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GESTDEM 2020/5436 and GESTDEM 2021/0559 FOURTH BATCH

/5436 and GESTDEM 2021/0559 FOURTH BATCH

STEERING BOARD MEETINGS_AGENDA	
Subject	
Meeting 03 07 2020 – Minutes	
SB Minutes_17 August 2020	
pro-rata adjusted+EUROSTAT'	
Email_SB Agenda_11 September 2020	
Agenda_SB Minutes_11 September 2020	
Scientific Presentation by AstraZeneca Representatives - 5 August 2020 - Report and Presentation	
Scientific Update by Sanofi Pasteur Representatives -17 December 2020 - Report and Presentation	
Scientific Update by CureVac Representatives, 17 November 2020 - Pre-Clinical and Clinical Development Data Upda	
Scientific Update by CureVac Representatives, 3 November 2020 - Report and Presentation	
Scientific Presentation by ReiThera Representatives, 8 October 2020 - Report and Presentation	
Follow-up Discussion to the Scientific Presentation by CureVac Representatives, 7 October 2020	
Scientific Presentation by CureVac Representatives, 28 September 2020 - Report and Presentation	
Scientific Presentation by Sanofi-GSK Representatives, 9 September 2020 - Report and Presentation	
Scientific Presentation by Johnson & Johnson Representatives, 4 September 2020 - Report and Presentation	
Scientific Presentation by CureVac Representatives, 28 August 2020 - Report and Presentation	
Scientific Presentation by Novavax Representatives, 11 August 2020 - Report and Presentation	
Scientific Presentation by BioNTech/ Pfizer Representatives - 7 August 2020 - Report	
Steering Board Meeting with Experts from the Scientific Board of France, Spain and the Netherlands, 27 July 2020 - 🛭	
Steering Board Meeting with Experts from the Scientific Board of France, Spain and the Netherlands, 27 July 2020 -	
Scientific considerations regarding the adenovirus vectored vaccines against SARS-COV-2 - Opinion of the Spanish	
Scientific Committee	
Steering Board Meeting with Experts from the Scientific Board of France, Spain and the Netherlands, 27 July 2020 - S	
Steering Board Meeting with Experts from the Scientific Board of France, Spain and the Netherlands, 27 July 2020 - S	
European Commission's advisory panel on COVID-19, report – videoconference 20/07/2020	
European Commission's advisory panel on COVID-19, Invitation letter—videoconference 20/07/2020	
European Commission's advisory panel Letter	
Scientific Update by AstraZeneca Representatives - Safety and efficacy - 15 December 2020	
Scientific meeting with Moderna, 15 July 2020	
Overview of contacts with companies on COVID-19 vaccine presented to the Steering Board, 26.02.2021	
Overview of contacts with companies on COVID-19 vaccine presented to the Steering Board, 03.11.2020	
Annex_Confidentiality_SB Meeting 25 September 2020	
Overview - contacts with other companies on COVID-19 vaccine presented to the Steering Board 30.07.20	
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ASTRA ZENECA

- 1. Draft APA negotiated between AstraZeneca and the Evaluation Committee on 13-08-20
- 2. Draft APA negotiated between AstraZeneca and EvaluationCommittee on 13-08-20 2

1.AstraZeneca COVID-19 Vaccine Update on developments sent to the European Commission

AW Draft Term Sheet for Supply of AstraZeneca COVID-19 vaccine (AZD 1222) in Europe - comments JNT 1 (DE)

Overview - contacts with other companies on COVID-19 vaccine presented to the Steering Board 14.07.20

3. AW Draft Term Sheet for Supply of AstraZeneca COVID-19 vaccine (AZD 1222) in Europe - comments JNT 2 (DE)

4. Follow up - AZ EC exploratory meeting

- 5. Re URGENT info about suspension of clinical trials for COVID-19 vaccine
- 6. RE Draft Term Sheet for Supply of AstraZeneca COVID-19 vaccine (AZD 1222) in Europe comments JNT 3 (FR)
- 7. RE Draft Term Sheet for Supply of AstraZeneca COVID-19 vaccine (AZD 1222) in Europe comments JNT 4 (FR)
- 8. TR Draft Term Sheet for Supply of AstraZeneca COVID-19 vaccine (AZD 1222) in Europe comments JNT 5 (FR)
- 9. WG Draft Term Sheet for Supply of AstraZeneca COVID-19 vaccine (AZD 1222) in Europe comments JNT 6 (DE)

Call for tenders SANTE/2020/C3/037 for the development, production, priority-purchasing options and supply of COVID-

Call for tenders SANTE2020C3037 for the development, production, priority-purchasing options and supply

Call for tenders SANTE2020C3037 for the development, production, priority-purchasing_Annex 6 - Financial offer

RE: CALL FOR TENDERS SANTE/2020/C3/037 - OFFER

SANTE/2020/C3/037 - Notification Letter : Call for tenders for the development, production, priority-purchasing options

Notification letter: SANTE/2020/C3/037: Development, production, priority-purchasing options and supply of

Notification letter: SANTE/2020/C3/037: Development, production, priority-purchasing options and supply of

SARS CoV-2 Vaccine (AZD1222) Progress Report 19 January 2021

FD tbcUKPAR_COVID_19_Vaccine_AstraZeneca_05.01.2021_RED

Email SARS CoV-2 Vaccine (AZD1222) Progress Report 19 January 2021

MHRA Public Assessment Report AZ Covid-19 Vaccine

FD tbc UKPAR COVID 19 Vaccine AstraZeneca 05.01.2021.pdf

RE: Follow up from yesterday meeting

Commission IR 2021/111 of 29 Jan 2021

Commission IR 2021/111 of 29 Jan 2021 Regulation FD

APA AstraZeneca – 2nd instalment payment – second request for full report

APA AstraZeneca – 2nd instalment payment request – Response letter

follow-up questionnaire - sent to Astra Zeneca

Email follow-up questionnaire - sent to Astra Zeneca

skype meeting with Astra Zeneca - 14/05/2020 - vaccines

BioNTech&Pfizer

- 2. Draft APA negotiated between BioNTech&Pfizer and Evaluation Committee (technical) 07-11-2020
- 3. Draft APA negotiated between BioNTech&Pfizer and Evaluation Committee (technical)09-11-2020 2
- 5. Draft APA negotiated between BioNTech&Pfizer and Evaluation Committee (technical) 09-11-2020
- 13. Follow up exploratory talks Pfizer call 08 06 2020

Tender submission (in 3 emails)

CALL FOR TENDERS SANTE/2020/C3/043 - OFFER - email 1 of 3

CALL FOR TENDERS SANTE/2020/C3/043 - OFFER - email 2 of 3

Notification Letter

Invitation to tender

Tender submission

Notification Letter

Notification Letter sent to Pfizer/BNT informing of the outcome of the award procedure

Advance purchase agreement signed by Pfizer/BNT (in 2 emails)

Janssen Pharmaceutica

1.Draft Advanced Purchase Agreement negotiated between J&J and the Evaluation Committee (technical) 04-09-

2. Draft APA negotiated between J&J and the Evaluation Committee 15-09-2020

- 3. Draft Advanced Purchase Agreement negotiated between J&J and the Evaluation Committee (technical) 18-09-
- 4.Draft Advanced Purchase Agreement negotiated between J&J and the Evaluation Committe (technical) 25-09-
- 5.Draft Advanced Purchase Agreement negotiated between J&J and the Evaluation Committee (technical) 28-09-
- 6. Draft APA negotiated between J&J and the Evaluation Committee 01-10-2020
- 7. Draft APA negotiated between J&J and the Evaluation Committee (technical) 02-10-2020
- 8. Draft APA negotiated between J&J and the Evaluation Committee (technical) 06-10-2020
- Janssen_J&J Expression of Intrest to the EC re COVID-19 vaccine
- 3. Jansen_J&J response to the questionnaire
- 4. Jansen_J&J COVID-19 vaccine proposal to the EC (1)- call 6-05-2020
- 5. Janssen J&J COVID-19 vaccine proposal to the EC (2)
- 6. Jansen J&J COVID-19 vaccine proposal to the EC (3) call 10-06-2020
- 7. Jansen J&J COVID-19 vaccine proposal to the EC (4)- follow up call 10-06-2020
- 8. Draft term sheet discussed with Jansen_J&J at the Joint Negotiation Team during the exploratory talks on 11-06-
- 9. Draft term sheet discussed with Jansen_J&J at the Joint Negotiation Team during the exploratory talks on 17-06-
- 10. Jansen_J&J COVID-19 vaccine proposal to the EC and EU4 (5)
- 11. Draft term sheet discussed with Jansen_J&J at the Joint Negotiation Team during the exploratory talks on 10-08-Call for tenders SANTE/2020/C3/047 for the development, production, priority-purchasing options and supply of CALL FOR TENDERS SANTE/2020/C3/047 OFFER

SANTE/2020/C3/047 - Notification Letter: Call for tenders for the development, production, priority-purchasing Notification letter: SANTE/2020/C3/047: Development, production, priority-purchasing options and supply of Follow-up questionnaire - sent to Johnson & Johnson / Janssen

skype meeting with Johnson & Johnson / Janssen - vaccine - 06/05/2020

Report from the TC with J&J on COVID 19 Vaccine

Summary: J&J TC on COVID 19 Vaccine

[Re] Summary: J&J TC on COVID 19 Vaccine

BTO: Johnson & Johnson meeting with Martin Seychell, 11 March 2020

RE: Study: Johnson and Johnson vaccine successfully prevents COVID-19 infections in monkeys

J&J accelerates COVID-19 vaccine development (Phase 1/2a Clinical Trials in Belgium starting July 2020) and

J&J Joins Industry Partners to Launch the \$1 Billion AMR Action Fund

Johnson & Johnson announces a Lead Vaccine Candidate for COVID-19

[Re] Johnson & Johnson announces a Lead Vaccine Candidate for COVID-19

RE: J&J Announces a Lead Vaccine Candidate for COVID-19

Johnson & Johnson COVID-19 vaccine development update: launch of Phase 3 clinical trials

Johnson & Johnson COVID-19 treatment development update

- 1. Draft APA negotiated between Moderna and the Evaluation Committee (technical) on 29-06-2020
- 2. Draft APA negotiated between Moderna and the Evaluation Committee on 04.11.2020- 4 pm
- 3. Draft APA negotiated between Moderna and the Evaluation Committee (technical) 12-11-2020
- 4. Draft APA negotiated between Moderna and the Evaluation Committee (technical) on 18-11-2020
- 5. Draft APA negotiated between Moderna and the Evaluation Committee (technical) on 18-11-2020 2
- 6. Draft APA negotiated between Moderna and the Evaluation Committee on 19-11-2020

Email 6. Draft APA negotiated between Moderna and the Evaluation Committee on 19-11-2020

- 7. Draft APA negotiated between Moderna and the Evaluation Committee on 19-11-2020 2
- 8. Draft APA negotiated between Moderna and the Evaluation Committee (model annex) on 19-11-2020
- 9. Draft APA negotiated between Moderna and the Evaluation Committee (technical) on 21-11-2020
- 10. Draft APA negotiated between Moderna and the Evaluation Committee (technical) 22-11-2020 2
- 11. Draft APA negotiated between Moderna and the Evaluation Committee (technical) 22-11-2020
- 12. Draft APA negotiated between Moderna and the Evaluation Committee (technical) on 24-11-2020 1

- 13. Draft APA negotiated between Moderna and the Evaluation Committee (technical) on 24-11-2020 2
- 14. Draft APA negotiated between Moderna and the Evaluation Committee (technical) on 24-11-2020 3

Question 1 in scope of Invitation to tender for procedure SANTE 2020/C3/054 (Moderna)

Answer to question 1 - Invitation to tender for procedure SANTE/2020/C3/054 (Moderna)

Question 2 in scope of Invitation to tender for procedure SANTE/2020/C3/054 (Moderna)

Questions in scope of Invitation to tender for procedure SANTE/2020/C3/054 (Moderna)

Answer to question 2 - Invitation to tender for procedure SANTE/2020/C3/054 (Moderna)

Complement Answer to question 2 - Invitation to tender for procedure SANTE/2020/C3/054 (Moderna)

Question 3 in scope of Invitation to tender for procedure SANTE/2020/C3/054 (Moderna)

Answer to question 3 - Invitation to tender for procedure SANTE/2020/C3/054 (Moderna)

Call for tenders SANTE/2020/C3/054 for the development, production, priority-purchasing options and supply of

CALL FOR TENDERS SANTE/2020/C3/054 - OFFER

SANTE/2020/C3/054 - Notification Letter: Call for tenders for the development, production, priority-purchasing

Notification letter: SANTE/2020/C3/054: Development, production, priority-purchasing options and supply of

Notification letter: SANTE/2020/C3/054: Development, production, priority-purchasing options and supply of

- 5. Moderna info on EMA submission timeline for mRNA1273 02-08-2020
- 8. Moderna draft Term Sheet discussed with the JNT (i&I clauses) 20-08-2020
- 7. Moderna draft Term Sheet discussed with the JNT (i clause) 14-08-2020
- 6. Moderna draft Term Sheet discussed with the JNT 11-08-2020
- 6. Moderna draft Term Sheet discussed with the JNT 11-08-2020
- 4. Moderna draft Term Sheet discussed with the JNT (i clause) 30-07-2020
- 3. Reply to Moderna proposal by the Commission (SB feedback) 22-07- 2020
- 2. Moderna revised proposal 10-07-2020.docx (153 KB)
- 1. Moderna Expression of Interest to the EC re COVID-19 vaccine 29-06-2020

Invitation to tender SANTE/2021/C3/010

Tender submission

request for clarifications and missing documents (call or tenders SANTE/2021/C3/010)

clarifications and missing documents (call or tenders SANTE/2021/C3/010)

RE: Meeting of the Evaluation Committee with Moderna- 12.02.2021 at 16.00

RE: Meeting of the Evaluation Committee with Moderna- today (15/02) at 21:00

Email RE: Meeting of the Evaluation Committee with Moderna- today (15/02) at 21:00

RE: SANTE/2021/C3/010- Meeting of the Evaluation Committee with Moderna - 11.02.2021

Notification Letter

Notification Letter sent to Moderna informing of the outcome of the award procedure

Meeting of the Evaluation Committee with Moderna- 12.02.2021 at 16.00

CureVac

- 1. Draft APA negotiated between CureVac and the Evaluation Committee on 18-09-2020
- 2. Draft APA negotiated between CureVac and the Evaluation Committee (technical) on 25-09-202
- 3. PreREADS CureVac Scientific presentation to Member States on 28-09-2020
- 4. CureVac Scientific presentation to Member States on 28-09-2020
- 5. CureVac Scientific presentation to Member States on 3-11-2020
- 6. Draft APA negotiated between CureVac and the Evaluation Committee on 12-11-2020
- 7. Draft APA negotiated between CureVac and the Evaluation Committee (technical) on 24-11-2020
- 1. CureVac Expression of Interest to the EC re COVID-19 vaccine- call 07-05-2020
- 2. CureVac Expression of Interest to the EC re COVID-19 vaccine feedback EIB
- 3. CureVac response to the questionnaire

Curevac Presentation

- 4. CureVac Proposal to the EC re COVID-19 vaccine
- 5. CureVac Proposal to the EC re COVID-19 vaccine- follow up
- 6. CureVac draft Term Sheet discussed with the Joint Negotiation Team (first draft)16-06-2020
- 7. CureVac draft Term Sheet Joint Negotiation Team comments (FR) 08-07-2020
- 8. CureVac draft Term Sheet Joint Negotiation Team comments (EC) 08-07-2020 2
- 9. CureVac draft Term Sheet discussed with the Joint Negotiation Team 28-07-2020
- 10. CureVac draft Term Sheet discussed with the Joint Negotiation Team on 11-08-2020
- 11. CureVac COVID-19 vaccine update and current data from clinical trials 17-08-2020
- 12. CureVac draft Term Sheet discussed with the Joint Negotiation Team (L&I clause) 17-08-2020
- 13. CureVac draft Term Sheet discussed with the Joint Negotiation Team 18-08-2020
- 14. CureVac draft Term Sheet discussed with the Joint Negotiation Team (L&I clause pre-final) 19-08-2020
- 15. CureVac draft Term Sheet discussed with the Joint Negotiation Team (L&I clause final) 19-08-2020
- 16. CureVac investigational brochure (IB) for COVID-19 vaccine

Question 1 in scope of Invitation to tender for procedure SANTE 2020/C3/049 (Curevac)

Question 2 in scope of Invitation to tender for procedure SANTE 2020/C3/049 (Curevac)

Question 3 in scope of Invitation to tender for procedure SANTE 2020/C3/049 (Curevac

Answer to question 1 & 3 - Invitation to tender for procedure SANTE/2020/C3/054 (Curevac)

Answer to question 2 - Invitation to tender for procedure SANTE/2020/C3/054 (Curevac)

Call for tenders SANTE/2020/C3/049 for the development, production, priority-purchasing options and supply of

Tender submission (see 8 below entries - submission in 8 emails)

Call for tenders SANTE/2020/C3/049 - Offer (1)

Call for tenders SANTE/2020/C3/049 - Offer (2)

Call for tenders SANTE/2020/C3/049 - Offer (3)

Call for tenders SANTE/2020/C3/049 - Offer (4)

Call for tenders SANTE/2020/C3/049 - Offer (5)

Call for tenders SANTE/2020/C3/049 - Offer (6)

Call for tenders SANTE/2020/C3/049 - Offer (7)

Call for tenders SANTE/2020/C3/049 - Offer (8)

SANTE/2020/C3/049 - Notification Letter : Call for tenders for the development, production, priority-purchasing

Notification letter: SANTE/2020/C3/049: Development, production, priority-purchasing options and supply of

Follow-up questionnaire - sent to CureVac

skype meeting with CureVac - vaccine - 07/05/2020

Sanofi - GSK

Call for tenders SANTE/2020/C3/042 for the development, production, priority-purchasing options and supply of CALL FOR TENDERS SANTE/2020/C3/042 – OFFER

SANTE/2020/C3/042 - Notification Letter: Call for tenders for the development, production, priority-purchasing

Notification letter: SANTE/2020/C3/042: Development, production, priority-purchasing options and supply of

1. Draft APA negotiated between Sanofi&GSK and the Evaluation Committee 27-08-20

Email 1. Draft APA negotiated between Sanofi&GSK and the Evaluation Committee 27-08-20

2. Draft APA negotiated between Sanofi&GSK and the Evaluation Committee 27-08-2020 App

Email 2. Draft APA negotiated between Sanofi&GSK and the Evaluation Committee 27-08-2020 App

3. Draft APA negotiated between Sanofi&GSK and the Evaluation Committee 03-09-20

Email 3. Draft APA negotiated between Sanofi&GSK and the Evaluation Committee 03-09-20

4. Draft APA negotiated between Sanofi&GSK and the Evaluation Committee 04-09-20

Email 4. Draft APA negotiated between Sanofi&GSK and the Evaluation Committee 04-09-20
5. Draft APA negotiated between Sanofi&GSK and the Evaluation Committee 05-09-20
6. Draft APA negotiated between Sanofi&GSK and the Evaluation Committee 10-09-20
Email 6. Draft APA negotiated between Sanofi&GSK and the Evaluation Committee 10-09-20
7. Draft APA negotiated between Sanofi&GSK and the Evaluation Committee 11-09-20
8. Draft APA negotiated between Sanofi&GSK and the Evaluation Committee 11-09-20 2
Email 8. Draft APA negotiated between Sanofi&GSK and the Evaluation Committee 11-09-20 2
9. Draft APA negotiated between Sanofi&GSK and the Evaluation Committee 11-09-20 3
10. Draft APA negotiated between Sanofi&GSK and the Evaluation Committee 14-09-20
11. Final APA sent to Sanofi&GSK for signature 16-09-20
12. Scan of a signed version of the APA sent to Sanofi&GSK 25-09-20
13. Sanofi-GSK COVID19 vaccine - Progress report 26-10-20
Sanofi&GSK proposed options on post approval studies 08-09-20
Sanofi&GSK Scientific technical presentation Sanofi-GSK 09-09-20
Summary of the meeting with Sanofi, 26 October, 12:00 – 12:45 pm, via WebEx
1. Sanofi response to the questionnaire 19-05-20 Email
1. Sanofi response to the questionnaire 19-05-20
2. GSK response to the questionnaire 21-05-20
3. Draft term sheet discussed with Sanofi&GSK at the JNT during the exploratory talks 12-06-20
4. Draft term sheet discussed with Sanofi&GSK at the JNT during the exploratory talks 22-06-20
5. Sanofi&GSK pre reads exploratory talks 24-06-20
6. Sanofi&GSK presentation exploratory talks 25-06-20
7. Draft term sheet discussed with Sanofi&GSK at the JNT during the exploratory talks 29-06-20
Answers to your questions list – guiding you in the Term Sheet version 2
Cover Letter explaining the principles of the revised Term Sheet (version 2)
8. Draft term sheet discussed with Sanofi&GSK at the JNT during the exploratory talks 10-07-20
Email 8. Draft term sheet discussed with Sanofi&GSK at the JNT during the exploratory talks 10-07-20
9. Draft term sheet discussed with Sanofi&GSK at the JNT during the exploratory talks 22-07-20
10. Draft term sheet discussed with Sanofi&GSK at the JNT during the exploratory talks 29-07-20
Sanofi and GSK to join forces in unprecedented vaccine collaboration to fight COVID-19
Sanofi and GSK to join forces in unprecedented vaccine collaboration to fight COVID-19
meeting with SANOFI on APIS on 2.04 - bto
follow-up questionnaire - sent to GSK
skype meeting with GSK - 12/05/2020 - vaccines
NOVAVAX
Novavax exploratory talks outcome 11.12.2020

Novavax exploratory talks outcome 11.12.2020	
Novavax exploratory talks with JNT Indemnity Liability Comments 5.11.2020	
Novavax exploratory talks with JNT 6.12.2020	
Novavax exploratory talks with JNT 9.12.2020	
Novavax exploratory talks with JNT 25.08.2020	
Novavax exploratory talks with JNT 26.08.2020	
Novavax exploratory talks with JNT Idemnification 19.09.2020	
Invitation to tender SANTE/2020/C3/087	
Invitation to tender Tender Specifications Vaccins COVID19	
Invitation to tender Annex 6 - Financial offer	

Q1 : RE: Call for tenders SANTE/2020/C3/087 for the development, production, priority-purchasing options and supply of

Answer to Q1 (part 1)

Answer to Q1 (part 2) : RE: SANTE/2020/C3/087 - question on deadline

Tender submission

Draft APA based on your tender

RE: CALL FOR TENDERS SANTE/2020/C3/087 - OFFER (request 1)

RE: CALL FOR TENDERS SANTE/2020/C3/087 - OFFER (answer 1)

Email RE: CALL FOR TENDERS SANTE/2020/C3/087 - OFFER (answer 1)

RE: CALL FOR TENDERS SANTE/2020/C3/087 - OFFER (request 2)

RE: CALL FOR TENDERS SANTE/2020/C3/087 - OFFER (answer 2)

RE: CALL FOR TENDERS SANTE/2020/C3/087 - OFFER (request 3)

RE: CALL FOR TENDERS SANTE/2020/C3/087 - OFFER (answer 3)

RE: CALL FOR TENDERS SANTE/2020/C3/087 - OFFER (request 1) - follow up

RE: CALL FOR TENDERS SANTE/2020/C3/087 - OFFER (request 1) - follow up - answer

RE: CALL FOR TENDERS SANTE/2020/C3/087 - New Subcontractors
Novavax / EU Commission Draft APA 03/02/2021

Novavax / EU Commission Draft APA 14/11/2020

Novavax Investigator Brochure 06/02/2021

RE: Meeting of the Evaluation Committee with Novavax- Thursday 04.03.21 at 4.30 pm

RE: Meeting of the Evaluation Committee with Novavax-Thursday 04.03.21 at 4.30 pm_2

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