Steering Board Meeting with Experts from the Scientific Board of France, Spain and the Netherlands

27 July 2020

Subject: Scientific Considerations and Recommendations on COVID-19 vaccine candidates

Independent Experts:

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3.

General remarks and introduction:

Before concluding an Advance Purchase Agreement with the vaccine producers, the European Commission gathered the independent scientific advice of the above-mentioned experts. The members of the Joint Negotiation Team supported the European Commission's initiative and encouraged the independent experts to provide their prompt scientific advice for the benefit of the Steering Board and other national experts nominated by the Steering Board members.

The Co-Chair	of the Steering	g Board	(European	Commission) welcomed	participants	and
introduced the	independent ex	perts.					
By way of intr	oduction						
	adenoviral vac			informed that	there are	te	ams
world-wide wo	orking on these v	accines					

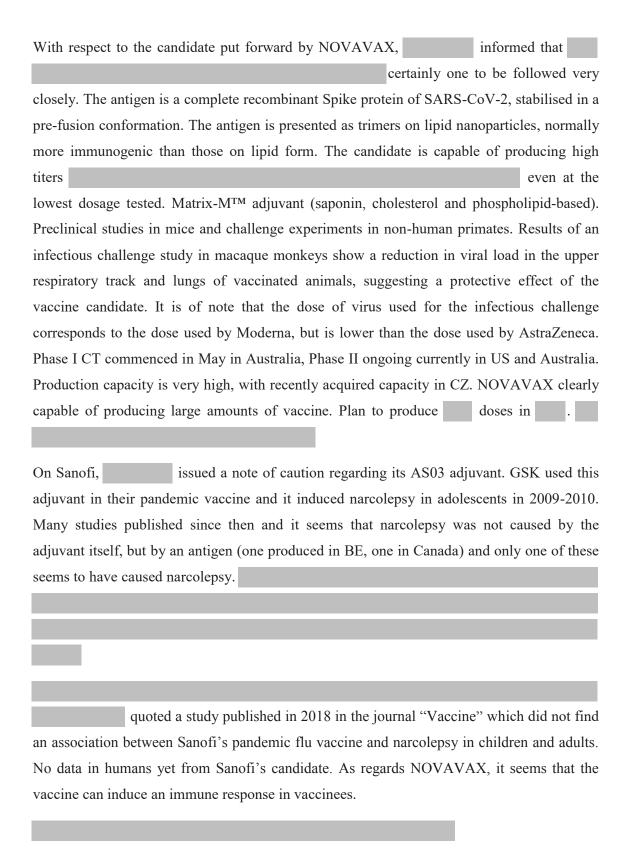
¹ Platforms are technologies used to express the viral antigens.

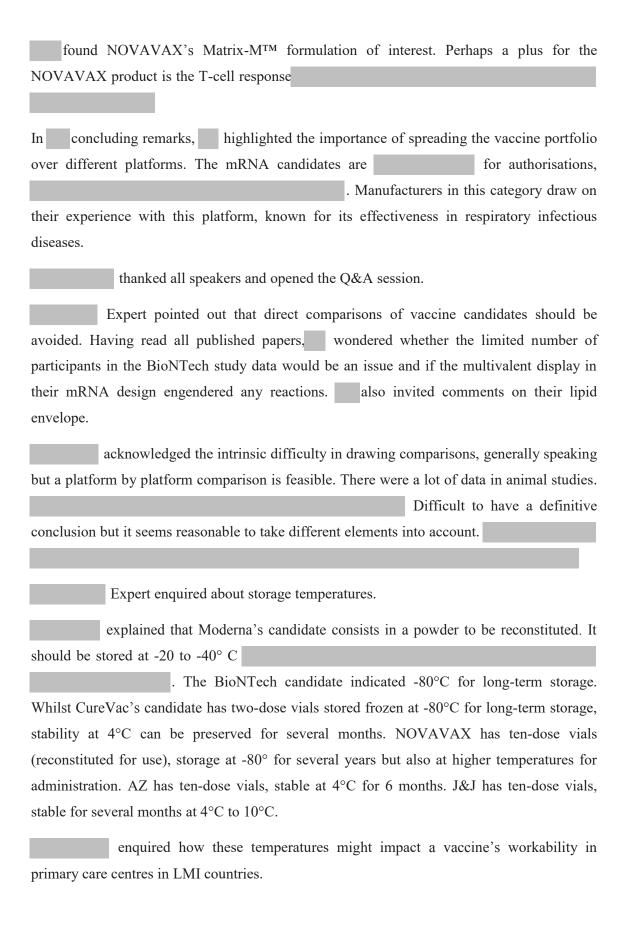
With respect to AZ, and the recent publication of their latest clinical trial results in <i>The</i>
Lancet medical journal, acknowledged that the vaccine can induce protection
in rhesus macaques, however the animals continue to secrete the virus via the nasal tract and
hence the vaccine would not effectively block transmission of the disease. The data in
humans show neutralising antibodies of moderate titers, good T-cell immunity as AZ is
relatively advanced in their Phase III clinical
trial. Whilst the advantage of this platform is the ease with which the vaccine could be
produced, the immunogenicity in older adults is yet to be demonstrated/ observed.
issued the recommendation to continue monitoring this candidate's evolution
With regards to Johnson & Johnson (J&J), a vaccine based on human Adenovirus 26 was
expected to enter Phase I clinical trials on July in Belgium and in US in people older than
55 years of age. The booster would follow the first administration at day 56.
Immunogenicity evidence was scarce to
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agreed
AZ product i
more advanced in development but the J&J product is from a company that is well aware o
the adenoviral platform and has a lot of expertise. Whilst both parties draw on their solid
background, 1:1 comparability of their products may well be hindered by the fact that assay
are likely different
. For the AZ candidate, immunogenicity
looked good, although painkillers may be needed for mitigating side-effects. She mentioned
NOVAVAX having a potentially serious candidate as well in the long run.
thanked for the contributions and moved on to the mRNA platform category.
explained that the assessments pertained to
the candidates put forward by Moderna, BioNTech and CureVac,
With regards to Moderna's and BioNTech's candidates, the mRNA used has a modification
which enhances the odds of inducing an immune response.
. Moderna is starting their Phase III clinical trials. In animal studies, Moderna'
candidate has shown partial protection against the disease, yet not against infection; in human
studies, it has triggered a relatively high reactogenic reaction
. A dose of 100 microgram is the highest tolerated by vaccinnees. Th
recruitment is completed for Phase II CT , with Phase III planned covering
30 000 vaccinees in the US. Moderna decided to cancel their European CT planned
highlighted that

With regard to BioNTech,		results of	out of
potential candidates in the pipeline was chose	en to be presented	by the compa	ny, so-called
	BioNTech	decided	
a 35 microgram dose which triggered mod	lerate immunogenio	city and high re	eactogenicity
of a lipid,			
On CureVac's candidate, the full length SARS	-CoV-2 vaccine,	highl	lighted that it
was much more immunogenic and only 2, 4, 8	microgram dose co	ompared to 10	0 microgran
for Moderna – all these vaccines are to be cons	sidered with a boost	er. CureVac st	arted phase
CT in DE and in BE			
	. A doubt	t was cast ove	er CureVac's
ability to produce large quantities of vaccines.			
confirmed that Moderna started I		July, with pre	
in DE and BE. suggested it was premature			
life. The information received from Moderna is	0.000 PE NO 100 PE NO 100 PE	2 2 2	100
% of participants experienced fever as a side			20 300
saw this as a mild pitfall. The 100 mid			
20 to 55 years of age. They should also cover the	ne over-75 years of	age contingent	
Regarding BioNTech, the short shelf life after of	defrosting was ment	tioned.	
For CureVac, gave indications	that more data on	immunogenici	ty is needed
although trials in humans seem promising thus	far.		

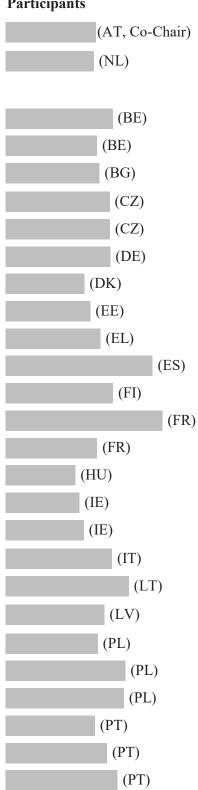
agreed that rather big differences	s in the data currently available exist with
hardly any results for CureVac, rendering rank	ing difficult. Moderna recently published a
study in the New England Journal of Medicine	for their mRNA-1273 candidate with similar
results in the older group as in other studied gro	ups. Moderna also shared some confidential
data for which a publication	is forthcoming.
Describes the Diskington and the A	did not consider to see
Regarding the BioNTech product,	did not completely agree with
counterpart.	
On CureVac's product, the	may well have more information and
theoretically, it could be a good candidate but lag	gging behind currently. The only official data
seen by was limited	
In conclusion, Moderna and BioNTech are prom	ising candidates for , with good
immunogenicity profile and good tolerability a	
inimulogementy prome and good tolerationty a	iso in the older age group.
then proceeded to the Sanofi-Past	eur and NOVAVAX category (the subunit
vaccines).	
explained that Sanofi-Pasteur are a	large producer and have vaccines in
their portfolio as well as the expertise of produc	
of timing, acknowledged that they	planning to start their Phase I
	om that developed for one of their seasonal
influenza vaccines (technology acquired from Pr	•
with a squalene-containing adjuvant	otem serences). The untigen is administered
with a squarene-containing adjuvant	
In terms of production consoi	ty, purification of antigens from insect cells
infected with a recombinant baculovirus enco	
controlled procedure adapted from that develop Pasteur has the necessary infrastructure to ensure	,
Pacieur hac the necessary intractricities to encline	very large-scale production.





responded that for Ebola vaccines in Africa, storage was in liquid nitrogen (in a
cold chain container), keeping the temperature quite well.
(SE) suggested that a more traditional adjuvanted
protein vaccine would be needed for the elderly. enquired whether adjuvants could be
avoided at all.
replied that the jury is still out on that aspect.
Similar uncertainties remain for
the other categories.
shared that current plans involve seeking to organise small immunogenic studies for
the very old – over 75 years of age. Some manufacturers want to work with on this.
wondered whether informing manufacturers of this forum's endorsement may bring value
added.
suggested that an independent organisation might compare samples from
different CTs.
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The Chair (EC) highlighted that Nobody
knows what the future will hold. The Steering Board, along with the EC, can make informed,
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Participants



(PT)

