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**Development Governance**

**(FiH / PoC / Filing decisions)**

[**Symphony E.Navigator**](https://evarooms.merckgroup.com/Topic/R-D-Governance/symphony-e-navigator)

*MEETING MINUTES*

*DEV-GOV Meeting – 22 Jan 2021*

--- Distributed on 02 Feb 2021 ---

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| **EXECUTIVE SUMMARY** |

**AVELUMAB UC LCM**

To strengthen the leadership position of avelumab in locally advanced / metastatic Urothelial Cancer (LA/m UC), the FiH committee approved the proposed life cycle management strategy, plan and budget focusing on the LA/m setting with a Merck-sponsored randomized PoC Ph II umbrella study (JAVELIN Bladder Medley) aiming to explore multiple avelumab-based maintenance combinations in LA/m UC, starting with:

* Sacituzumab govitecan (SG, a first-in-class TROP-2 ADC developed by Immunomedics)

Sourcing planned from the market, as our discussions with Immunomedics was interrupted by the GILEAD acquisition.

* M6223 (our internal TIGIT inhibitor Ab).
* NKTR-255 (IL-15 receptor agonist), contingent on totality of dada from the ongoing pre-clinical studies run internally and at Nektar (read-out expected June 2021).

Sourcing will require a collaboration agreement with Nektar (they are ready to co-fund the study; we expect them to co-fund 50% of the NKTR-255 combination).

Primary endpoint will be mPFS (from maintenance start) and secondary end-point OS (tentative timelines is KSA in March 2024).

The FiH committee has made substantial comments on the design of the study and advised to seriously explore the usage of a synthetic control arm, or at minimum, borrow power from the JAVELIN Bladder 100 trial to innovate in this design, given the non-registrational nature of the trial. The final decision regarding the design will be taken by the ONC DU LT.

The FiH committee acknowledged that though the EV-302 study (Ph III of enfortumab vedotin (EV) + pembro in LA/m UC 1L) is expected to read in Nov 2023, the team is confident that because Javelin 100 UC has set an extremely high hurdle to beat in OS, there is no guarantee that EV + Pembro will do that.

The FiH committee released the budget (direct cost) of 45.6 m€ (8 m€ in 2021), including SG acquisition cost, and assuming a contribution ~8 m€ from Nektar. Additional saving of up to 8 m€ possible if we secure a supply agreement with Gilead for sacituzumab govitecan.

**EVOBRUTINIB: Modified Release Formulation for BID to QD switch**

Evobrutinib will be first marketed for RMS with immediate release (IR) formulation, BID.

For best positioning vs. future competitors, the DPoC committee approved the proposed development strategy, plan and budget of a modified release (MR) QD formulation to be introduced approximately 12-18 months post IR launch. In addition, a patent filing of MR in 2023 could restrict generic competition to 2044 (the current LOE is estimated for 2037).

The DPoC committee released the budget (direct cost) of 21 Mio€ over 2020 to 2025 (6 Mio€ in 2021), with 7 Mio€ to be spent until the 1st stage gate decision in Q3-2022.

The base case scenario aims at waiving a safety and efficacy bridging study in MS patients. In case such a study is also required, this will lead to a delay for filing of up to 9 months and an additional cost direct cost estimate of 16.5 Mio€.

**EVOBRUTINIB: LCM/Ph IV studies for RMS**

Following up on the request from the Investment Board (IB) on Nov 23rd, 2020, to consider options to strengthen differentiation of evobrutinib in RMS and to mitigate the impact of not having a PPMS indication in the scenario that other BTKs have this indication, the team was seeking feedback on the proposed overarching strategy and concepts for additional clinical studies in support of the RMS Ph III studies as an alternative to studies in PPMS.

Though some proposals were favourably considered, such as a PoC study in Progressive MS to bridge the gap between disease activity and disability progression to differentiate amongst BTKi’s and other classes, or a Ph IIIb study to position Evobrutinib as a treatment of choice for patients switching from anti-CD20 therapies, the proposals to explore essentially untapped disease stages earlier than RMS (e.g. acute demyelinating optic neuritis, radiologically isolated syndrome) were seen as scientifically attractive but challenging to get a label and were not considered as a priority.

The DPoC committee advised to further look at what can be done to generate more data than our competitors in RMS at time of launch, that can change the clinical practice (e.g. for specific patient sub-groups, on cognition, link to digital devices, non-conventional MRI approaches, and other needs expressed by the patients), and to leverage as much as possible the specificities of our BTKi.

*Post-meeting note: The HEC (25 Jan 2021), confirmed the previous IB decision to continue the regulatory diligence with FDA/EMA on PPMS protocols to maintain the optionality of starting such a study in the summer. IB discussion will be held in March/April after we hear back from FDA (EMA feedback comes later) and the team is asked to continue working on RMS scenarios as discussed at the DPoC meeting.*

**PEPOSERTIB (DNA-PK, M3814) combo (C)RT Ph I in H&N: termination of Ph I study**

As the single decision maker for the FiH Governance body, Danny Bar-Zohar approved by e-mail (22 Jan 2021) the team’s request to terminate the peposertib + (C)RT Ph I study in H&N & thorax region.

The strategy in H&N tumours has been adjusted to focus on LA H&N patients not eligible for cisplatin. This will be addressed by a collaborative study that has recently been initiated together with CTEP, as well as presenting an option for a combination with RT and IO (decision planned March 2021).

**ATR M4344: termination of the program**

As the single decision maker for the FiH Governance body, Danny Bar-Zohar approved by e-mail (19 Jan 2021) the team’s request to terminate the ATRi M4344 program.

Based on the findings from M4344 dose escalation trials, the clinical development with the backup M1774 was started in January 2020.

As planned, a data driven decision on which molecule to move forward with (M4344 or the back-up M1774) was taken by the team based on safety, tolerability, PK, and PD data from the dose escalation Ph I studies which showed clear superiority profile of the back-up molecule. The team will move forward prioritizing M1774 and stopping M4344 development.

The switch from M4344 to M1774 will impact the timelines of the oral ATR program and the team will come back to the FiH Governance committee in Q2-2021 for approval of the updated timelines and budget. The strategy for ATRi oral development remains unchanged.

**PERGOVERIS in US**

Rehan Verjee approved by e-mail (22 Jan 2021) the team’s request to proceed with pre-IND consultation of FDA and preparatory activities for pergoveris in US, with the aim to establish what the registration path could be (the minimum viable). With this validation, the team can then work to explore alternative strategic options to secure pergoveris in the US and value for Merck.

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| **FULL MINUTES** |

**ATTENDEES**

**FiH (ONC) Members:**

Danny Bar-Zohar (decision maker & co-chair); Rehan Verjee; Joern-Peter Halle; ~~Zhen Su~~ (co-chair, del- to Keir Woods; ~~Oliver Maschinsky~~ (del. to Ilona Griner); Imran Shah; Maria Rivas; Elke Sylvester; Andree Blaukat; ~~Klaus Urbahns~~; ~~Ewen Sedman~~; ~~Teresa Rodo or del. to Kerstin Seemann~~; ~~Ivan Kugener~~ (del. to Neal Mitra and Stefan Meyer); Lisa Benincosa; ~~John Oidtman~~; Francois Beckers; Klaus Edvardsen; Byron Robinson; Kevin Chin; Paul Lyne; Praveen Marapaka.

Members at large: ~~Chris Round~~, ~~Andreas Stickler~~

Others: Hervé Dupont (governance); Rafaela Endert (CoS Global Dev.)

**DPoC (N&I) Members:**

Danny Bar-Zohar (decision maker & co-chair); Rehan Verjee (decision maker); Joern-Peter Halle; Jakob Hoppe (co-chair); Oliver Maschinsky (for RMS) or delegate Jens Hoffart (for BID to QD); Imran Shah; Maria Rivas; Elke Sylvester; ~~Ewen Sedman~~; ~~Teresa Rodo~~ (del. to Kerstin Seemann; Ivan Kugener (for RMS) or delegate Grace You (for BID to QD); Amy Mahery; ~~Britta Paschen~~; Lisa Benincosa; John Oidtman; Francois Beckers; Eric Jacobson and Pierre-Yves Berclaz; Fernando Dangond; Robert Henderson; ~~Bodo Hammes~~ (del to Lisa Bruns).

Members at large: ~~Chris Round~~; ~~Andreas Stickler~~

Others: Hervé Dupont (governance); Rafaela Endert (CoS Global Dev.)

**FiH ONC Decisions**

**AVELUMAB UC LCM – Request ID: 143**

*Presenters: Eric Mallard; Mary Ruisi; Allison Scott Fidler-Lehn*

*Other attendees: Byron Robinson; Mark Zhang; Shaohui Wang; Julia Xiong; Patricia Soulard; Janet Wang*

*From the TIGIT team: Roseann Waterhouse; Keyvan Tadjalli Mehr*

*Member of the ATSA Supervisory Committee; Susan Herbert*

To strengthen the leadership position of avelumab in locally advanced / metastatic Urothelial Cancer (LA/m UC), which is approved as monotherapy in 2L and in 1L maintenance, the team recommended a life cycle management strategy focusing on the LA/m setting (discussed, developed and vetted by our UC LCM Steering Committee comprising 6 of the top US and EU KTLs).

DECISIONS

*The decision was taken in presence of Susan Herbert, Chair of the ATSA Supervisory Committee for the Pfizer Alliance.*

* **The FiH committee approved the proposed strategy and plan and released the budget** for a Merck-sponsored randomized PoC Ph II umbrella study (JAVELIN Bladder Medley) aiming to explore multiple avelumab-based maintenance combinations in LA/m UC, with the following recommendation:
  + Further evaluate the value of having an avelumab control arm (ensuring comparable patient population in the different arms and understanding potential different OS from historic data in light of risk of future phase III), and seriously explore the usage of a synthetic control arm, or at minimum, borrow power from the JAVELIN Bladder 100 trial (using propensity score matching) to innovate in this design, given the non-registrational nature of the trial.

The final decision will be in the remit of the Oncology Development Unit (head, Klaus Edvardsen).

* Merck-sponsored JAVELIN Bladder Medley Ph II study design:
  + Newly diagnosed, previously untreated LA/met UC patients.
  + Standard induction chemo (gem/cis or gem/carbo) for 4-6 cycles.
  + Randomization after induction phase into four arms (1:1:1:1, N=62 per arm) for maintenance.
  + One stratification factor will be chosen among:
    - Best Response to 1L chemo (CR/PR vs SD)
    - metastatic site at diagnosis of LA/met (visceral vs non-visceral);
    - PD-L1 expression
  + Avelumab control arm (**final decision to keep it or not to be made**, see above)
  + Three combinations groups as starting point:
    - Avelumab + sacituzumab govitecan (SG, a first-in-class TROP-2 ADC developed by Immunomedics)

SG has showed promising data in UC 2L.

To limit toxicity, SG would be administered for a limited number of cycles (5-6).

* + - Avelumab + M6223 (our internal TIGIT inhibitor Ab).

PoC for anti-TIGIT/PD-L1 combination has been achieved with tiragolumab and atezolizumab showing encouraging Ph II data in a PD-L1 high NSCLC cohort.

TIGIT ligand (PVRL-1- stabilizer of TIGIT) high expression is associated with worse OS to Avelumab in JAVELIN Bladder 100 Biomarkers suggesting TIGIT as a potential mechanism of resistance to Avelumab switch maintenance.

Initiation of this arm will require the determination of the RDE from the M6223 monotherapy Ph I DE study. The initial safety data from the M6223 + bintrafusp alfa DE study (or possibly M6223 + avelumab DE) will also support the dose selection for avelumab +M6223.

* + - Avelumab + NKTR-255 (IL-15 receptor agonist), **contingent on** positive signals detected in the pre-clinical studies designed in partnership with Nektar team to address remaining questions in solid tumour model (read-out expected June 2021 at the latest).

Analysis of immune cell gene signatures from JAVELIN Bladder 100 suggest that cell types expressing Fc receptors may contribute to the JAVELIN Bladder regimen outcomes, including NK cells.

Unique opportunity to bring the first IL-15/anti-PDx combination to UC patients, in a setting where we believe that innate immunity, and particularly NK cells, contributes to clinical outcomes based on Javelin Bladder 100 Pfizer bioinformatic analysis.

* + IDMC meeting on safety after initial 20 patients (5 per group), pause enrolment until after analysis by IDMC.
  + Futility analysis will be considered during protocol development.
  + Primary endpoint will be mPFS (from maintenance start) and secondary end-point OS.
  + “Go criteria” (HR <=0.70) designed to be robust enough to give us enough confidence to initiate a pivotal study if it is met.
  + Long Term Follow-up (LTFU)
* The team does not plan for a consultation with FDA prior to submitting the CTA but may request scientific advice in the regions of Europe and Asia prior to submitting the CTA.
* Sourcing of:
  + SG planned from the market, as our discussions with Immunomedics was interrupted by the GILEAD acquisition.
  + NKTR-255 will require a collaboration agreement with Nektar (they are ready to co-fund the study; we expect them to co-fund 50% of the NKTR-255 combination)
* Risks are evaluated as standard for such a Ph II LCM program, but with significant scientific speculation to be considered.
* The PoS for each combination will be determined by the project team based on the standard assessment tool.
* The FiH committee acknowledged that though the EV-302 study (open-label, randomized Ph III study of enfortumab vedotin (EV) + pembro and/or CT vs. CT alone in LA/m UC 1L) is expected to read in Nov 2023, the team is confident that because Javelin 100 UC has set an extremely high hurdle to beat in OS, there is no guarantee that EV + Pembro will do that.
* The FiH committee encourages more ambitious thinking on protecting the avelumab stronghold in UC, i.e. team to strategize how to move avelumab to frontline (induction) treatment.
* Example timelines (illustrative only as the availability of combination partner drug and the starting dose for M6223 need to be assessed and factored into the final plan):
  + FSFD (for all groups): Aug 2021
  + Safety IDMC after 5 pts enrolled per group: Mar 2022
  + KSA for primary analysis: Mar 2024
  + Final CSR: Jun 2025
  + In case of positive outcome of the Ph II (for 1 or more combination), a pivotal study will be proposed to the DPoC committee for a potential start in 2024 and expected read-out by 2028.
* Estimated budget (direct cost):
  + Total: ~45.6 m€ (~8 m€ in 2021)
  + Including SG acquisition cost.
  + Assuming a contribution ~8 m€ from Nektar.
  + Additional saving of up to 8 m€ possible if we secure a supply agreement with Gilead for sacituzumab govitecan.
* In addition, a study of the combination with VEGFi XL092 (Exelixis) is planned to be embedded into the XL092 Ph Ib basket study running at Exelixis (external partnership with drug supply deal).

ACTIONS

* Final decision regarding the inclusion of the avelumab control arm to be taken by the Oncology Development Unit.
* Final decision on including the combination with NKTR-255 to be taken by the Oncology Development Unit on the basis of the totality of the scientific evidence to date, including the outcome of the ongoing pre-clinical studies run internally and at Nektar (read-out expected June 2021).

**DPoC N&I Decisions**

**EVOBRUTINIB: Modified Release Formulation for BID to QD switch – Request ID 145**

*Presenters: Robert Henderson*

*Other attendees: Frédéric Bernard; Ilona Rosebrock; Martin Dyroff; Marco Poma; David Mitchell; Alan Gillett; Kevin Coyne; Soham Paul; Johannes Dasenbrock; Karthik Venkatakrishnan*

The ongoing RMS Ph III are conducted with immediate release (IR) formulation, BID. Evobrutinib will be first marketed as such.

For best positioning vs. future competitors, the development of a modified release (MR) QD formulation is planned to be introduced approximately 12-18 months post IR launch. In addition, a patent filing of MR in 2023 could restrict generic competition to 2044 (the current LOE is estimated for 2037).

DECISIONS

* **The DPoC committee approved the proposed strategy and plan and released the budget** for the development of a MR formulation of evobrutinib to allow the switch from BID to QD, with the following recommendation:
  + Ensure that the target occupancy (which will be assessed in the PK study for prototype selection, read-out Q2-2022) is not comprised by the MR formulation / QD regimen (i.e. keeping the same proportion of patients reaching 95% BTK occupancy) as it is key to maintain the high level of clinical efficacy, which is the best driver for evobrutinib differentiation.

It was acknowledged that for an irreversible inhibitor such as evobrutinib, the total amount of drug (AUC) rather than the peak concentration (Cmax) is critical for target occupancy.

* + The size of the tablet (which is not a defined parameter in the target product profile) must be considered as an important feature for acceptability by MS patients who have swallowing issues. Regarding the taste, it was acknowledged that the coating is masking it anyway.
  + Ensure that at the time of prototype selection (mid-2022) the technology is defined as it is a pre-requisite before transferring to a CMO.
  + Explore options to gain positive differentiation attribute such as an innovative technology to achieve a once a week formulation. However, it was acknowledged that there might be a safety concern with this regimen.
* A series of prototypes will be developed (at Merck + Glatt + Quotient) and characterized in vitro by end of Q3-2021. Prototypes will be further evaluated in a relBA study (PK study). This PK study will be driven by Quotient using a so called ‘design-test-make’ iterative model allowing for rapid adjustment/refinement of formulations in response to the data. This process is expected to be completed by Q2-2022 and will allow the selection of a prototype to be moved into full process development and tech transfer.

In parallel the team is planning for HA interactions in Q3-2022 to discuss/agree on critical PK parameters to be considered and the proposed model-informed drug development (MIDD) approach **aiming at waiving a safety and efficacy bridging study in MS patients** before registration.

In the base plan, a relBA study will be conducted with the intended commercial MR formulation to support submission/registration (outcome in Q4-2024).

* Initial assessment of PoS:
  + Formulation development: 80%
  + Regulatory: 80% (assuming prior approval by HAs of prototype selection and full development plan).

Note that the probability that the HAs accept the base case for full development (i.e. without efficacy bridging study) is moderate.

* Planned timelines:
  + 1st stage gate decision (no governance meeting needed) after read-out of the PK study for prototype selection (Q2-2022) and feed-back from FDA/EMA:

Q3-2022 (7 Mio€ to spend up to this point).

* + 2nd stage gate decision (no governance meeting needed) to start the PK bridging study for commercial formulation selection: after acceptance of RMS filing, early Q2-2024.
  + Filing of MR (base case scenario without efficacy bridging study): Q2-2025 with potential approval and launch Q1-2026.
  + In case an efficacy bridging study is also required (up to 12 months, direct cost estimate 16.5 Mio€), filing will be delayed up to 9 months.
* Budget (direct cost) for base case scenario (without efficacy bridging study):

21 Mio€ over 2020 to 2025 (6 Mio€ in 2021), in line with the OP2021/SD.

7 Mio€ to be spent until the 1st stage gate decision in Q3-2022.

**EVOBRUTINIB: LCM/Ph IV studies for RMS – Request ID: 163**

*Presenters: Robert Henderson; Davorka Tomic*

*Other attendees: Frédéric Bernard; Ilona Rosebrock; Yann Hyvert; Christian Henke; Paul Korathu; Alan Gillett; Jerzy Bojanowski; Karthinathan Thangavelu; Soham Paul; Emily Martin*

Following up on the various requests from the Investment Board (IB) on Nov 23rd, 2020, which included considering options to strengthen differentiation of evobrutinib in RMS and to mitigate the impact of not having a PPMS indication in the scenario that other BTKs have this indication (options to include EARLY RRMS, PoC PPMS (biomarker driven, not necessarily label enabling) etc…), the team was seeking feedback and endorsement of the proposed overarching strategy and concepts for additional clinical studies in support of the RMS Ph III studies as an alternative to studies in PPMS.

DECISIONS

* The chairs of the DPoC governance body (Rehan Verjee and Danny Bar-Zohar) expressed that, independent on whether we go for PPMS development or not, the strategic question is how to create more medical value to evobrutinib to entrench our position in RMS.
* The proposal to conduct a PoC study in Progressive MS (nrSPMS+naPPMS) based on biomarkers and imaging to bridge the gap between disease activity and disability progression to differentiate amongst BTKi’s and other classes was favourably considered by the DPoC. Final decision will be taken after a complete recommendation can be made to the IB.
* The DPoC committee gave support to the Ph IIIb study (to be launched at Ph III RMS key stats) to generate data to position Evobrutinib as a treatment of choice for patients switching from anti-CD20 therapies (dominant Rx class by 2025).
* While the proposed options to explore essentially untapped disease stages earlier than RMS are scientifically attractive (ADON, RIS), the potential to get a label was challenged and was not considered as a priority. Feed-back from HAs will be key to better understand the potential and the path forward.

ADON: Acute Demyelinating Optic Neuritis

RIS: radiologically isolated syndrome

* The DPoC chairs advised to further look at what can be done to generate more data than our competitors in RMS at time of launch, that can change the clinical practice (e.g. for specific patient sub-groups, on cognition, non-conventional MRI approaches, link to digital devices, and other needs expressed by the patients), and to leverage as much as possible the specificities of our BTKi.

It was acknowledged that competitors potentially having broad labels in RMS constrains the choice of sub-group analysis.

* It was acknowledged that it would be difficult to enter the Asian market for RMS as it is not included in the current RMS Ph III.

ACTION

* Further align with the DPoC governance body on additional options to strengthen our position in RMS per guidance given at the meeting.

*Post-meeting note:*

*Given that evobrutinib PPMS proposal was brought to IB on Nov 23rd, 2020, and following this discussion at DPoC, the DPoC chairs presented that topic to HEC on Jan 25th.*

*As there are still several moving parts in the bigger picture of the portfolio, the HEC confirmed the previous IB decision to move forward with approaching FDA/EMA with our PPMS protocols to get the necessary input and advice, therefore maintaining the optionality of starting such a study in the summer. By the time we hear from at least FDA on PPMS, we will also have a DMC read and more data on RMS.*

*This is not a decision to move with the PPMS Ph III study, just to continue the regulatory diligence. If there are additional activities from the clin ops perspective, this will be dealt at the DCM.*

*IB discussion will be held in March/April after we hear back from FDA (EMA feedback comes later) and the team is asked to continue working on RMS scenarios as discussed at the DPoC meeting.*

***Report of decisions taken off-line (by e.mail) prior to or after the meeting***

**PEPOSERTIB (DNA-PK, M3814) combo (C)RT Ph I in H&N: termination of Ph I study**

DECISION

* As the single decision maker for the FiH Governance body, Danny Bar-Zohar approved by e-mail (22 Jan 2021) the team’s request to terminate the peposertib + (C)RT Ph I study in H&N & thorax region ([NCT02516813](https://clinicaltrials.gov/ct2/show/NCT02516813)).

All FiH ONC members were in copy.

Background:

No further development is planned with palliative RT following the recent completion of the DE. This was the last arm of this study still ongoing.

The same study also investigated Peposertib in LA H&N in combination with cisplatin/RT (curative intent). As sufficient exposure of peposertib in this combination could not be reached, and data indicated a combination with RT alone might be efficacious, the strategy in H&N tumours has been adjusted to focus on LA H&N patients not eligible for cisplatin. This will be addressed by a collaborative study that has recently been initiated together with CTEP, as well as presenting an option for a combination with RT and IO.

The team plans to come to FiH Governance in March 2021 for this new SCCHN strategy and plan.

**ATR M4344: termination of the program**

DECISION

* As the single decision maker for the FiH Governance body, Danny Bar-Zohar approved by e-mail (19 Jan 2021) the team’s request to terminate the ATRi M4344 program.

All FiH ONC members were in copy.

Background:

Based on the findings from M4344 dose escalation trials, the clinical development with the backup M1774 was started in January 2020. The aim was to come to a data driven decision on which molecule to move forward with. In December 2020, the team concluded that even if M1774 dose escalation beyond the just finalized cohort (130 mg qd) would not be possible, this dose is already clearly superior to the M4344 RDE

(250 mg) in terms of safety, tolerability, PK, and PD.

The team planned to move forward prioritizing M1774 and stopping M4344 development.

The switch from M4344 to M1774 will impact the timelines of the oral ATR program. The team will come back to the FiH Governance committee in Q2-2021 for approval of the updated timelines and budget. The strategy for ATRi oral development remains unchanged.

**PERGOVERIS in US**

DECISION

* Rehan Verjee approved by e-mail (22 Jan 2021) the team’s request to proceed with pre-IND consultation of FDA and preparatory activities for pergoveris in US, with the aim to establish what the registration path could be (the minimum viable). With this validation, the team can then work to explore alternative strategic options to secure pergoveris in the US and value for Merck.

The team would come to DPoC governance in May/June 2021 for decision on next step.

All the other relevant DPoC members were in copy.

Budget:

* + 200 K€ in 2020: to be taken from project/WBS code G.70064202, planned in OP2020 LCM budget as New Demand of 2500k in OP and 600k in F3.
  + 420 K€ in 2021: to be planned in global R&D (non-LCM) budget with a new project code for Pergoveris US (WBS code to be created).

Background:

Objective of the FDA interaction is to identify the minimum viable option for developing Pergoveris liquid for the US market.

Project activities associated with FDA consultation and Ph II/III DPoC preparation comprise of tasks such as briefing book writing, regulatory consulting, protocol writing and DSC reviews, external assessment, site feasibility, market research, etc. as achievable by the team within the given budget framework.

Performing these activities will provide clarity for an informed DPoC decision (in May/June2021) and for potential external funding/collaboration options, which are to be explored following FDA consultation and DPoC.

*Submitted by Hervé Dupont and aligned with project team**s*