes long-acting oral (LAO) and long-acting injectable (LAI) combination regimens.

Q. Why is there a need to partner? What is the benefit of this particular combination?

- HIV treatment regimens require multiple therapies with complementary mechanisms of action because each class of medicine targets different aspects of viral replication. Merck's islatravir and Gilead's lenacapavir are investigational (in development and not yet approved by any health authority) agents that have orthogonal and complementary mechanisms of action. Both have established proof-of-concept data, and together offer the potential to bring a long-acting combination to market faster.

- The collaboration reflects input from providers, people living with HIV, and patient groups who have consistently suggested that we collaborate to co-develop these two molecules.

- The collaboration will increase the level of resources dedicated to innovation which is good for people living with HIV.

Q. How does the partnership accelerate Gilead's and Merck's timelines of getting a long-acting combination to market?

- There is still work ahead, but – if successful – we believe that this collaboration could decrease our timeline for getting a complete long-acting regimen for treatment to market by up to two years.

- Given the stage of lenacapavir and islatravir, this combination can accelerate time to market significantly as opposed to a combination with an earlier-stage agent.

Q. What are the next clinical steps, and possible first commercialization dates?

- We believe the tasks for each regimen (oral, injectable) will require different approaches and we will initiate co-formulation work for both regimens immediately.

Formulation	Clinical Activity	Earliest Target Commercialization *(if successful)*
LAO	Launch of Gilead-led study (Phase 2) in 2H21	2025
LAI	Launch of Merck-led study (Phase 1) in 2022	2027

Q. What are the biggest technical hurdles in formulating an oral combination and an injectable combination? How confident are you that you can do each of these? Is it different for the oral vs. the injectable? Why do you think these two mechanisms of action will work together?

- Combining the scientific capabilities and experience of both Gilead and Merck, this gives us confidence that together, we'll be able to develop a long-acting regimen for people living with HIV.

- On the oral combination, Gilead has a lot of experience developing single tablet regimens (STRs), but there is still work to be done on this particular combination.

- On the injectable, Merck will take the lead on the clinical trials and Gilead will focus its efforts on co-formulation of a long-acting injectable.

- Lenacapavir and islatravir (both investigational agents) have different, novel, and highly potent and complementary mechanisms of action, that together we believe will impact HIV at multiple stages of the lifecycle.

Q. What was the rationale for Gilead taking the commercial lead in the US for oral formulation and the ex-US lead for the injectable?

- For operational purposes, each company agreed to "lead" in the respective territories. Within each territory, both companies will work together under mutually agreed commercial plans.

- In 9 countries (U.S., Canada, UK, France, Germany, Italy, Spain, China, Japan) the parties have agreed to co-promote these combination products under a co-promotion agreement.

- Given Gilead's global leadership in oral STRs, and a 20-year track record of regulatory approvals and commercialization, Gilead will be leading commercialization for the oral formulation in the US.

- Merck will lead commercialization for the injectable in the US, with development efforts split between both Gilead and Merck.

Q. What do you think peak sales will be for this combination therapy?

- We do not provide long-term product guidance.

Q. How will economics be split between Merck and Gilead?

	Net Product Sales and Costs	Gilead Share	Merck Share
LAO	< $2B Net Product Sales	50%	50%
	≥ $2B Net Product Sales	65%	35%
LAI	< $3.5B Net Product Sales	50%	50%
	≥ $3.5B Net Product Sales	65%	35%
LAO/LAI	Costs	60%	40%

Q. How will revenue be recorded by Gilead?

- There are different terms for different geographies, allowing each company to lead commercialization efforts for a particular formulation and in different geographies.

	Gilead	Merck
LAO (US)	100% Net Product Sales (Lead Partner)	Net Profit Sharing
LAO (Ex-US)	Net Profit Share (Recognized as Other Revenue)	100% Net Product Sales (Lead Partner)
LAI (US)	Net Profit Share (Recognized as Other Revenue)	100% Net Product Sales (Lead Partner)
LAI (Ex-US)	100% Net Product Sales (Lead Partner)	Net Profit Sharing

Q. How will the accounting work?

- For the Long-Acting Oral (LAO), Gilead is the Lead Party in US and Merck is the Lead Party in ex-US.

Line	Gilead for LAO	Notes
Revenue	LAO Net Product Sales (for US)	
	LAO Net Profit Share Received (for ex-US)	Payment received from Merck
COGS	LAO COGS (for US)	
	LAO Net Profit Share Payment (for US)	Payment made to Merck
Opex	LAO S&M (for US and Ex-US co-commercialization territories)	Gilead's Gross Spend
	LAO R&D (for US and Ex-US)	Net of Cost Share

- For the Long-Acting Injectable (LAI), Gilead is the Lead Party in ex-US and Merck is the Lead Party in US.

Line	Gilead for LAI	Notes
Revenue	LAI Net Product Sales (for ex-US)	
	LAI Net Profit Share Received (for US)	Payment received from Merck
COGS	LAI COGS (for ex-US)	
	LAI Net Profit Share Payment (for ex-US)	Payment made to Merck
Opex	LAI S&M (for US as a co-commercialization territory and ex-US)	Gilead's Gross Spend
	LAI R&D (for US and ex-US)	Net of Cost Share

Q. On the main partnership for lenacapavir and islatravir, what drove the revenue and cost split between Gilead and Merck?

- We strongly believe that this revenue and cost split creates value for both companies' shareholders and reflects the value of the programs and capabilities that each party brings to bear.

- Our comprehensive analysis includes the value to be created from the long-acting collaboration and other factors including our commercial infrastructure and intellectual property to be contributed to the collaboration.

- Through a collaborative negotiation we agreed upon these terms, we will share revenues with Merck equally until certain sales thresholds are met. After that, Gilead will receive 65% of net product sales ≥$2 billion for the oral formulation and ≥$3.5 billion for the injectable formulation, reflecting Gilead's decades' long track record of successful R&D and commercial excellence within the HIV market.

Q. Why does this collaboration extend to oral integrase inhibitors?

- Both Merck and Gilead are focused on maximizing the probability of success of a long-acting therapy for people living with HIV, and believe that integrase strand transfer inhibitors (INSTIs) could play a meaningful role.

- Shared access to Merck's and Gilead's once weekly oral INSTI development programs increases the optionality to pursue combination therapies with optimal agents (Gilead's or Merck's) offering less frequent dosing and, if approved by the appropriate regulatory authorities, a more rapid path forward.

Q. How does this change your future HIV revenue expectations?

- We believe that long-acting HIV combinations offer the next wave of HIV growth, with the potential to offset the potential impact of upcoming losses of exclusivity (LOEs) in the mid-2020s.

- We expect to be a leader in the long-acting treatment market should we be successful in developing and commercializing a long-acting HIV regimen, as we anticipate some people living with HIV would shift from daily oral therapy including Biktarvy, non-Gilead products, and generics.

- We expect that long-acting regimens will take equal share from all daily oral regimens, including from non-Gilead products and generics.

- We do not give long-term guidance on sales of any product, including Biktarvy. That said, we have conducted a comprehensive analysis of the impacts to Gilead, including potential impact on Biktarvy revenue, on both binary and risk-adjusted bases, and believe that this collaboration creates significant value for people living with HIV, providers and our shareholders.

- We are focused on continuing the growth of Biktarvy where the underlying trends remain strong. With runway to 2033 (patent expiry) and more than 35% share today, Biktarvy has significant headroom for growth. That said, we believe long-acting therapies will be a growth driver to our HIV business and increase the sustainability of our HIV cash flows post the Biktarvy LOE.

Q. What is the financial impact of this transaction to Gilead's 2021 guidance?

- We will begin working on this collaboration immediately and are targeting a clinical trial for the oral combination as soon as the second half of this year.

- While there will be some modest, incremental expense in 2021, we expect to absorb this in the guidance range we shared previously.

Q. How does this transaction impact Gilead's EPS beyond 2025?

- Pending successful commercialization, we expect this to be accretive to EPS in the second full year post product commercialization.

Q. What will be the impact to Gilead's gross margins if the combination product is successful?

- If the collaboration is successful, this will have a positive impact on our revenue and cash flows in the mid-to-long term.

- In the pre-commercial phase, there is no impact on gross margin. As we have mentioned earlier, there will be strong focus on prioritization and execution across the portfolio.

- The profit sharing arrangement in the commercialization phase will impact gross margin for the combination product as we share gross profits for territories that Gilead leads commercialization. At this time, it is premature to comment on impact on overall Gilead gross margin, as it will depend on portfolio and product mix.

Gilead Forward-Looking Statements

This communication 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 the risk that Gilead may not realize any anticipated benefits from this collaboration; difficulties or unanticipated expenses in connection with the collaboration and the potential impact on Gilead's earnings and cash flows; the ability of the companies to initiate and complete clinical trials involving the combinations of lenacapavir and islatravir and other investigational oral integrase inhibitors in the anticipated timelines or at all; the possibility of unfavorable results from ongoing and additional clinical trials, including other Gilead trials involving lenacapavir; the ability of the companies to successfully co-develop and co-commercialize long-acting HIV treatments; uncertainties relating to regulatory applications and related filing and approval timelines, including the risk that regulatory authorities may not approve such applications in the anticipated timelines or at all, and any marketing approvals, if granted, may have significant limitations on its use; and the possibility that the companies may make a strategic decision to terminate this collaboration. These risks, uncertainties and other factors could cause actual results to differ materially from those referred to in the forward-looking statements. The reader is cautioned not to rely on these forward-looking statements. These and other risks are described in detail in Gilead's Annual Report on Form 10-K for the year ended December 31, 2020, as filed with the U.S. Securities and Exchange Commission. All forward-looking statements are based on information currently available to Gilead, and Gilead assumes no obligation to update any such forward-looking statements.