

8 May 2020

## Questionnaire to Johnson & Johnson on COVID-19 Vaccine

Thank you for the constructive discussion held on 6 May on the Johnson & Johnson/Janssen plans for the development, production and introduction of a vaccine for prophylaxis against COVID-19. As discussed, we would be grateful if you could reply to the following questions by **Friday 15 May close of business**.

As also previously discussed, it would be helpful if you could share with us the slide deck you used in our discussion on 6 May.

Insofar as the information provided by you contains business secrets, your information will obviously be kept confidential (see Article 339 TFEU).

### Vaccine in Development

1. Please provide a brief description of your vaccine (the “**Vaccine**”) and a high level overview of the complete manufacturing process for active substance and finished product (flow chart)- to define up front the type of product, including need and type of adjuvant as applicable and intended target population, and the complexity of the manufacturing process.
2. Please provide a time-line and an estimate of the costs of the different steps/phases necessary for the clinical development, and a brief description of each one of such phases.
3. Have you already experienced any difficulties in progressing through clinical development steps? Are there any areas where you expect difficulties in progressing through clinical trial development, (except for financing), e.g., identifying a sufficient number of subjects for the clinical trials, etc.? What support will you need to complete all stages of clinical trials (except for financing)? Are clinical trial sites already recruited? Where?

### Production Capacities

4. **Envisaged set-up of the production:** How do you envisage the set-up for the production of the Vaccine (e.g. production in your own facilities, outsourced production, production via licensing partner)? Are there any particular complexities? How long will it take to produce the first doses and subsequently scale-up to anticipated maximum capacity? If possible, please provide a flow-chart of the different phases.
5. Following your presentation, we understand that some of the production of the Vaccine should be carried out by a CMO by way of a tech-transfer. Please explain how far the negotiations with candidate CMOs have developed, where such a

production would be located, whether the necessary investments for the production of the Vaccine at the CMO site would be financed by your company and whether your company would contractually control the use of such a production site. Please also explain whether such a control of the site would cover the “option” in case the development of the Vaccine should not be successful, as proposed in your presentation.

### Agreements for the Production of the Vaccine

6. Do you have agreements in place to share production capacity for specific steps of the manufacturing process with other pharmaceutical companies or do you envisage entering into such arrangements?
7. Do you have agreements in place with specialised production companies (tech transfer agreements, licensing arrangements, outsourcing of production, or for ancillary materials eg adjuvants, etc.) or with CMO/ consultancies/organisations with expertise in vaccine development and regulatory submissions or do you envisage to conclude such agreements? If yes, could you please describe with whom you have concluded or intend to conclude such agreements and their content?
8. Where would such a production facility – either the shared production facility or the facility of the third party production company – be located?

### Further Steps for the Finalisation of the Vaccine

9. Please describe the further steps for making the Vaccine available for distribution (e.g., filling, labelling, etc.). Are arrangements in place to ensure the availability of hardware (bottles, syringes, reagents etc) throughout the process?
10. We understand that there may be bottlenecks in ensuring timely availability of vaccines in such large volumes (e.g., glass for the filling of the vaccines, personnel limitations etc). Could you please indicate whether you see any such bottlenecks specific to your product and explain how they could be overcome?

### Marketing and Distribution

11. Distribution: Do you have marketing and distribution arrangements in place for vaccines that would be suitable for the proposed storage conditions for your product?
  - a. For the EU and all the Member States?
  - b. In the rest of the world?
12. Do you envisage distributing the Vaccine in the EU/ rest of the world via your own distribution network or via third parties with whom you have entered into agreements?

## Administration of the vaccine

13. Do you already have any insights on how many doses of your vaccine will be needed per person to protect against COVID19 and how long will protection last (i.e. need for any booster already foreseen?)?

## Overall Time-frame

14. Please specify the full timeline to bring the vaccine to the EU market, including development, regulatory approval, starting production and finally distribution? Include capacities/delivery plans.

## Main Risks for the Successful Development and Production

15. Where do you see the main risks in terms of successful development and production of the Vaccine? E.g. going through the different testing phases, demonstrating efficacy of the Vaccine, development of production, regulatory review, scaling-up of production, etc.? Are there any expertise or personnel limitations? Are the ways that the EU could help mitigate these risks?
16. Any exit strategies in place if expected results are not satisfactory?
17. Please specify the return on the financial support provided by the EU in this case.

## Agreements with Government and International Organisations

18. Do you have agreements with governments, governmental agencies or international organisations in place for the Vaccine?
19. Do you receive financing via these agreements for the outstanding steps up to the production of the Vaccine?
20. Do these agreements include an envisaged allocation of the Vaccine for specific countries/organisations, including pre-arranged timelines? Could these agreements lead to additional (non-currently envisaged by contractually possible) obligations imposed by governments or international organisations to reserve capacity for certain countries or regions? How will this impact availability in the EU and the rest of the world? CEPI and WHO allocations?

## Documents

21. It would be very helpful if you could provide us with a business plan in relation to the development and production of the Vaccine, in particular with regard to the outstanding steps.
22. Could you please share with us any other documents detailing the financing needs for the development and the production of the Vaccine (e.g. reports of financing documents prepared for bank financing)?

23. Do you have a presentation/documents showing past experiences with the development and production of new vaccines, including the time-line and the costs entailed by the different steps?

### Financing

24. What is the amount of at-risk financing already committed to the vaccine project under discussion?
25. What parts of that project's at-risk financing has been provided from the company itself and what from other sources and partners? What claims have those partners acquired in return for that financing?
26. Would you please provide a short explanation of the financing needs in the baseline and the top-up scenarios?
27. From your presentation, we understand that you intend to sell the Vaccine on a non-profit basis and that you envisage paying back the proposed loan financing via a discount on the sales price. Would you please provide a short description of the precise financing mechanism including all cash-flows and embedded options? Would you please explain in detail how you would calculate the "at-cost" price, in particular which costs you would take into account?
28. From your presentation we understand your proposal to be that the loan should be written off in case the vaccine is not viable, or if demand for the vaccine proves to be too low. Do you already have an idea of what level of demand would represent the cut-off point for the second of those two conditions? For the envisaged option in case of non-viability of the Covid-19 vaccine to use the facility for a different vaccine and repay through discount – would you envisage setting the baseline price for those alternative vaccines products also at cost for the purpose of the repayment of the financing for the Covid-19 vaccine?

### Liability

29. Would you expect product liability to be limited? If so, under which circumstances and how?

### Regulatory Flexibility

30. Do you see any need for the provision of additional regulatory flexibilities than those already available (conditional marketing authorisation and national early access schemes prior to authorisation) for bringing the Vaccine successfully to the market as soon as possible, provided that appropriate quality, safety and efficacy are demonstrated? If yes, what are the specific regulatory difficulties that you envisage and what do you propose to overcome these?
31. What are the plans of the company for a marketing authorisation in the EU and internationally and the foreseen timelines?

32. Is the company willing to share with other companies knowledge from clinical trials (results of success or failure) to help advance the development of a successful vaccine?
33. **GMO/BSL issues-** Does the company envisage any issues with the GMO legislation or biosafety level requirements for the Vaccine?

#### Looking to the Future

34. Can any elements of the technology/facilities you are using be 'standardised' to making them particularly suitable for rapid response to emerging infectious diseases i.e. platform approach? What kind of investment would be required to maintain this outside of a pandemic scenario?
35. What are the key lessons learned, at this stage, from the COVID19 outbreak which in your view are particularly relevant for the future crises preparedness?
36. Which vaccine capacities would the company offer in return to any support? Please specify along a timeline in 2021. In case the company's Covid-19 vaccine was not approved in the EU, what alternative return is offered?