

 GILEAD	Development Committee	
	Executive Report	
	17 April 2003	
	Chairman	Norbert Bischofberger
	Manager	Phil Zack

Participants

DC Committee Members: N. Bischofberger, C. Brosgari, T. Caracciolo, M. Hitchcock, M. Inouye, B. Lee, J. Martin, J. Milligan, A. Taylor, J. Teale, S. Weisbrich, T. Yang, and P. Zack.

Members Absent: M. Perry and F. Rousseau.

Other Attendees: K. Abell, Z. Abraham, K. Campbell, A. Cheng, J. Choi, A. Elsom, C. Garabedian, N. Helton, J. Hyde-Dunn, and M. Viziato.

Key Development Committee Discussions and Decisions:

Administrative Affairs

N. Bischofberger stated that the primary purpose for the 17 Apr 03 meeting was to review the Key Assumptions for all products in our current portfolio primarily focusing on the development objectives and associated necessary resources. Commercial assumptions were included but were presented in draft form and still subject to change. The R, B, D assumptions agreed upon at this meeting were used to provide input for the Direct Product Contribution spreadsheets compiled for each product as part of the business review analysis planned for the May Operating Group meeting. NB briefly discussed the outcome of the review of development strategies conducted at the 3 Apr 03 Review Committee meeting. NB also pointed out that the Key Assumptions drafted by the Project Teams were designed to serve as a high-level draft for product development plans and as a reference (starting point) for the 2004 Business Review.

Hepsera

The Key Assumptions for Hepsera were approved without changes.

Viread

The Key Assumptions for Viread were approved without changes.

Emtricitabine

- M. Hitchcock asked if developing the liquid suspension of FTC was warranted commercially. He pointed out that this part of the development program required significant resources, and the ROI may not be positive. NB responded that he agreed that the pediatric indication represented a minor opportunity but that there were several reasons why it is still part of the development plan. First the submission to both the FDA and EMEA contained pediatric data. Secondly, both the rapporteur and the CPMP prompted the data be filed. MH commented that based upon the questions received, it was unlikely that we would receive pediatric approval at this time. NB stated that while we may ultimately need to conduct additional studies, the timing was flexible. He then requested that the Project Team re-evaluate the pediatric program and provide status and recommendations to the DC during the May meeting.

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- Remaining Key Assumptions for emtricitabine were approved without changes.

Viread/Emtricitabine Fixed Dose Combination

- NB commented that Study 934 was carried under the Viread budget.
- The committee discussed if there was merit to packaging FTC in blister packs for the EU. Blister packs were included in the MAA and for this reason we will need to present mockups to the EMEA. The DC, however, was of the opinion, as has been discussed previously for both Viread and Hepsera, that this type of packaging would not provide us with an advantage. MH pointed out that an additional disadvantage was that maintaining moisture control might be difficult with this type of package. The question of using blister packs for the Fixed Dose Combination (single pill) is still under review. C. Garabedian stated that patient market research was currently being conducted and that within a month we should know if blister packs were suitable packaging for the FDC.
- JCM asked if we had completed formulation development on the single pill for the FDC. NB replied yes, and that the next improvement would be to reduce the size of the tablet. CG asked if we still had an option for the color of the tablet. NB responded that this item would be discussed at the next Project Team meeting.
- The Key Assumptions for the FDC were approved without changes.

GS-7340

NB briefly discussed the results of the 3 Apr 03 review committee meeting at which time the proposed development plan for GS-7340 was discussed extensively. The recommendation of the Review Committee was to stop development due to the likelihood that GS-7340 would ultimately cannibalize Viread regardless of its efficacy and safety profile. One reason for continuing/restarting development would be to obtain patent extension. Corporate Development has agreed to compute the NPV for this scenario. NB commented that if the patent extension proves worthwhile, development of GS-7340 might resume. The program is to be reevaluated in Spring 2004.

Protease Inhibitor

The Key Assumptions for GS-9005 were approved without changes.

AmBisome

- The Key Assumptions for AmBisome were approved without changes.
- The status of the AmBiLoad trial enrollment was briefly discussed. Currently, evaluable patient accrual is on schedule.

Vistide

No Key Assumptions were compiled for Vistide.

DaunoXome

No Key Assumptions were compiled for DaunoXome.

Amdoxovir

- NB informed the DC that the decision had been made to delay conduct of the DAPD-202 clinical trial until Mar/Apr 04. DAPD-202 is a Ph II study designed to 1) define the optimal dose, and 2) determine if administration of DAPD is associated with lenticular opacities. While patients had begun to undergo

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screening for the study in 1Q03, none had been enrolled at the time the study was stopped. Letters have gone out to the investigators describing the rationale for putting the study on hold.

- DAPD-5185 is the key study for assessing future DAPD development. It is a viral dynamics study which evaluates the efficacy of DAPD with or without mycophenolic acid in experienced patients. NB asked how much money had already been spent on the study. N. Helton replied \$0.75M. NB stated that by delaying the study we will save an additional \$4M (in 2003).
- C. Garabedian asked the DC if we were willing to consider conducting a viral dynamics study, like DAPD-5165, to evaluate efficacy in patients with multiple TAMs. NB and J. Toole agreed that such a study should be reconsidered later on this year.

Clevudine

- The Key Assumptions for Clevudine were approved without changes.
- Discussions are planned with Bukwang to explore the possibility of changing our current agreement which stipulates filing an NDA in 2006. The latter timeline is not feasible given the remaining issues with Clevudine including selection of dosing schedule, understanding mechanism of action, and determining that there is not long-term accumulation in cells. Bukwang, however, has the right to take the drug back if we default on the current contract requirements.

FTC-HBV

- The Key Assumptions for FTC-HBV were approved without changes.
- M. Inouye asked for clarification of the license requirements. NB replied that by filing a type II variation for FTC-HIV with the EMEA, we will fulfill our obligation. While we might be approved for the indication, at a minimum we should receive safety language in the label. JCM asked if we plan to discuss this option with the FDA in Jul/Aug 03. NB added that he believed we had a good chance of obtaining approval in the US. CG commented that the pricing would be the same for HIV or HBV due to the fact that both indications will be in the same label. JCM asked how this would impact the FDC. NB replied that we might get Viread and the FDC approved for HBV as a result of FTC. CG added that a fixed dosing combination of Hepsera and FTC could be priced differently than FTC/TDF and achieve incremental sales.

Research Projects

- B. Lee briefly reviewed the research projects. A proposal to gain access to utilize the HCV genome was to be considered by senior management during the last week of April. Of the other programs, the HIV integrase inhibitor program was considered the one most likely to yield the next IND candidate.

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