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European Commission
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By email to: EC-VACCINES@ec.europa.eu

Saint-Herblain, July 30, 2020

Subject: Proposal for a COVID-19 vaccine Advanced Purchase Agreement (APA)

To the COVID-19 vaccines Steering Board,

In response to the European Commission announcing on 17 June 2020 the European strategy to accelerate the development, manufacturing and deployment of vaccines against COVID-19, VALNEVA, a specialty vaccine company focused on prevention against diseases with major unmet medical needs, is hereby submitting for consideration its Non-binding Term Sheet for a COVID-19 vaccine Advanced Purchase Agreement (APA).

We are looking forward to receiving the European Commission`s answer to our attached proposal as soon as possible, and will be happy to answer any questions or to participate in any follow-up discussions.

Best regards,

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Non-binding Term Sheet by VALNEVA
for a COVID-19 vaccine Advanced Purchase Agreement (APA)

This Non-binding Term Sheet includes the provisional outline terms proposed by VALNEVA for a COVID-19 vaccine Advanced Purchase Agreement (APA) with the European Commission, subject to a definitive agreement ("**Definitive Agreement**"). The terms of this Non-binding Term Sheet do not describe all the terms and conditions that would be included in the Definitive Agreement. Nothing herein shall be deemed an offer, invitation, acceptance or binding contract between the Parties. It is furthermore understood that any of the Parties are free to terminate discussions at any time and for any reason prior to the execution of the Definitive Agreement.

Preamble

VALNEVA (as defined below) is developing an inactivated, highly-purified, adjuvanted, whole virus human vaccine candidate in respect of SARS-CoV-2 ("VALNEVA VACCINE") utilizing its Vero cell based Japanese Encephalitis Virus (JEV) platform, aiming at similar biological, physical and chemical properties as the licensed Japanese Encephalitis vaccine IXIARO®.

Such Vero cell-based technology is used in various commercial vaccines, including VALNEVA'S EMA/FDA approved IXIARO®, and is suitable for a broad population, including for instance the elderly and immunocompromised patients.

The adjuvant may be either Dynavax's CpG 1018, or GSK`s AS03 and/or aluminium hydroxide; such adjuvant strategy to be evaluated during the development phase.

Fill & Finish, quality control and release of the VALNEVA VACCINE will be done in the EU and possibly in the UK.

Subject to CTA approval and funding, VALNEVA clinical trials for the VALNEVA VACCINE will commence by the end of 2020.

On 20 July 2020 the UK Government announced that the UK secured early access to 90 million doses of promising COVID-19 vaccine candidates from three pharmaceutical and vaccine companies, including VALNEVA.*

VALNEVA is in negotiations with the UK Government to contribute to funding for clinical studies and manufacturing expansion. The deal between the UK Government and VALNEVA has been agreed in principle for 60 million doses. If the vaccine is proven to be safe, effective and suitable, the UK has secured an option to acquire a further 40 million doses.*

In 2021 VALNEVA`s total maximum capacity of VALNEVA VACCINE is expected to be 60m Doses (as defined below) subject to capacity expansion, site qualification and manufacturing assumptions.

In 2021 VALNEVA could supply any remaining Doses that may be available above the quantities committed to the UK. [Note: UK Govt. is negotiating with several companies, therefore VALNEVA might not be required to deliver the full 60m Dose commitment to the UK in 2021.]

*https://www.gov.uk/government/news/millions-could-be-vaccinated-against-covid-19-as-uk-secures-strong-portfolio-of-promising-vaccines

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	In 2022 VALNEVA`s total maximum capacity of VALNEVA VACCINE is expected to exceed 200m Doses subject to capacity expansion, site qualification and manufacturing assumptions. In 2022 VALNEVA could supply between 150m to 180m Doses with the possibility of additional quantities should the UK not request fulfilment of its optional 40m Doses*. The supply of VALNEVA VACCINE to the Member States in 2021 and 2022 is subject to the EC placing a binding pre-order by 15 September 2020 (see below) and VALNEVA not signing a 3rd party deal prior to such date that would give such 3rd party priority over the EC.
Definitions	
Definitive Agreement	Means the Advanced Purchase Agreement to be signed by the Parties by 31 August 2020.
Dose	Means a single dose of VALNEVA VACCINE for a healthy adult. [Note: two Doses required for full immunization: initial vaccination + re-vaccination]. The number of Doses mentioned throughout this Non-binding Term Sheet is subject to final formulation and yields.
Parties	(1) Valneva SE, a company registered in France under registered number 422,497,560 whose registered office is at 6 rue Alain Bombard 44800 Saint Herblain, France (provided that it is envisaged that the party to the Definitive Agreement will be Valneva Austria GmbH, a company registered in Austria under registered number FN 389960 x / HG Wien whose registered office is at Campus Vienna Biocenter 3, 1030 Vienna, Austria) which company, together with its subsidiaries, owns all relevant Valneva assets and is intended to hold the marketing authorization for the VALNEVA VACCINE in the EU) and (2) The European Commission, on behalf the Member States
Subject Matter	Advanced Purchase Agreement (APA) for the supply of 150m to 180m Doses of VALNEVA VACCINE in 2022 and, under certain circumstances, supply of available quantities in 2021, and partial funding by the EC of the development and manufacturing costs of the VALNEVA VACCINE.
Funding provided by the European Commission	[The EC shall fund: (i) up to €25m** for the Fill & Finish scale-up of VALNEVA`s facility in Solna, Sweden; and (ii) up to €80m*** for the clinical development of the VALNEVA VACCINE ((i)+(ii) hereinafter the "**EC Funding**"). **A table with the breakdown of estimated Fill & Finish scale-up costs is attached to this Non-binding Term Sheet. ***Subject to funding received from the UK Government* and actual final costs of the clinical development.

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	From such EC Funding the EC shall make an upfront payment to VALNEVA in the total amount of €25m by 31 August 2020 in order that VALNEVA may immediately start the scale-up of its F&F facility in Sweden. VALNEVA commits not to request funding from the EC for the development or manufacturing of the VALNEVA VACCINE to the extent such costs will be funded by the UK Government* or a 3rd party.
Pre-order by the EC	The EC shall place a binding pre-order for 150m to 180m Doses of VALNEVA VACCINE by 15 September 2020 ("**Pre-Payment**").
Pricing	First 150m to 180m Doses to be priced at €8 + adjuvant at cost / Dose*. * This price is indicative and subject to supply terms with the adjuvant supplier, i.e CpG from Dynavax, or AS03 from GSK (alum is part of the VALNEVA VACCINE COGS).
Payment terms	The EC Funding the Pre-Payment shall be paid according to the payment terms agreed in the Definitive Agreement. Upfront and milestone payments will be used exclusively for the development and manufacturing of the VALNEVA VACCINE. The EC Funding and the Pre-Payment will be offset 100% against the supply price.
Development of VALNEVA VACCINE	VALNEVA will use commercially reasonable efforts to develop the VALNEVA VACCINE to secure marketing authorization in the EU. VALNEVA will devote the necessary resources to expedite the regulatory process of approval of the VALNEVA VACCINE for the EU market. In case VALNEVA is unable to develop an effective vaccine, VALNEVA would be ready to cooperate with the EC on contract manufacturing of a vaccine successfully developed by a 3rd party.
Manufacturing of VALNEVA VACCINE	VALNEVA has existing facilities and capabilities in Europe and UK, including Sweden, Austria, France, and will use commercially reasonable efforts to manufacture and to deliver to the Member States between 150m to 180m Doses of VALNEVA VACCINE latest in 2022, or under certain circumstances, supply of available quantities already in 2021 and possibly additional quantities in 2022.
Supply of VALNEVA VACCINE	Supply will commence after marketing authorization for the VALNEVA VACCINE has been granted, unless the EC requests otherwise. VALNEVA will use commercially reasonable efforts to supply the ordered VALNEVA VACCINE to the Member States according to agreed timelines.
Delivery	VALNEVA cannot commit to a fixed and binding delivery schedule given the uncertainties, including yield, regulatory approval timings, etc. However, VALNEVA commits itself to communicate the anticipated delivery date of the first Doses of VALNEVA VACCINE as soon as practically possible and will provide an anticipated real time delivery schedule on a weekly basis based on the VALNEVA

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	VACCINES actually released.
Term and termination	The Definitive Agreement shall contain a mechanism whereby in case of termination by the EC, VALNEVA shall not be required to refund any EC Funding or Pre-Payment received prior to termination and the EC shall reimburse VALNEVA for any committed but unrecovered costs and any costs associated with wastage or scrapped work in progress arising out of such termination.

Caveat:

VALNEVA agrees to act and conduct negotiations for the Definitive Agreement in good faith and acting reasonably and reflecting the above non-binding terms in the Definitive Agreement. However, this Non-binding Term Sheet was prepared by VALNEVA based on several assumptions as outlined in the Presentation attached hereto, and due to evolving circumstances with regard to the COVID-19 pandemic and vaccine companies racing for licensure, those assumptions might change. Further, the Definitive Agreement shall be subject to due diligence by both Parties.

VALNEVA agrees that (i) it will make every effort so that all information disclosed to the European Commission during the diligence process shall be true, complete, accurate and not misleading, noting that some aspects of this project depend on third parties, including adjuvant suppliers, which Valneva does not control; and (ii) it shall provide documents and information, and cooperate with the European Commission to fully and truthfully disclose the pre-clinical and clinical data available to VALNEVA in respect of the VALNEVA VACCINE; and to provide evidence of VALNEVA's current manufacturing capacity.

Annex:

- VALNEVA`s presentation entitled "Inactivated SARS-CoV-2 vaccine / VLA 2001 Project";
- Table with breakdown of estimated Fill & Finish scale-up costs.

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Breakdown of estimated Fill & Finish scale-up costs

Description C-house project	Budget [M€]
Equipment, fill line	5.1.1c
Equipment, packaging and inspection	
Reconstruction, fill line	
Reconstruction, packaging and inspection	
Validation/design/project management	
Cold room storage (100) (internal flow)	
Sum	
Contingency	
Total	**25**

*https://www.gov.uk/government/news/millions-could-be-vaccinated-against-covid-19-as-uk-secures-strong-portfolio-of-promising-vaccines