Questionnaire to CureVac on COVID-19 Vaccine

Thank you for the constructive discussion held on [redacted] 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 [redacted] **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.

   Our Vaccine is based on mRNA technology: [redacted]

   Due to the specific optimization process, CureVac's vaccine technology secures both: high levels of protein produced in the cells and the appropriate activation of innate immunity. This helps to activate immune system in an efficient and natural way, by generating virus neutralizing antibodies and T cells recognizing and eliminating virus.

   All our product candidates go through an integrated optimization and GMP process

   [redacted]

GMP process

CureVac has multiple advantages in the mRNA vaccine space:

- Along with Moderna, we are the only mRNA company with most Vaccine experience
- 
- 

Of course, the lower the dose the higher the number of vaccines can be made at constant manufacturing capacity.

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.

[redacted]

The clinical has been discussed at length with the authorities. Many designs were thought of. Last week the design was [redacted]

The Phase I/IIa is composed of 2 studies: Cost €18m (O/W ~€14m taken care for by CEPI)

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

For reference, please find here attached a Lancet paper on cost of drug development in virology

3. In the call, you mentioned [redacted] ave you already experienced [redacted] hrough clinical development steps? Are there any areas where you [redacted] in [redacted] ? What support will you need to complete all stages of clinical [redacted] ? Are [redacted] already recruited? [redacted]

[redacted]

- [redacted]
- [redacted]

4. In the call, you mentioned that you [redacted]

This is correct for the early part of the trial (see above)

[redacted]

5. In the call, you mentioned that [redacted]

The numbers here only cover [redacted]

- [redacted]

[redacted]

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 capacity? If possible, please provide a flow-chart of the different phases including the expected increase of the production capacity over the time, in particular when the GMP4 site would operate.

7. From the discussions, we understand that you consider 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?

The company is

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?

At this stage, the company

10. Do you have agreements in place with specialized production companies (such as CMOs/consultancies/organizations 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?

The company As a matter of fact, the company Since then, we have

As per question 7 and 8, the company is

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.?

Yes, please see above.

13. In the call, you mentioned that you have

Could you please explain Could you please indicate the state-of-play of

Both

- One
- The other keeps all

IV)

None of these [redacted]

Further Steps for the Finalization 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?

As per the above question, the company is [redacted]
Alternatively, should all [redacted]

- [redacted]
- [redacted]
- [redacted]

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 specialized companies for filling, packaging, etc.? Please indicate whether you have already booked capacity with such companies.

Please see above. [redacted]

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?

[redacted]

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?

[redacted]

At this stage, [redacted]

[redacted]

Generally speaking the company would use [redacted] It is likely that the company would [redacted]

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?

Please above.
[redacted]

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?)?

[redacted]
The results from the clinical trials will provide the answer.
[redacted]
Covid-19 vaccine is thought to stay for several years. We plan to [redacted]

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.

CureVac will start [redacted]
[redacted] and rolled out in multiple geographies.
Pending Safety and efficacy, we expect to have the [redacted]

As referred to in an earlier question, the company plans to [redacted]
to have as [redacted]
We have already [redacted]
in our [redacted] The first is now [redacted]
and [redacted]
We have planned to resume [redacted]
The company [redacted]

We are currently using all the available capacity in [redacted]

The company is trying the [redacted] This suite is a [redacted] that is the source of the current vaccine and as a result is [redacted] The objective is to have [redacted]

21. **Please precise the exact timing in your clinical development when you expect EUA/conditional approval in selected populations.**

In best case- depending on [redacted] – we could imagine [redacted] In general, we expect [redacted] even if thereafter [redacted]

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?**

CureVac and Moderna are the only mRNA significant company with clinical Vaccine experience (prior to SARS-Cov-2). We have been in multiple vaccine clinical trials (prophylactic and therapeutic).

The infectious disease Area is the largest of all CureVac areas (vs. Oncology and Protein Therapies) and our Board of Directors has tremendous vaccine development experience.

[redacted]
CureVac decided to [redacted] At this stage, the company has [redacted]
[redacted] To even more mitigate risks, CureVac is working on [redacted]

In parallel, the company decided to immediately leverage its [redacted]

One of the major risk lies in the [redacted] Drug development is complex and sometimes require to [redacted] The following risks exist:

[redacted]

- ...

23. Any exit strategies in place if expected results are not satisfactory?

Based on these data we are

Beyond and even if

The company nevertheless always thinks of backup strategies in case of unsatisfactory outcomes as point out above.
Moreover, the Company believes Covid-19 is here to stay at least to the midterm.

24. Please specify the return on the financial support provided by the EU in this case.

During the meeting, the Company underlined to the EU that

The current situation requires The company proposes to stage

The chart below shows that:

-

Agreements with Government and International Organizations

25. Do you have agreements with governments, governmental agencies, foundations or international organizations in place for the Vaccine? Please specify.

As of the Company has

[redacted]

26. Do you receive financing via these agreements for the outstanding steps up to the production of the Vaccine? Please specify.

[redacted]

27. Do these agreements include an envisaged allocation of the Vaccine for specific countries/organizations, including pre-arranged timelines? Could these agreements lead to additional (non-currently envisaged by contractually possible) obligations imposed by governments or international organizations 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?

[redacted]

Documents

28. It would be very helpful if you could you provide us with a business plan in relation to the development and production of the Vaccine, in particular with regard to the outstanding steps.

Please see the elements above

29. 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)?

Please see document attached below – Shared with the EC team on [redacted]

[redacted]

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?

Covid-19 is a specific to the current outbreak situation, the best example for required capital (for clinical trials and production capacity) are:

- BARDA financing of Moderna

  Barda awards up to $483m to moderna t

- CEPI financing of Novavax: http://ir.novavax.com/news-releases/news-release-details/novavax-receive-388-million-funding-cepi-covid-19-vaccine#

- Also please see the Lancet paper attached higher in the document

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.)?

       Please see the chart below

    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?

    In current context of health emergency and traditional financial context of biotech companies

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

[redacted]

[redacted]

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?

The company does its best to find a solution against Covid-19 to provide relief to both people and economies. mRNA may prove to be the fastest and best answer to the current situation. CureVac has the potential of be more visible and bring its first vaccine to the market. [redacted]

Certainly, the pricing of the Covid-19 vaccine should not take advantage of the current pandemic situation, but should be competitive with other comparable vaccines developed, e.g. such like flu-vaccine.

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.)?

The company is mainly [redacted] to bring this novel technology to everyone. The upside for the EU is to potentially have [redacted]

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 amortize the investment / expenditure? Could those alternative products be supplied to the EU – provided that the EU might be interested?

Clinical trial costs and at risk manufacturing cost [redacted]

For example, the total cost [redacted] The company is [redacted]

Liability

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

[redacted]

Regulatory Flexibility

40. Do you see any need for the provision of additional regulatory flexibilities than those already available (conditional marketing authorization and national early access schemes prior to authorization) 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?

In the current outbreak situation or in more normal times, the regulatory flexibility is (and should be) on the shoulders of authorities.

The authorities [redacted]

With several companies now seeking to produce vaccines with this platform technology,

will also need to be considered as the vaccines are developed. Quality standards will need to be met, however, under the current circumstances,

The company believes that

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

This will be dependent on the safety and efficacy requirements discussed with the EMA Task Force and the ability to achieve these with data

The required follow-up for this registration is expected to be

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?

Data from all studies are submitted to local authorities as they become available and will be discussed with the EMA to reach decisions on the submission of a Marketing Authorization Application (MAA). Although EMA does not share company proprietary information, their guidance to other companies is influenced by their knowledge of this information. This may be a preferable means of 'sharing knowledge' rather than publicly distributing data, study designs, etc.

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 'standardized' 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?

[redacted]

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?

Outbreaks do happen. Our societies are never sufficiently prepared.
mRNA is showing its potential. There is a clear strategic need to have local (European) capacity to better and quickly respond to needs.

[redacted]

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?

[redacted]