1

Van: [redacted]
Aan: [redacted]
Onderwerp: FW: COVID-19 vaccine
Datum: woensdag 29 april 2020 15:31:29
Bijlagen: Covid Vaccine Demand Mapping.pptx
Vaccine brief final.docx

Ter info

Van: [redacted]
Verzonden: woensdag 29 april 2020 15:28
Aan: [redacted]
Onderwerp: FW: COVID-19 vaccine

Dag [redacted]

Zie bijgaand het mailtje van [redacted]. Ik zal Halix zelf even mailen en daarna bellen.

Kennen jullie het bedrijf?

Groet

[redacted]

Van: [redacted] [mailto:[redacted]@gmail.com]
Verzonden: woensdag 29 april 2020 10:27
Aan: [redacted]
CC: Pieter Omtzigt
Onderwerp: COVID-19 vaccine

Beste [redacted]

Heel goed je gisteren gesproken te hebben over de potentiële investering in een Nederlands bedrijf voor de productie van COVID-19 vaccines. Hierbij, zoal beloofd, een brief voor Premier Rutte met de details. Ik zal het ook delen met de Minister van Financiën.

Vriendelijke groeten,

[redacted]

+44 [redacted]

1a

Geachte Minister President/Dear Prime Minister,

I am writing to you in relation to a vaccine for COVID-19 in general and the vaccination trial that is being run by the Jenner Institute and Oxford Vaccine Group, in particular. [redacted] referred to this project yesterday and we promised to send you the details.

It is believed that Oxford has a highly competitive COVID19 vaccine development programme, which may be the first to reach the point of licensure & multi-million dose availability. They have very encouraging animal data, started clinical trials last week, and are aiming for large-scale availability of vaccine for high-risk groups in the autumn. Obviously there are no guarantees, but the signs are encouraging so far.

They think one of the strengths of their vaccine is the fact that the manufacturing process is relatively simple and very productive (many doses of vaccine from a small volume of cell culture). Manufacturing of any vaccine does however take a few months – mostly time spent preparing for the manufacturing, and then testing the product. Given the likely enormous demand for whichever vaccine is successful in clinical trials, it is highly likely that quantities of manufactured product will be limiting for some months after a positive clinical trial result. To avoid significant delay there is no real alternative other than to scale up manufacturing capacity now, *in advance* of the trial results.

They have assembled a consortium of contract manufacturers to scale up production over the coming months. Alongside UK companies, this includes Halix, a company in Leiden. Based upon their current estimates, Halix' existing equipment could produce approximately 2m doses of vaccine per month. They think there is scope to increase this to approximately 10m doses / month, maybe more, with some quite modest capital investment – probably less than 10 million Euro. It seems relatively unlikely that this would be funded by the UK government, which is funding much of the rest of their work.

I have spoken to [redacted] who is leading on the vaccine manufacturing scale-up project. They are wondering whether there may be Dutch government interest in supporting this. This could be a huge win for the Netherlands for a relatively small investment especially if the vaccine is ready before a possible second wave this autumn and it has the co-benefit that is stimulates the Dutch pharmaceutical industry. An important component would be to ensure that the vaccine is available to whoever needs it most, and that a proportion of the production is dedicated to a global pool that is accessible to all countries. I.e. the vaccine does not go to the highest bidder and poor countries are not the last ones to receive it. This is consistent with your excellent OpEd in the Financial Time. In doing so you guarantee a true global public good.

Please find attached a presentation with a proposal for the distribution of vaccines and, if helpful, I can connect you with Professor [redacted] Economics Professor at the Blavatnik School of Governance, University of Oxford. He was the former chief economist at DfID, and the brains behind the $2bn CEPI appeal for vaccine development acceleration launched at the G20, that you so generously supported, and the equitable distribution of vaccines.

The next step is to call the MD of Halix, [redacted]@halix.nl, +31 6 [redacted] to open a channel of communication.

I hope this is helpful and please do not hesitate to contact me if you have any further questions or if I can support you in any way.

Very best wishes,

[redacted]
+44 [redacted]

1b

Discussion Materials regarding
COVID VACCINE MANUFACTURING CONSIDERATIONS

27th April 2020

LION'S HEAD
global partners

Contents

LION'S HEAD
global partners

I. Background

LION'S HEAD
global partners

I. Background
(As of April 23, 2020)

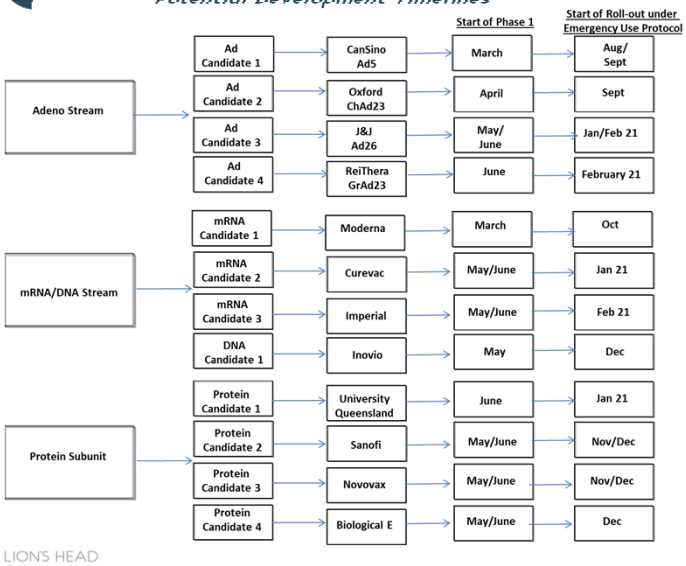
- ❑ The Covid-19 outbreak has led to an unprecedented race to develop a vaccine
- ❑ Progress is being made with 4 vaccines now in phase 1 clinical trial - a record achievement. It is estimated that over 100 other candidates are under development
- ❑ There are many challenges ahead not least how late stage trials are carried out to prove efficacy within a reasonable timetable balancing with the extraordinary economic burden being caused by physical measures to prevent viral spread
- ❑ However if we assume that a vaccine can be made, focus must turn to how to manufacture it and distribute it in an equitable format. This needs to balance the reality that without an upfront agreement manufacturing countries will wish to prioritise their own most vulnerable citizens before allowing export, with the fact that global equity is critically important
- ❑ We present a proposal of the principals of an equitable distribution plan and an advance purchase programme

II. Overview of Vaccine Candidates

LION'S HEAD
global partners

II. Vaccine Candidates

Potential Development Timelines



- 7 candidate vaccines could be available under an emergency use protocol in 2020
- Of these
  - **CanSino** – domestic use China
  - **ChAdOx1** – domestic use India + export, domestic use US + export and Europe + export
  - **Moderna** – domestic use US
  - **Inovio** – domestic use Korea
  - **Sanofi** – domestic use US + export *if US demand is met*
  - **Novovax** – domestic use US
  - **Biological E** – domestic use India

Of next wave only J&J has capacity to supply domestic and export markets

LION'S HEAD
global partners

6

II. The Fastest Strategy to Roll-Out

- One of the large cell culture strategies offers the fastest route to a true global scale with a vaccine that regulators understand and is known to be safe
- This gives us the Adeno candidates (**CanSino, ChAdOx1, J&J & ReiThera**) with the protein subunits strategies of **Sanofi** and possibly **Biological E** as other options where massive scale could be achieved.
- **Moderna**, **Curevac**, **Inovio** and **Novovax** could supply in the region of 100-200mm doses per annum each, a valuable addition to the overall supply, but not the solution. Given their time to regulatory approval it is expected that these are back-up candidates if ChAdOx1 or J&J fail.
- Of the Adeno candidates, **CanSino** is a domestic China play, **ChAdOx1** has the potential to supply all markets alone, **J&J** could cover the World if supported by additional vaccines e.g. **Sanofi. ReiThera** could be a back-up if ChAdOx1 failed, but would be simplified if the were using an identical production approach to ChAdOx1, or if vaccines could be trialled in parallel.
- Note there is a possibility that even after the pandemic is controlled Covid-19 vaccination will become a regular requirement especially for the elderly, this explains the breadth of interest as the pandemic conquering vaccine may not be the best vaccine for regular use in years to come.

III. Vaccine Production & Demand

III. Regional Plans - The US

- The US has the largest number of candidate vaccines under development and strong potential to both meet domestic demand and export
- These cover all of the candidate technologies: Adeno - J&JAd26, mRNA - Moderna, DNA - Inovio, Other – Sanofi and Novovax. Discussions are underway for a US manufacturer to licence ChAdOX1
- Multiple other research groups are developing vaccines as back-up
- Only J&J, Sanofi and a US vaccine giant like Merck have the production capacity to make a vaccine for both domestic and export supply. AstraZeneca could potentially manufacture for US domestic supply.
- 1bn dose target could be easily met if two of J&J, Sanofi or Merck had a viable vaccine in production. Potential for export could rise if more innovative approaches such as Moderna and Inovio secured licensure, but these should be viewed as 'nice to have' back-ups to beat the current pandemic (although they may have a different role to play as regular vaccine to prevent further outbreak)

III. Regional Plans - Europe

- Candidates in both the Adeno with ChAdOx1, Reithera and Janssen (J&J); and the mRNA with Curevac, Taksis and Imperial College under development. Plans to build a Moderna facility underway in Switzerland
- Target production 1.2bn doses - this will require a scale up in manufacturing and fill & finish
- ChAdOx1 - Production in Netherlands and Italy for ChOx1; UK could also consider scale-up domestically
- Can AZ or GSK be brought into the picture?
- Target can be achieved if ChAdOx1 and J&J vaccine succeed. Timetable for Curevac & Moderna likely too late to have impact for vaccine coverage of vulnerable populations across Europe, but both could play a role as vaccines for the future if coronavirus vaccination was required regularly. NB The Adeno candidates will become less efficacious over time due to antibodies in the body against the adeno vaccine from previous vaccinations.

III. Regional Plans - China

- First candidate CanSino in clinical trial, based on Adeno 5
- ChAdOx1 in partnership with WuXi for domestic supply
- Starting capacity expected to be in the region of 600mm pa, rising to the necessary 1.2bn pa capacity within 6 months
- China currently lack a vaccine manufacturing facility with WHO-PQ approval, thus production will likely remain in domestic market (and will not be able to supply a global access pool).

III. Region Plans - India

- Serum Institute of India (SII) and Biological E are both in discussions with promising candidates
- Serum has back-up with Codagenix and could tech transfer an alternative Adeno candidate e.g. ReiThera
- Timing and capacity to export will depend on the success of a Serum candidate, as Biological E could not supply both India and the export market alone
- Depending upon doses per vial, SII's supply could rise to as much as 2.8bn per annum, this could rise further if larger dose supply vials were considered (e.g. 30-50 dose)

IV. Vaccine Production & Advance Purchase Pool

LION'S HEAD
global partners

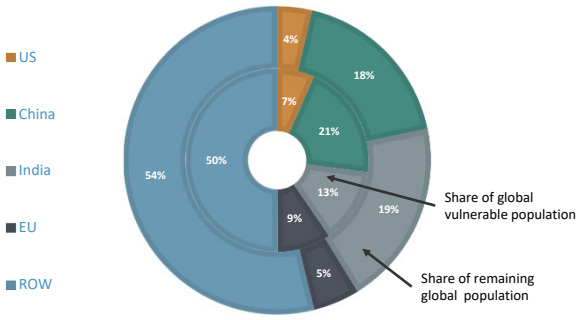
III. Problem Statement: Supply, Demand, and Equitable Distribution

- ❑ Between the major potential production sites, there will be sufficient manufacturing capacity to both fulfil initial domestic demand and export to non-producing countries
- ❑ Production is likely to be concentrated in a small number of countries, so ensuring equitable distribution across non-producing nations will be critical
- ❑ Without intervention, excess volumes will be sold into the global market, disproportionately to high-income countries (who will likely want to extend coverage beyond an initial list of 'vulnerable' due to economic benefits of widespread immunisation
- ❑ Donor countries would likely fund Gavi-eligible countries to the extent volumes were made available, but this would leave a large swathe of middle-income countries without secure access to vaccine supply
- ❑ We see the key market failure as not uncertainty of demand, but inefficient allocation of vaccine doses, if no global coordination takes place

LION'S HEAD
global partners

III. Distribution of Global Demand

Global vulnerable (1.7bn) and remaining (5.9bn) population



- Out of a total global population of 7.6bn it is estimated that 1.7bn are in urgent need of a vaccine. (Health care workers, >65 and otherwise vulnerable)
- EU, US, India and China represent 50% of initial demand with a further 50% in the rest of the World
- Overall producing countries represent a greater proportion of global vulnerable vs. non-vulnerable population
- We classify EU, US and India as potential vaccine export regions
- We believe China will target self vaccination, but not export
- Tech transfer could enable self vaccination programmes in Bangladesh, Brazil, Indonesia, Mexico, South Africa, Thailand and Vietnam

LION'S HEAD global partners

15

III. Theoretical Map of Supply

Key: Vulnerable pouplation; Second priority tranche; Additional demand

Doses per course 1
Potential Vaccine supply

Months after licensure		1	2	3	4	5	6	7	8	9	10	11	12
US production	**Total**	**100**	**100**	**100**	**100**	**100**	**100**	**100**	**100**	**100**	**100**	**100**	**100**
	Domestic	*50*	*50*	*50*	*50*	*50*	*50*	*25*	*25*	*25*	*25*	*25*	*25*
	Advance Purchace Pool	*50*	*50*	*50*	*50*	*50*	*50*	*75*	*75*	*75*	*75*	*75*	*75*
India Production	**Total**	**200**	**200**	**200**	**200**	**200**	**200**	**200**	**200**	**200**	**200**	**200**	**200**
	Domestic	*100*	*100*	*100*	*100*	*100*	*100*	*50*	*50*	*50*	*50*	*50*	*50*
	Advance Purchace Pool	*100*	*100*	*100*	*100*	*100*	*100*	*150*	*150*	*150*	*150*	*150*	*150*
EU production	**Total**	**100**	**100**	**100**	**100**	**100**	**100**	**100**	**100**	**100**	**100**	**100**	**100**
	Domestic	*50*	*50*	*50*	*50*	*50*	*50*	*50*	*50*	*50*	*50*	*50*	*50*
	Advance Purchace Pool	*50*	*50*	*50*	*50*	*50*	*50*	*50*	*50*	*50*	*50*	*50*	*50*
China production	**Total**	**50**	**50**	**50**	**50**	**100**	**100**	**100**	**100**	**100**	**100**	**100**	**100**
	Domestic	*50*	*50*	*50*	*50*	*100*	*100*	*50*	*50*	*50*	*50*	*50*	*50*
(No WHO PQ facility)	*Advance Purchace Pool*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*
Total available Global Supply		**450**	**450**	**450**	**450**	**500**	**500**	**500**	**500**	**500**	**500**	**500**	**500**
Total available for Advance Purchase Pool		**200**	**200**	**200**	**200**	**200**	**200**	**275**	**275**	**275**	**275**	**275**	**275**

- We propose that export countries will be guaranteed 50% of their supply for their domestic purposes
- This illustrates the scale of supply required if a 3 month urgent care target and 6 month 2nd priority patients are to be met
- Global target manufacturing **US** 1.2bn p/a, **India** 2.4bn p/a **EU** production 1.2bn p/a **China** 600mm-1.2bn p/a

LION'S HEAD global partners

16

IV. Covid Vaccine Purchase Options

- We foresee countries fitting into one of two states
  - Vaccine Manufacturers
  - Vaccine Non-Manufacturers
- Manufacturers can either be manufacturing for domestic use only or domestic and export
- A Vaccine Purchasing Pool – would be established for non-manufacturing countries, or manufacturing countries that have excess demand. **This would be funded by purchasing countries upfront – Advance Purchase Pool**
- The pool would be open to all countries and any country can apply for upto their vulnerable population demand (definition to be defined healthworkers + >65 + key workers etc)
- All countries (including Gavi) would purchase from the pool at a single price, representing the blended cost of the vaccines in the pool
- A country that manufactures can choose to be outside the pool and rely on self-supply

IV Additional countries with manufacturing potential

- A number of countries may be able to establish production of an Adeno vaccine candidate in order to satisfy domestic demand. We consider the most likely countries for this approach to be the following:

Country	Total Vulnerable Population	Total Population
Brazil	51,195,223	209,469,333
Indonesia	59,026,335	267,663,435
Mexico	30,583,490	126,190,788
South Africa	18,046,572	57,779,622
Vietnam	21,383,820	95,540,395
Thailand	21,571,114	69,428,524
United Kingdom	26,450,960	66,460,344

- If domestic production in these countries was sufficient to meet domestic demand then these countries would likely exit the pool (and any excess supply would be sold to regional neighbours/internationally)
- This could potentially reduce pool size by up to 230m doses.

IV. Covid Vaccine Advance Purchase Pool

- Companies with export capacity may seek access to supply the pool. In doing so they would have to commit to supply a minimum of 50% of their production on a *pro rata* basis to the "export pool". Funders seeing to supply export supply should make access to capital conditional upon participation.
- Failure to supply would be a breach of contract. Exporters would require securing domestic Govt approval to export 50% of production ahead of joining the pool.
- Companies would receive an agreed COGS + [15]% pricing for vaccine exported to the pool
- After initial 900 mm doses have been provided further supply into the pool will be on a competitive bid basis
- Allocation to meet pool country demand will be on a fully equitable basis as product is shipped

IV. Covid-19 Vaccine Advance Purchase Pool

- The price of vaccine to all members of the pool would be identical, based on the blended average price of vaccine supplied to the pool
- After the critical need demand has been met by the pool, supply of vaccine to Gavi countries would be guaranteed at a price of no more than COGS + [20%] for a period of 3 years
- Pool would commit to purchase vaccine from a specific supplier [3] months in advance
- Failure to supply requested volumes to the pool would result in termination of the manufacturing licence and/or capacity for CEPI/donor funder to direct a tech transfer of the license to a new group
- Failure to meet supply agreements into the pool would ban future access to the pool
- Countries may apply for a domestic manufacturing licence via tech transfer to an authorised manufacturer. At this point they will exit entitlement to receive vaccine under the pool mechanism unless their domestic manufacturer had WHO PQ and committed to supply to the pool on the same terms as others, but would have certainty of domestic supply

IV. Covid Vaccine Purchase Pool - Incentives

- ❑ Countries that have manufacturing facilities will seek to secure domestic supply
- ❑ Pool demand countries will work with CEPI & Gavi to identify predictable supply and to ensure that companies with the necessary export potential are committed to supply the pool
- ❑ This would either be embedded in the vaccine development agreement from CEPI, or under a bilateral agreement with the company and the pool. The incentive for participation is access to R&D/scale-up funding
- ❑ All funding from CEPI to manufacturers that results in the establishment of permanent facilities must be repaid with a fair royalty attached to any product subsequently sold in the private market. This will ensure a level playing field with private companies that have self-developed a viable product
- ❑ Companies that are not willing to supply 50% of their capacity on a *pro rata* basis would be excluded from selling to the pool

IV. Covid Vaccine Purchase Pool - Incentives

- ❑ Countries in the pool would commit on good faith to only buy from the pool. However if they purchase from outside the pool, they will still be committed to pay for their quota of vaccine agreed when they entered the pool (although would not receive vaccines in return)
- ❑ Vaccine amounts purchased outside the pool would reduce the threshold at which the pool will operate a COGS +10%. Any payments made to the pool for breakage will be passed back to the pool vaccine suppliers on a pro rata basis depending on the weighting of their supply into the pool at the time that a country chose to purchase outside of the pool
- ❑ The existence of the pool does not in the first instance provide a direct 'pull' incentive as the pool is not committed to purchasing specific volumes from any one manufacturer. We believe in this case a more binding APC is not required given the size of the market outside of the pool is also likely to be significant in size and likely higher margin.
- ❑ Transactions outside of the pool for participating countries would require both country and manufacturer to 'cheat'. Political pressure and surveillance on demand/supply should reduce this issue.

IV. Covid Vaccine Purchase Pool - Incentives

- ❑ Countries who choose not to enter the pool (manufacturing countries) may support their own manufacturers as they wish
- ❑ Countries within the pool may support companies supplying into the pool as they wish, however all supported companies must agree to a repayment of support for manufacturing facilities and a royalty to create a level playing field between supported and non-supported companies
- ❑ In the event that the pool agrees to pay more than COGS + 10% for a vaccine, the new additional spread will be made available to all suppliers into the pool
- ❑ Companies will wish to supply the pool if they have the capacity to export and find the volumes of demand attractive. However prices outside of the pool are likely to be higher(although demand less certain) and therefore where possible, levers should be used to secure pool participation (e.g. conditionality in R&D/licensing/manufacturing funding agreements)

V. Governance

V. Covid Vaccine Purchase Facility - Governance

- ❑ All paying members of the pool purchase facility would have a seat, with Gavi representing Gavi countries
- ❑ Procurement would be centrally managed by [ ]
- ❑ An independent agency would be chosen to serve as the secretariat of the pool purchase facility by majority vote of the pool members
- ❑ An independent entity eg WHO would verify a country's vulnerable population needs and therefore supply quota into the pool
- ❑ It would be impossible to prevent a country in the pool from taking the vaccine and not providing it to their vulnerable populations, but it is assumed that Civil Society groups would monitor this activity. We would note that as long as the world has visibility to plentiful supply of vaccine, these risks will be greatly diminished, but will become issues in a supply constrained market

2

Van: [redacted]
Aan:
Cc: [redacted]
Onderwerp: kort (bulletsgewijs) gesprekverslag Halix en vervolgstappen
Datum: maandag 4 mei 2020 17:04:56

[redacted]

4 mei 2020
Gesproken:
Halix: [redacted]
VWS: [redacted]
Aanleiding (zie onderstaande mail via [redacted] AZ)
www.halix.nl
Er is een consortium gevormd rondom Oxford initiatief. AstraZeneca heeft zich recent daarop aangesloten
Halix is gevraagd (als uitvoerende partij) om voor dit consortium vaccins te produceren. Halix kan maximaal 12 miljoen dosis per jaar produceren. Zij maken API. Afvullen naar vials zal in Duitsland gebeuren.
Halix heeft nu geen (acute) vragen voor Nederlandse overheid:

1. IGJ audit staat gepland voor eind juni. Zij zoeken zelf contact met IGJ om dit te vervroegen
2. Bureau GGO heeft snel toestemming gegeven voor hun vergunning.

Consortium zelf heeft nog wel geld nodig. [redacted] zal dit 'verzoek' naar ons doorsturen.
Thema's die spelen (wat dus op dit moment loopt):

1. GGO (is tot nu toe goed gegaan)
2. IGJ voor GMP (so far so good)
3. Gekwalificeerd personeel. Hier zit zorgpunt. Uitbreiding en opschaling van huidige capaciteit is lastig. Ook voor eventuele uitbreiding aan fabriek: moeilijk om gekwalificeerde aannemers te vinden, zeker nu concurrentie op dit vlak groot is. Halix heeft vraag om gekwalificeerd personeel ook bij Astra Zeneca uitstaan
4. Klinisch onderzoek (dit regelt consortium, dus gaat Halix niet over)
5. Transport issues. Nu nog niet beperkend, maar hoe gaat het met invliegen expert personeel. En transport van goederen als UK geen EU meer is.

Afspraken:

1. Wij ontvangen info over consortium en hun geld behoefte
2. Geen concrete vervolg afspraak gepland. We weten elkaar te vinden als er wat speelt

Groeten [redacted]

3

Van: [redacted]
Aan:
Cc:
Onderwerp: RE: Contactgegevens [redacted] - HALIX
Datum: dinsdag 5 mei 2020 13:26:10

Dag [redacted]

Even een checkvraag op deze bijzondere Bevrijdingsdag. Ik begrijp het toch goed dat er inmiddels vanuit vws contact is met Halix?

Groet,
[redacted]

Verzonden met BlackBerry Work
(www.blackberry.com)

Van: [redacted]
Datum: donderdag 30 apr. 2020 10:15 PM
Aan: [redacted]@minvws.nl>, [redacted]@minaz.nl>
Kopie: [redacted]@minvws.nl>, [redacted]@minvws.nl>, [redacted]@minvws.nl>, [redacted]@minvws.nl>
Onderwerp: RE: Contactgegevens [redacted] - HALIX

Hallo [redacted] dank voor het verbinden, [redacted] en [redacted] hebben al even contact ihkv snel contact met Halix

Inmiddels heb ik een paar dagen een VWS mailadres, het [redacted] adres gebruik ik nu niet meer voor VWS

[redacted]@minvws.nl

Bel je morgen even om je bij te praten over (goed) po minvws en minmzs vanmiddag

Groeten, [redacted]

Verzonden met BlackBerry Work(www.blackberry.com)

Van: [redacted]
Verzonden: 30 apr. 2020 18:56
Naar: [redacted]
Cc: [redacted]
Onderwerp: RE: Contactgegevens [redacted] - HALIX

Dag [redacted]
Dank voor de informatie. In de adreslijn het e-mailadres van [redacted] die nu de activiteiten voor Vaccins coordineert.
Zijn jullie ook gelijk op de hoogte van elkaar.
Groet
[redacted]

Van: [redacted]
Verzonden: donderdag 30 april 2020 18:45
Aan: [redacted]
CC: [redacted]
Onderwerp: FW: Contactgegevens [redacted] - HALIX

Dag [redacted]

In aanvulling op ons telefoon gesprek van afgelopen dinsdag het volgende. Ik heb inmiddels [redacted] gesproken over de bijdrage van HALIX aan vaccinontwikkeling. Ze zijn in Oxford bezig met klinische testen en verwachten eigenlijk al rond sept een vaccin te kunnen leveren. HALIX is gevraagd voor een halffabricaat en (uiteraard) graag opschalen en de universiteit van Oxford zoekt nog funding voor opschaling (ik begrijp dat het totaal om ong nog 20-60 mln gaat; wv 10 mln vanuit HALIX, waar dan weer 8 mln nog open staat; dus de facto gaat het om de ongeveer 8 mln ordegrootte). Het klinkt als een veelbelovend initiatief, maar dat kunnen jullie bij VWS beter beoordelen dan ik kan.

Lijkt mij goed als er vanuit VWS contact opgenomen wordt met [redacted] om te kijken wat er nodig is en wat we vanuit de overheid kunnen betekenen, zowel procedureel als financieel.

Kun jij laten weten wie vanuit de vaccin-club (task force?) dit evt op kan pakken? Dan geef ik de naam vast door aan [redacted]

Groet,

[redacted]

Nb. Ik heb eerder ook contact gehad met [redacted] over vaccins, dus die zet ik vast in de cc. Er [redacted] internationale contacten en overleggen die lopen.

Van: [redacted]@halix.nl]
Verzonden: donderdag 30 april 2020 18:16
Aan: [redacted]
Onderwerp: Contactgegevens [redacted] - HALIX

Beste [redacted]

Dank voor het gesprek zojuist. Onderstaande vind je mijn gegevens. Hieronder vind je een toelichting en een verwijzingen naar relevante artikelen.

Met een vriendelijke groet,

[redacted]

The Chancellor Masters and Scholars of the University of Oxford, vertegenwoordigd door het Jenner Institute, verder genoemd Oxford, coördineert een reactie op de huidige COVID19 uitbraak door klinische studies te starten met een vaccin-kandidaat, op basis van het chimpansee adenovirus ("ChAdOx") technologieplatform. Het vaccin heet ChAdOx1 nCoV-19 en wordt snel ontwikkeld door een consortium van partners onder leiding van Oxford, met als doel om op korte termijn te starten met farmaceutische productie. De productie verloopt in parallel met Oxfords klinische studie fase 1 en 3. De fase 1 studie is gestart in april. Oxford heeft zich als doel gesteld om in september 2020 het vaccin beschikbaar te maken voor vaccinatie.

Oxford heeft HALIX B.V. dringend verzocht om bij te dragen aan de bestrijding van de COVID-19 pandemie. HALIX kan en wil hier op korte termijn hulp bieden door de levering van farmaceutisch geproduceerd halfproduct (ofwel API of Drug Substance genoemd). De verwerking naar het eindproduct (het vaccin) wordt uitgevoerd door IDT biologika GmbH in Duitsland.

De financiering van 20 mio GBP komt volledig van de UK overheid hetgeen voldoende is voor een beperkte hoeveelheid vaccin. Het productieniveau wordt opgeschaald naar zogenoemd 200 liter bioreactorvolume per batch. Het volume is een maatstaf voor de productieschaal. Een productie batch van 200 liter komt overeen met ca. 1 mio dosis vaccin. Oxford heeft HALIX gevraag om 12 batches te produceren in 2020, voldoende voor 12 mio dosis vaccin. Hiervoor is het budget van Oxford onvoldoende. Intussen wordt opschaling naar 1.000 liter volume besproken waarbij ook

andere fabrikanten dan HALIX door Oxford worden benaderd. Vandaag is bekend geworden dat Astra Zeneca een overeenkomst zal sluiten voor verregaande opschaling.
Recent heeft Oxford verzocht de belangstelling van de Nederlandse overheid na te gaan. HALIX is intussen met de productie vanuit de faciliteiten in het Leiden Bioscience park gestart en wordt onder grote druk de opschaling naar 12 batches voorbereid.
https://www.jenner.ac.uk/about/news/covid-19-vaccine-development-at-the-jenner-institute
https://www.jenner.ac.uk/about/news/press-statement-coronavirus-vaccine-development
https://www.jenner.ac.uk/about/news/press-release-oxford-covid-19-vaccine-programme-opens-for-clinical-trial-recruitment
https://covid19vaccinetrial.co.uk/blog-how-long-will-it-take-get-oxford-vaccine-deployment
http://www.ox.ac.uk/news/2020-04-30-landmark-partnership-announced-development-covid-19-vaccine
https://www.halix.nl/2020/04/15/halix-enters-collaboration-university-oxford-gmp-manufacturing-covid-19-vaccine/

HALIX
BIOSCIENCE AS A SERVICE [redacted]
Phone: [redacted] Mobile: +31 [redacted]
[redacted]@halix.nl | www.halix.nl
HALIX B.V. | J.H. Oortweg 15-17 | 2333 CH Leiden, The Netherlands
[redacted]

[redacted]

Van: [redacted]
Verzonden: vrijdag 8 mei 2020 15:14
Aan: [redacted]
Onderwerp: RE: Contactgegevens [redacted] - HALIX

Dank. Ik had je mailadres dus al. Wat fijn!

Goed weekend.

Verzonden met BlackBerry Work
(www.blackberry.com)

Van: [redacted]
Datum: vrijdag 08 mei 2020 2:55 PM
Aan: [redacted]@minaz.nl>
Onderwerp: RE: Contactgegevens [redacted] - HALIX

Dag [redacted] goed elkaar te spreken, ik zie nu deze mail, als net besproken is [redacted]@minvws.nl waarmee ik nu werk, groet! [redacted]

Verzonden met BlackBerry Work(www.blackberry.com)

Van: [redacted]@minaz.nl>
Verzonden: 5 mei 2020 13:26
Naar: [redacted]
Cc: [redacted]@minvws.nl>; [redacted]@minvws.nl>
Onderwerp: RE: Contactgegevens [redacted] HALIX

Dag [redacted]

Even een checkvraag op deze bijzondere Bevrijdingsdag. Ik begrijp het toch goed dat er inmiddels vanuit vws contact is met Halix?

Groet,
[redacted]

Verzonden met BlackBerry Work
(www.blackberry.com)

Van: [redacted]
Datum: donderdag 30 apr. 2020 10:13 PM
Aan: [redacted]@minvws.nl>; [redacted]@minaz.nl>
Kopie: [redacted]@minvws.nl>, [redacted]@minvws.nl>, [redacted]@minvws.nl>, [redacted]@minvws.nl>
Onderwerp: RE: Contactgegevens [redacted] - HALIX

Hallo [redacted], dank voor het verbinden, [redacted] en [redacted] hebben al even contact inkv snel contact met Halix

Inmiddels heb ik een paar dagen een VWS mailadres, het [redacted]adres gebruik ik nu niet meer voor VWS

[redacted]@minvws.nl

Bel je morgen even om je bij te praten over (goed) po minvws en minmzs vanmiddag

Groeten, [redacted]

Verzonden met BlackBerry Work(www.blackberry.com)

Van: [redacted]@minvws.nl>
Verzonden: 30 apr. 2020 18:56
Naar: [redacted]@minaz.nl>; [redacted]
Cc: [redacted]@minvws.nl>; [redacted]@minvws.nl>; [redacted]@minvws.nl>; [redacted]@minvws.nl>; [redacted]@minvws.nl>
Onderwerp: RE: Contactgegevens [redacted] - HALIX

Dag [redacted]
Dank voor de informatie. In de adreslijn het e-mailadres van [redacted] die nu de activiteiten voor Vaccins coordineert. Zijn jullie ook gelijk op de hoogte van elkaar.

Groet
[redacted]

Van: [redacted]
Verzonden: donderdag 30 april 2020 18:45
Aan: [redacted]@minvws.nl>
CC: [redacted]
Onderwerp: FW: Contactgegevens [redacted] HALIX

Dag [redacted]

In aanvulling op ons telefoon gesprek van afgelopen dinsdag het volgende. Ik heb inmiddels [redacted] gesproken over de bijdrage van HALIX aan vaccinontwikkeling. Ze zijn in Oxford bezig met klinische testen en verwachten eigenlijk al rond sept een vaccin te kunnen leveren. HALIX is gevraagd voor een halffabricaat en (uiteraard) graag opschalen en de universiteit van Oxford zoekt nog funding voor opschaling (ik begrijp dat het totaal om ong nog 20-60 mln gaat; wv 10 mln vanuit HALIX, waar dan weer 8 mln nog open staat; dus de facto gaat het om de ongeveer 8 mln ordegrootte). Het klinkt als een veelbelovend initiatief, maar dat kunnen jullie bij VWS beter beoordelen dan ik kan.

Lijkt mij goed als er vanuit VWS contact opgenomen wordt met [redacted] om te kijken wat er nodig is en wat we vanuit de overheid kunnen betekenen, zowel procedureel als financieel.
Kun jij laten weten wie vanuit de vaccin-club (task force?) dit evt op kan pakken? Dan geef ik de naam vast door aan [redacted]

Groet,
[redacted]

Nb. Ik heb eerder ook contact gehad met [redacted] over vaccins, dus die zet ik vast in de cc. Er [redacted] ivm internationale contacten en overleggen die lopen.

Van: [redacted]@halix.nl]
Verzonden: donderdag 30 april 2020 18:16
Aan: [redacted]
Onderwerp: Contactgegevens [redacted] HALIX

Beste [redacted]
Dank voor het gesprek zojuist. Onderstaande vind je mijn gegevens. Hieronder vind je een toelichting en een verwijzingen naar relevante artikelen.
Met een vriendelijke groet,
[redacted]

The Chancellor Masters and Scholars of the University of Oxford, vertegenwoordigd door het Jenner Institute, verder genoemd Oxford, coördineert een reactie op de huidige COVID19 uitbraak door klinische studies te starten met een vaccin-kandidaat, op basis van het chimpansee adenovirus ("ChAdOx") technologieplatform. Het vaccin heet ChAdOx1 nCoV-19 en wordt snel ontwikkeld door een consortium van partners onder leiding van Oxford, met als doel om op korte termijn te starten met farmaceutische productie. De productie verloopt in parallel met Oxfords klinische studie fase 1 en 3. De fase 1 studie is gestart in april. Oxford heeft zich als doel gesteld om in september 2020 het vaccin beschikbaar te maken voor vaccinatie.
Oxford heeft HALIX B.V. dringend verzocht om bij te dragen aan de bestrijding van de COVID-19 pandemie. HALIX kan en wil hier op korte termijn hulp bieden door de levering van farmaceutisch geproduceerd halfproduct (ofwel API of Drug Substance genoemd). De verwerking naar het eindproduct (het vaccin) wordt uitgevoerd door IDT biologika GmbH in Duitsland.

De financiering van 20 mio GBP komt volledig van de UK overheid hetgeen voldoende is voor een beperkte hoeveelheid vaccin. Het productieniveau wordt opgeschaald naar zogenoemd 200 liter bioreactorvolume per batch. Het volume is een maatstaf voor de productieschaal. Een productie batch van 200 liter komt overeen met ca. 1 mio dosis vaccin. Oxford heeft HALIX gevraag om 12 batches te produceren in 2020, voldoende voor 12 mio dosis vaccin. Hiervoor is het budget van Oxford onvoldoende. Intussen wordt opschaling naar 1.000 liter volume besproken waarbij ook andere fabrikanten dan HALIX door Oxford worden benaderd. Vandaag is bekend geworden dat Astra Zeneca een overeenkomst zal sluiten voor verregaande opschaling.

Recent heeft Oxford verzocht de belangstelling van de Nederlandse overheid na te gaan. HALIX is intussen met de productie vanuit de faciliteiten in het Leiden Bioscience park gestart en wordt onder grote druk de opschaling naar 12 batches voorbereid.

https://www.jenner.ac.uk/about/news/covid-19-vaccine-development-at-the-jenner-institute
https://www.jenner.ac.uk/about/news/press-statement-coronavirus-vaccine-development
https://www.jenner.ac.uk/about/news/press-release-oxford-covid-19-vaccine-programme-opens-for-clinical-trial-recruitment
https://covid19vaccinetrial.co.uk/blog-how-long-will-it-take-get-oxford-vaccine-deployment
http://www.ox.ac.uk/news/2020-04-30-landmark-partnership-announced-development-covid-19-vaccine
https://www.halix.nl/2020/04/15/halix-enters-collaboration-university-oxford-gmp-manufacturing-covid-19-vaccine/

HALIX
BIOSCIENCE AS A SERVICE
[redacted] fficer
Phone:+31 (0)[redacted] Mobile: +31 (0)[redacted]
[redacted]@halix.nl | www.halix.nl
HALIX B.V. | J.H. Oortweg 15-17 | 2333 CH Leiden, The Netherlands
Managing Directors: [redacted]

5

Van: [redacted]
Aan: [redacted]
Onderwerp: RE: Halix, update, gespreksnotitie
Datum: vrijdag 29 mei 2020 12:02:04

Dank!

Van: [redacted]
Verzonden: donderdag 28 mei 2020 16:25
Aan: [redacted]
Onderwerp: Halix, update, gespreksnotitie

Beste,
Net met [redacted] (Halix) gesproken:

1. De vraag die het consortium had of Nederland wilde bijdragen was een dag na ons overleg al ingetrokken, toen AstraZeneca in het consortium stapte. Huiselijk gezegd: het geld probleem was toen opgelost. Dus geen info of vraag komt nog naar ons toe.
2. Verder gaat alles goed. IGJ komt binnenkort inspecteren.
3. Als borrelpraat:
    a. temperen van gedachte dat vaccin goed werkend en zeer effectief zal zijn… blijft toch wel zeer ongewis… maar nogmaals: dit was meer borrelpraat.
4. En verder geen aanvullende vragen, behoeftes die door VWS of overheid (anders dan dus igj, maar dat loopt) nu vervult moeten worden.

Groeten [redacted]

https://www.astrazeneca.com/media-centre/press-releases/2020/astrazeneca-and-oxford-university-announce-landmark-agreement-for-covid-19-vaccine.html

AstraZeneca and Oxford University announce landmark agreement for COVID-19 vaccine

PUBLISHED30 April 2020

Collaboration will enable global development, manufacturing and distribution of the vaccine

AstraZeneca and the University of Oxford today announced an agreement for the global development and distribution of the University's potential recombinant adenovirus vaccine aimed at preventing COVID-19 infection from SARS-CoV-2.

The collaboration aims to bring to patients the potential vaccine known as ChAdOx1 nCoV-19, being developed by the Jenner Institute and Oxford Vaccine Group, at the University of Oxford. Under the agreement, AstraZeneca would be responsible for development and worldwide manufacturing and distribution of the vaccine.

Pascal Soriot, Chief Executive Officer, AstraZeneca, said: "As COVID-19 continues its grip on the world, the need for a vaccine to defeat the virus is urgent. This collaboration brings together the University of Oxford's world-class expertise in vaccinology and AstraZeneca's global development, manufacturing and distribution capabilities. Our hope is that, by joining forces, we can accelerate the globalisation of a vaccine to combat the virus and protect people from the deadliest pandemic in a generation."

Mene Pangalos, Executive Vice President, BioPharmaceuticals R&D, AstraZeneca, said: "The University of Oxford and AstraZeneca have a longstanding relationship to advance basic research and we are hugely excited to be working with them on advancing a vaccine to prevent COVID-19 around the world. We are looking forward to working with the University of Oxford and innovative companies such as Vaccitech, as part of our new partnership."

Alok Sharma, UK Business Secretary, said: "This collaboration between Oxford University and AstraZeneca is a vital step that could help rapidly advance the manufacture of a coronavirus vaccine. It will also ensure that, should the vaccine being developed by Oxford University's Jenner Institute work, it will be available as early as possible, helping to protect thousands of lives from this disease."

Professor Sir John Bell, Regius Professor of Medicine at Oxford University, said: "Our partnership with AstraZeneca will be a major force in the struggle against pandemics for many years to come. We believe that together we will be in a strong position to start immunising against coronavirus once we have an effective approved vaccine. Sadly, the

risk of new pandemics will always be with us and the new research centre will enhance the world's preparedness and our speed of reaction the next time we face such a challenge."

Professor Louise Richardson, Vice-Chancellor of Oxford University, said: "Like my colleagues all across Oxford, I am deeply proud of the work of our extraordinarily talented team of academics in the Jenner Institute and the Oxford Vaccine Group. They represent the best tradition of research, teaching and contributing to the world around us, that has been the driving mission of the University of Oxford for centuries. Like people all across the country, we are wishing them success in developing an effective vaccine. If they are successful, our partnership with AstraZeneca will ensure that the British people and people across the world, especially in low and middle income countries, will be protected from this terrible virus as quickly as possible."

The potential vaccine entered Phase I clinical trials last week to study safety and efficacy in healthy volunteers aged 18 to 55 years, across five trial centres in Southern England. Data from the Phase I trial could be available next month. Advancement to late-stage trials should take place by the middle of this year.

ChAdOx1 nCoV-19

Developed at the University of Oxford's Jenner Institute, and working with the Oxford Vaccine Group, ChAdOx1 nCoV-19 uses a viral vector based on a weakened version of the common cold (adenovirus) containing the genetic material of SARS-CoV-2 spike protein. After vaccination, the surface spike protein is produced, which primes the immune system to attack COVID-19 if it later infects the body.

The recombinant adenovirus vector (ChAdOx1) was chosen to generate a strong immune response from a single dose and it is not replicating, so cannot cause an ongoing infection in the vaccinated individual. Vaccines made from the ChAdOx1 virus have been given to more than 320 people to date and have been shown to be safe and well tolerated, although they can cause temporary side effects such as a temperature, flu-like symptoms, headache or sore arm.

AstraZeneca

AstraZeneca (LSE/STO/NYSE: AZN) is a global, science-led biopharmaceutical company that focuses on the discovery, development and commercialisation of prescription medicines, primarily for the treatment of diseases in three therapy areas - Oncology, Cardiovascular, Renal and Metabolism, and Respiratory and Immunology. Based in Cambridge, UK, AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. Please visit astrazeneca.com and follow the Company on Twitter @AstraZeneca.

Contacts

For details on how to contact the Investor Relations Team, please click here. For Media contacts, click here.

Adrian Kemp
Company Secretary
AstraZeneca PLC