12 May 2020

Questionnaire to CureVac on COVID-19 Vaccine

Thank you for the constructive discussion held on 7 May on CureVac 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 **Tuesday 19 May close of business**.

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, and intended target population, and the complexity of the manufacturing process. Please specify the advantage of CureVac’s technology as compared to other RNA based products.
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 phases.
3. In the call, you mentioned potential difficulties linked to clinical trials, mainly the potential scarcity of clinical trials infrastructure and competition from other resources. 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, access to clinical trials infrastructure etc.? What support will you need to complete all stages of clinical trials (except for financing)? Are clinical trial sites already recruited? Where?
4. In the call, you mentioned that you would intend to carry out clinical trials in a limited number of Member States and that you were in discussions with the Member States authorities on that. Would a broader scope of clinical trials among more Member States or also outside the EU improve the confidence in those trials?
5. In the call, you mentioned that CEPI will finance phase I of clinical trials, please specify your financial needs for the subsequent phases of clinical trials and timeline/financial needs.

**Production Capacities**

6. **Envisaged set-up of the production**: How do you envisage the set-up for the production of the Vaccine? Are there any particular complexities? How long will it take to produce the first doses and subsequently scale-up to anticipated maximum
7. From the discussions, we understand that you consider building additional production capacity pending the pre-orders of the vaccine. Please specify the critical milestones and timelines for this decision.

Agreements for the Development and Production of the Vaccine

8. Do you have agreements in place or do you plan to enter into agreements with other companies to carry out the development phase, in particular the clinical development, or to assist in the regulatory approval processes?

9. 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? What would be the drivers of such arrangements?

10. Do you have agreements in place with specialised production companies (such as CMOs/consultancies/organisations with expertise in vaccine development and regulatory submissions) to assist in, or take over parts of the production 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?

11. Where would such a production facility – either the shared production facility or the facility of the third party production company – be located?

12. Do you have capacity reserved or agreements for raw materials including delivery systems e.g. lipid nanoparticles etc.?

13. In the call, you mentioned that you have been in discussions with other pharmaceutical companies on the development and the production of the Vaccine. Could you please explain with whom you have been in discussions and what cooperation you envisaged? Could you please indicate the state-of-play of such negotiations?

Further Steps for the Finalisation of the Vaccine

14. 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?

15. Do you envisage carrying out the further steps for making the Vaccine available for distribution within your company or do you plan to enter into agreements with specialised companies for filling, packaging, etc.? Please indicate whether you have already booked capacity with such companies.

16. 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

17. Distribution: Do you have marketing and distribution arrangements in place for vaccines that would be suitable for the proposed storage conditions (please specify) for your product? Are there particular challenges foreseen?
   a. For the EU and all the Member States?
   b. In the rest of the world?
18. 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? What are the distribution obligations stemming from investors, incl the Gates Foundation?

Administration of the vaccine

19. 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

20. Please specify the full timeline to bring the vaccine to the EU market, including development, regulatory approval, starting production and finally distribution. Please include capacities/delivery plans.
21. Please precise the exact timing in your clinical development when you expect EUA/conditional approval in selected populations.

Main Risks for the Successful Development and Production

22. 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?
23. Any exit strategies in place if expected results are not satisfactory?
24. Please specify the return on the financial support provided by the EU in this case.

Agreements with Government and International Organisations

25. Do you have agreements with governments, governmental agencies, foundations or international organisations in place for the Vaccine? Please specify.
26. Do you receive financing via these agreements for the outstanding steps up to the production of the Vaccine? Please specify.
27. 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

28. 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.

29. Could you please share with us any other documents detailing the financing needs for the development and production of the Vaccine (e.g. reports of financing documents prepared for bank financing)?

30. 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

31. What is the amount of at-risk financing already committed to the vaccine project under discussion?

32. 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?

33. What are your detailed additional financing needs in order to
   a. Continue and conclude the R&D process (research, clinical trials, approval process, etc.)?
   b. Scale up production to the expected level (please clarify and explain that level in terms of doses and the associated financing needs)?

34. Which of those financing needs would you see covered by the EU?

35. What type of financing structure do you envisage for that coverage (grants, loans, financial instruments – what structures, etc.)?

36. What is your reward calculation, i.e. what do you expect as financial return on investment and other benefits of that project and how do you see the pricing of the vaccine in that context?

37. In view of the risk sharing provided through the EU financing, how do you envisage the sharing of rewards with the EU (repayment of the financing, remuneration, success linkers, advance purchase agreements at discount, etc.)?

38. What options do you see to share the risk of failure? Is there an option to reuse the acquired capacities / resources for alternative products that could be used to amortise the investment / expenditure? Could those alternative products be supplied to the EU – provided that the EU might be interested?
Liability

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

Regulatory Flexibility

40. 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?

41. What are the plans of the company for a marketing authorisation in the EU and internationally and the foreseen timelines?

42. 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?

43. GMO/BSL issues- Does the company envisage any issues with the GMO legislation or biosafety level requirements for the Vaccine?

Looking to the Future

44. 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?

45. 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?

46. 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?