To: 5.1.2e [5.1.2e @rivm.nl]; 5.1.2e [5.1.2e @rivm.nl]
Cc: 5.1.2e [5.1.2e @rivm.nl]
From: 5.1.2e
Sent: Fri 4/24/2020 11:26:37 AM
Subject: RE: Coronavirus countermeasure - broad spectrum vaccine and preventive nasal spray
Received: Fri 4/24/2020 11:26:38 AM

Hi allebei,
Dit is een van de vele mogelijke vaccin concepten voor covid-19 en hoewel 'universeel' nice to have is, ben ik het met 5.1.2e eens dat dat niet zomaar vergelijkbaar is met influenza (wat ook nog niet gelukt is) en dat SARS-CoV-2 de must-have is.

Ik begrijp (hierdoor) dat VWS zelf benaderd wordt met initiatieven maar het lijkt me ondoenlijk cq onwenselijk om dit zo ad hoc af te handelen en te selecteren waar op ingezet moet worden (en inderdaad met welk geld?). Dit zou ik liever gekoppeld zien aan inzichten vanuit de werkgroepen binnen de WHO.

Is het een idee om hiervoor met de VWS een brainstorm meeting te organiseren en daar ook IntraVacc bij te betrekken? 5.1.2e gaat/wil hier zeker een rol in spelen en dan kunnen we het beste als VWS experts vanuit de verschillende subdepartementen samen op trekken.

Groet, 5.1.2e

Van: 5.1.2e <5.1.2e @rivm.nl>
Datum: 24 april 2020 om 12:29:27 CEST
Aan: 5.1.2e <5.1.2e @rivm.nl>, 5.1.2e <5.1.2e @rivm.nl>
CC: 5.1.2e <5.1.2e @rivm.nl>
Onderwerp: RE: Coronavirus countermeasure - broad spectrum vaccine and preventive nasal spray

Hoi 5.1.2e

Ik ken Flu-V wel. Dat concept hebben we zelf ook nagejaagd (niet met hen). Wat ik mij zo herinner van hen publicaties is dat ik daar niet heel enthousiast over was, maar daar moet ik nog weer even induiken. De huidige situatie is anders en ook het virus is anders. Opzich is een universele aanpak zoals zij dat noemen een hele mooi approach. Ik heb echter alle sequenties van de humane coronavirussen al bestudeerd en kom tot 1 conclusie, datgene wat voor Flu geldt (veel homologie tussen interne eiwitten), geldt niet voor Corona. Er is niet zoveel homologie tussen de stammen, op 1 eiwit na, daar zitten meerdere strechtes van > 9AZ die geconserveerd zijn. Ze zijn in hen presentatie niet open over welke target ze gebruiken. Dat zou ik op zijn minst willen weten. Ik vind het verder verwarrend dat er zo'n nasal spray doorheen fietst….daar wil je denk ik eerst niets mee tenzij dit in een klinische studie aantonen dat het voor COVID werkt, wat overigens best kan zijn. We weten ook voor flu dat TLR agonisten bescherming kunnen bieden.

Wat bedoel je verder met uitwerken? VWS gaat hier toch geen geld in steken? Ik denk wel dat het zinvol is een dergelijk vaccin uit te testen. Het hoeft niet per se universeel te zijn. Als we eerst SARS2 eens oplossen komt dat universele later wel. Dit vaccin induceert T-cell responsen en die kunnen wel eens heel nuttig zijn. Vooral omdat we nog niet weten hoe het met enhanced disease zit voor de S1 humorale vaccins. Niet dat T-vaccins geen immuunpathologie op kunnen wekken, daar moet je ook voor waken.

5.1.2e

From: 5.1.2e <5.1.2e@rivm.nl>
Sent: vrijdag 24 april 2020 11:07
To: 5.1.2e <5.1.2e@rivm.nl>; 5.1.2e <5.1.2e@rivm.nl>
Cc: 5.1.2e <5.1.2e@rivm.nl>
Subject: FW: Coronavirus countermeasure - broad spectrum vaccine and preventive nasal spray

Beste 5.1.2e, beste 5.1.2e

VWS weet ons op dit moment goed te vinden voor allerhande vragen over vaccin ontwikkeling.

Bijgaande vraag lijkt me met name een vraag die bij jullie expertise past.

Kunnen jullie hier een blik op werpen? Lijkt dit een nuttig voorstel (van een commerciele partij) om verder uit te laten werken?

Groet 5.1.2e

From: 5.1.2e) <5.1.2e@minvws.nl>
Sent: woensdag 22 april 2020 20:02
To: 5.1.2e <5.1.2e@rivm.nl>; 5.1.2e <5.1.2e@rivm.nl>
Cc: 5.1.2e <5.1.2e@minbzk.nl>
Subject: FW: Coronavirus countermeasure - broad spectrum vaccine and preventive nasal spray

Beste 5.1.2e en 5.1.2e

Kunnen jullie van onderstaande een eerste beoordeling geven? Zou het iets zijn om verder te (laten) bestuderen?

Alvast dank!

Vriendelijke groet

5.1.2e

Van: 5.1.2e) <5.1.2e@minvws.nl>

Datum: woensdag 22 apr. 2020 7:53 PM

Aan: 5.1.2e) <5.1.2e@minvws.nl>

Kopie: 5.1.2e) < 5.1.2e @minvws.nl>, 5.1.2e) < 5.1.2e @minvws.nl>

Onderwerp: FW: Coronavirus countermeasure - broad spectrum vaccine and preventive nasal spray

Hoi 5.1.2e

Zie bericht 5.1.2e

Kun jij dit uitzetten? (Rivm denk ik?)

Gr

5.1.2e

Van: 5.1.2e < 5.1.2e @dsm.com>
Verzonden: woensdag 22 april 2020 10:26
Aan: 5.1.2e) < 5.1.2e @minvws.nl>
Onderwerp: FW: Coronavirus countermeasure - broad spectrum vaccine and preventive nasal spray

FYI

Weet niet of we dit willen overwegen

5.1.2e

From: 5.1.2e < 5.1.2e @dsm.com>
Sent: Wednesday, April 22, 2020 2:42 AM
To: 5.1.2e < 5.1.2e @dsm.com>
Subject: FW: Coronavirus countermeasure - broad spectrum vaccine and preventive nasal spray

Hi 5.1.2e

Don't know them nor whether any merit in this (not a biotech expert), but looks more legit than most stuff coming in these days and maybe someone in NL can judge if worth pursuing.

Hope all well

5.1.2e

From: 5.1.2e < 5.1.2e @geneworxcapital.com>
Sent: Tuesday, April 21, 2020 7:51 PM

To: 5.1.2e <5.1.2e@dsm.com>
Subject: Coronavirus countermeasure - broad spectrum vaccine and preventive nasal spray

CAUTION - This email originated from outside DSM
Please forward suspicious emails as attachments to 5.1.2e@dsm.com

5.1.2e

I'm a 5.1.2e of GeneWorx Capital with 5.1.2e at Wasserstein Perella and Techfarm Venture Capital. GeneWorx is a life sciences venture development firm in Cambridge, MA. We are working with PrEP Imutex, a biopharma with programs focused on preventing the full spectrum of respiratory viral illnesses including COVID-19:

1. **Universal Coronavirus Vaccine**

A single dose of this vaccine may provide **long term protection against a broad spectrum of coronavirus infections including COVID-19 and its potential variations and mutations**. We have selected peptide chains in the viral protein sequence that 1) trigger a T-cell response, and 2) are located in areas of high conservation. We synthetically manufacture the selected peptides (via Fmoc chemistry), and process them using cost efficient, rapidly scalable manufacturing steps to make an easily transportable, non-cold chain vaccine. Vaccine is in pre-clinical development.

2. **Coronavirus-Preventing Nasal Spray**

PrEP-001 is a once-daily nasal spray that **protects against all respiratory viruses, including the novel coronavirus**. It is neither vaccine nor antiviral but is an immunomodulator that safely stimulates the host's innate immune response in the upper respiratory tract providing robust protection against all RNA respiratory viruses including SARS-CoV-2 (COVID-19). Proof of concept demonstrated in Phase 2a challenge studies.

3. **Universal Flu Vaccine**

Using the same peptide vaccine platform on which the coronavirus vaccine is being developed, the company has developed a universal flu vaccine, FLU-v, which is ready for Phase 3 trials. FLU-v is the **only universal flu vaccine with clinically confirmed reduction in infections and symptoms** in phase 2b studies.

PrEP Imutex is the merger (in process) of two UK-based biopharmas, PrEP Biopharm and Imutex. It brings together complementary assets for preventing coronavirus, flu and all other respiratory viral illness, with a team of seasoned executives and technologists from J&J, GSK, Lilly and other pharma leaders.

The company is seeking partners and investors to rapidly advance its programs:

- **Universal Coronavirus Vaccine**

$4M to develop through completion of Phase 1 trial; **<12 months**

- Coronavirus-Preventing Nasal Spray

$10M to complete a Ph 2 field trial against COVID-19 and all other respiratory viruses; **12 months**

- Universal Flu Vaccine

$53M to complete Phase 3; **30 months**

More info is below and an overview deck is attached.

Please let me know if you would have time and interest in a telcon to discuss this in the next week or two.

Thanks and regards,

5.1.2e

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5.1.2e
GeneWorx Capital
5.1.2e
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5.1.2e @GeneWorxCapital.com
www.GeneWorxCapital.com

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Universal Coronavirus Vaccine

A universal coronavirus vaccine that utilizes synthetic peptides matched to T cell reactive epitopes within conserved regions of viral protein sequence

Our vaccine platform relies on in silico identification of protein antigens as potential components of the vaccine to induce T-cell responses. Recent literature indicates that T-cells are able to fight COVID-19 naturally in the same manner that they fight influenza infection. PrEP Imutex's computer algorithms are able to predict which areas in the viral protein sequence are likely to be recognized by the immune system and trigger a T-cell response. We select those highly reactive regions that are located in areas of high conservation within the coronavirus family. Conserved areas with a high number of reactive regions and between 30-40 amino acids long are selected and manufactured synthetically via Fmoc chemistry.

- Provides cross-protection against broad range of coronavirus strains.
- Decreases symptomatology.
- Reduces hospitalizations.
- Remains the same year after year allowing all year round manufacturing.
- Less complex and cost-effective manufacturing so larger population can be vaccinated.

PrEP-001

Once-daily, nasal spray containing a double-stranded RNA viral mimic (Poly I:C) in a dry powder formulation

PrEP-001 delivers a synthetic viral RNA surrogate (PolyIC) to stimulate the innate immune response prior to a viral exposure. The product prevents viruses from replicating effectively in the nasal lining and from spreading throughout the nose, as well as improving the final clearance. Poly IC has been used for decades in the research lab, but has never been brought to market because formulation challenges made it impractical. PrEP Biopharm solved these challenges and patented encapsulation and delivery technologies to deliver this first-in-category pan-viral agent that protects patients from coronaviruses, influenza, RSV and all other respiratory viruses.

PrEP-001 has shown excellent results in two double-blinded, placebo-controlled phase 1b/2a challenge studies with rhinovirus and the H3N2 influenza virus. Use resulted in a 10 to 50-fold reduction in viral shedding and a 2 to 3-fold reduction of clinical illnesses compared to placebo with a safety profile similar to placebo.

- Pre-activates the pan-viral innate immune response in the upper respiratory tract via TLR3, MDA5 and RIG-I
- Non-allergenic, no systemic exposure, degrades into recyclable nucleosides
- Proof of concept demonstrated in phase 2a challenge studies with rhinovirus and influenza virus
- Reduced incidence, severity and duration of influenza illness and common colds
- Reduced viral shedding >90% in infected subjects
- Safety and tolerability similar to placebo in >200 patients dosed
- Highly stable, dry-powder formulation. No cold-chain storage.
- Phase 2b-ready. Study design has received scientific advice from FDA and other Health Authorities
- 3 drug patent families provide protection through 2035. Patents granted in US, EU, Japan, China, Russia, Australia, New Zealand, etc.

FLU-v

Robust and differentiated advanced-stage influenza vaccine candidate
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FLU-v is a Universal Influenza T-cell Vaccine targeting conserved internal proteins common to all flu viruses. This approach eliminates the sensitivity to strain variability seen with traditional vaccines, and promotes single vaccine coverage for all flu strains with efficacy for years following a single vaccination.

In Phase 2b field study, FLU-v has shown 83% reduction in confirmed severe symptom influenza, and 60% reduction in confirmed influenza infections overall. A challenge study showed statistical significance in reduction of MMID, and reduced symptoms vs placebo.

FLU-v has been tested across multiple A&B strains and covers conserved protein regions of all human and animal strains (pandemic protection) while activating both T & B immune cells.

- Targets conserved regions of internal proteins found in all influenza A and B human/animal strains (vs seasonal and other universal flu vaccines reliant on stem/stalk epitopes subject to variation)
- Multi-peptide vaccine is broad spectrum, well tolerated, and easy to manufacture (vs TIV, QIV, LAIV, and viral vector vaccines)
- Highly supportive positive Phase II-b results; statistically significant reduction in influenza ($P<0.05$)
- Ready for Phase III
- Safety and tolerability similar to placebo in >350 patients dosed
- Low cost, synthetic manufacturing process. Freeze-dried; no cold-chain storage.
- Broad impact for a burden on global public health in a ~$10-20B market

- Wide-ranging multi-national patents and market exclusivities covering both polypeptides and

polypeptide-inclusive compositions, as well as their homologies

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Securities transactions conducted through StillPoint Capital, LLC, Tampa, FL

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