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Brussels, 4th October 2019

Dear Pablo

Please find attached the responses of Janssen Vaccines & Prevention BV on behalf of both applicants to the questions you kindly conveyed to us on 16th of September. Two separate versions have been created due to the questions regarding the CAS numbers of alternatives being considered.

The information regarding specific substances considered for substitution is a business secret whose publication could harm the commercial interests of the applicants. We have instead chosen to reveal the families of the main substances being considered so that the committees and the general public can ascertain the general nature of the (lack of) hazard they pose.

In the confidential version you will then find the detail of the substances with CAS numbers. The hazard phrases (where applicable) for each substance within each family have been retained for public scrutiny. We believe we thereby meet the requirement of publishing all relevant information relating to safety for man and/or environment

Kind regards

Julius Waller

ANNEX – Response to questions

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ANNEX

Questions from RAC

1. On p. 29 of the CSR it is stated that "Release to air, waste or surface water and soil is prevented by rigorous means. Monitoring for Octylphenol or Octylphenol Ethoxylate residues in environmental compartments or waste has not been performed for the facility". Can you please specify if any monitoring for Octylphenol or Octylphenol Ethoxylate residues is planned for the facility in the future?

Monitoring of the water waste stream in the sewer systems is not foreseen in a future authorization period. The segregation of the liquid waste streams of the process steps which contain OPnEO from those that do not contain OPnEO is absolute due to the biological safety requirements inherently designed and built in the manufacturing plant (BSL-2 containment). Therefore OPnEO-containing liquid waste streams physically cannot leave the manufacturing plant other than by the controlled route designed and built for this purpose.

The RMMs will assure that no OPnEO is introduced in the municipality sewer system and monitoring would not result in any informative data or control.

2. Please describe in more detail the procedures in place to prevent the emissions during maintenance

The BSL-2 part of the manufacturing plant where OPnEO is used in the process is completely segregated from the outside environment with a dedicated sewage system, which contains an obligatory heat treatment (Biokill) system. The production is a batch process. BSL-2 activities and hence OPnEO use only occur when the heat treatment (Bio-Kill) is active. Maintenance on the biokill system, which is the only foreseeable maintenance with OPnEO relevance, will be performed when the facility is not producing.

More explicitly stated: maintenance will be carried out in between batch production. The frequency will be according to a fixed schedule defined in a preventive maintenance plan based on a risk assessment executed according to the reliability-centered maintenance method used by the applicants.

Emission from maintenance activities will not occur from the manufacturing process steps, because the process is based on disposable technology. Disposable materials are collected and disposed of as hazardous waste (incinerated). Equipment parts that

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are not disposable, have not been in contact with OPnEO and thus maintenance on these will not contribute to OPnEO emissions.

Any potential for emission during maintenance is therefore in practice only considered applicable to the dedicated sewer system.

The piping to and from the heat treatment system is designed not to require regular maintenance. Piping towards the Biokill system is double-walled and equipped with sensors. Piping for the effluent from the Biokill treatment to the tanker truck is yet to be engineered (see answer to question 3). This engineering is – because of the application for authorization – specifically taking into account zero emission design. Any piping above ground towards the tanker truck will be fully welded and regularly (visually) inspected.

Only trained and authorized staff are allowed to perform maintenance activities, for which working permits are a prerequisite. Current available (preliminary) written maintenance procedures[1] will be adjusted and/or finalized when construction and testing is completed.

Any waste from the maintenance activities will be collected separately and labelled as hazardous waste and added to the waste streams from the manufacturing process. The waste will be incinerated.

3. In "Executive Summary" of the CSR you state that "All liquid waste streams from the BSL-2 area are led through dedicated piping to a buffer tank and are subsequently thermally treated to deactivate active virus components ('biokill-system'). From this system the liquid waste is led by means of dedicated piping to tanker trucks and shipped to a certified waste handler for waste treatment that results in 0 (zero) emission to the environment (incineration)". However on p. 28 of the CSR you say "The loading of the tanker truck will be on a water retaining floor, so any potential spill will be collected and kept within the dedicated system" which implies that RMMs for collection of liquid waste are not yet in place. Thus, please clarify: is the system to collect liquid waste streams, that might be contaminated with Octylphenol or Octylphenol Ethoxylate residues, currently in place in the facility? If not, please specify when such system will be in operation.

The manufacturing plant was designed, built and commissioned. Resulting in a manufacturing plant ready to manufacture the adenovirus-based vaccines. Due to the placement of OPnEO on the REACH annex XIV additional RMMs for OPnEO control were however needed. These RMMs were designed to assure a 0-emission of OPnEO into the environment.

[1] Vervangen ventfilters Biokill (Replacing vent filters Biokill) TNK-001 (1Y) (PMPD: 15265); Vervangen ventfilters Biokill Leidingbeluchting (replacing vent filters Biokill conduits aeration system(1Y) (PMPD: 15266); NEN 3140 Keuring Arbeid middelen (certification of working materials), DS-TEC-63075 (NVT); NEN 3140 Keuring (Certification), DS-TEC-151527 (2Y) (PMPD: 15268) -

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All the piping inside the plant was in place as designed and built because of biological safety requirements (BSL-2) and therefore also dedicated to all OPnEO-containing liquid waste streams. The piping outside the building and the collection into tanker trucks is to be engineered and built. The high-level timelines for the build and implementation of these RMMs to assure a 0-zero emission of OPnEO into the environment is shown in the Table below. Current planning shows the RMMs will be implemented as soon as possible and well before the sunset date of 04JAN21.

RMM implementation status	**Time**
Feasibility phase	completed
Basic design	completed
Detailed design	Oct-Nov 2019
Construction	Feb-Apr 2020
Commissioning	May-Sep 2020
Ready for use	Oct 2020
100% OPnEO collection	04 Jan 2021

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Questions relating to the AoA

1. Table 3 in the AoA document, lists "Risk of future environmental ban" as one of the selection criteria for alternatives. Could you please elaborate on the overall reduction of risk (hazard) of the alternatives considered? You can do this by indicating in the following table whether the alternative(s) is/are considered safer than OPnEO and explain why you think this is the case.

The selection of replacement detergents is focussed on finding candidates that are not considered svhc compounds (now and in the foreseeable future). They should be able to replace OPnEO in the lysis process with similar characteristics and not critically impacting the functions identified (cell permeabilization, compatibility with the DNA precipitation and viral clearance). All octylphenol and nonylphenol compounds were therefore automatically deselected as deemed unsuitable as replacement detergent.

A shortlist of detergents that is identified as potential replacers on basis of predefined selection criteria amongst which "Risk of future environmental ban" is scrutinized in a next round of more detailed assessments one of them being environmental considerations based on publicly available information. The table contains the detergents mentioned in the AoA (AoA page 52, Table 2: Examined alternatives to OPnEO) that are part of a plan for actual experimental testing. The first column mentions the main chemical group, the second column the CAS number, the third column a specified chemical classification and the fourth column a safety assessment on basis of H-phrases in the SDS. The list contains three chemical groups: alkyl ethoxylates, polysorbates and alkyl glucosides. For these groups an environmental assessment has been made. All chemical groups identified are considered as safer compounds than OPnEO.

Chemical group	**CAS**	**Identification**	**Safer alternative (y/n)**
Alkyl ethoxylates	[redacted]		
			Yes, alkyl ethoxylates are well described in literature Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008

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	[redacted]	Yes, alkyl ethoxylates are well described in literature Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008
		Yes, alkyl ethoxylates are well described in literature Classification according to Regulation (EC) No 1272/2008 H302, H315, H318
		Yes, alkyl ethoxylates are well described in literature Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008
Polysorbates		
		Yes, polysorbates are well characterized and known pharmaceutical excipients and food-additives

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	[redacted]	Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.
Alkyl glucosides		
		Yes, alkyl glucosides are considered safe. SDS text: This item is not a hazardous substance and does not contain hazardous ingredients, substances with European Community workplace exposure limits or substances of very high concern (SVHC) above their respective disclosure limits. Hence a safety data sheet is not required according to Regulation (EC) No. 1907/2006 (REACH) and also not available in this case.

2. Question about the Substitution Plan: (…)

The applicants were aware of the court judgement and in any case are proposing to substitute the substance as described in the AoA. When the application was being drafted the business rules of ECHA prevented the submission of a substitution plan together with a SEA and outside the scope of a control of risk application. This placed the applicant in a quandary which was resolved by including the full substitution plan in the analysis of alternatives.

For the sake of absolute clarity: the applicants are convinced there are alternatives to OPnEO and have already started the substitution process. This process will

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require 15 years as is explained in the submitted documentation and justifies the review period. The application is in fact a bridging application to allow the applicant to go through all the necessary qualification processes to implement the substitute substance. In the submitted application the applicant described the requested review period as: 'Substitution Review Period' (p. 61 AoA section 5.4)

The applicant has, therefore, submitted a completed substitution plan. In correspondence with ECHA following the mass mailing of all applicants by the agency the applicant also responded already that the substitution plan was included in the AoA. (Correspondence to Thierry Nicot).

To aid the committees, we have copied the section heads of the template on substitution and linked them to the submitted analysis of alternatives for clarity. The committees can verify that all elements of the substitution plan template are included.

The ECHA substitution plan template contains the following headings:

FACTORS AFFECTING SUBSTITUTION

Section 3.5 p.p. 27-36. FACTORS AFFECTING SUBSTITUTION BEYOND THE TECHNICAL FUNCTION REQUIREMENTS

LIST OF ACTIONS AND TIMETABLE WITH MILESTONES

Section 5 p.p. 37-60 LIST OF ACTIONS AND TIMETABLES WITH MILESTONES – PROPOSED - SUBSTITUTION STRATEGY

MONITORING OF THE IMPLEMENTATION OF THE SUBSTITUTION PLAN

Section 6 p.p. 64-66 MONITORING OF THE IMPLEMENTATION OF THE SUBSTITUTION PLAN

CONCLUSIONS

Section 5.4 p.p., 61-64 TOTAL REVIEW PERIOD REQUIRED

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SEA questions

Non-use scenario

1. As a single NUS delay of production of 7 years was considered. No further scenarios, e.g. relocation to production facilities in e.g. USA were analysed. Does this mean that relocation, outsourcing of parts of the production process are no options at all?

Relocation is not a realistic scenario; Janssen acquired the original Dutch company Crucell for good reason and has worked at expanding its products and bringing them to market. What was purchased was human resources and know-how. It is not conceivable to convince so many people to move to another continent.

Furthermore, Advac® production technology is linked to the platform in Leiden. To the applicant's knowledge this platform is unique and therefore there is no pool of personnel that could be recruited at another location. Construction, validation and homologation of a new facility outside of the EU would also take many years. The installation in Leiden has been in development for more than 6 years and has yet to produce a commercial product.

Another motive preventing the second hypothetical alternative NUS would be corporate social responsibility: Janssen does not "export" risks to third countries.

Yet, as shown in the CSR, in this specific AfA, no risk is involved therefore the applicants do not really see any motive to relocate or to outsource, even if the corporate social responsibility commitments were not in place. The plant in Leiden, characterized by zero emission, is already in place and there is no realistic motivation to move that plant outside the EEA.

2. Use of economic measure EBIT overestimates profit losses since interest costs are excluded. Can you explain in more detail which cost components are covered by "other expenses linked to the production of vaccines", especially whether labour costs are included.

"Other expenses linked to the production of vaccines" include the following cost components:

- Labour costs
- Sales and marketing
- Medical affairs
- Administrative costs
- R&D costs

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We use the EBIT as a conservative approach to estimate the economic impacts. We follow the ECHA guidelines as reported in: "Checklist for preparing an application for authorization or a review report", dated 12 May 2017, version 1.1, page 16, sub-section 7.3.e).

In that ECHA report it is stated that for a temporary stop of the production, the value added (or gross profits) is the relevant variable to consider for estimating the economic impacts. Therefore, the use of EBIT in the SEA *underestimates* the economic impacts of a refused authorization in case the consequent stop of the production is temporary like in this AfA (7 years of delay). The gross profits are simply represented by sales revenue minus the costs of goods sold.

The (net) profit loss is the relevant variable in the alternative case of a permanent stop of the production, which is not the case for this AfA.

3. Could the AdVac production technology in Leiden be used for production of vaccines which do not need OPnEO as process chemical?

No.

All vaccines based on Advac® technology rely on OPnEO as process chemical. The Advac® production technology is intrinsically connected with the use of OPnEO in order to function.

4. For some of the newly developed vaccines, competitors may provide vaccines against the same viruses but with a different production process, and for some viruses the applicants will be the first ones entering the market with a new vaccine (e.g. HIV). Please, explain whether some competitors would be able to take over future market shares of the applicant´s new vaccines during the time period when the market introduction of the applicant's vaccine is delayed?

The two vaccines in the applicants' pipeline that are closest to market introduction are an HIV Vaccine[2] and an RSV Vaccine.

While the applicants do not have direct insight into competitors' development program, to the best knowledge of the applicants, there are no competitors that are as advanced in development of an HIV vaccine for a global population.

Additionally, according to clinicaltrials.gov, Janssen is the only company in Phase III clinical trials for an HIV vaccine. It is unlikely that a competitor could come to market in the short-term with a vaccine against HIV, and any delay in the

[2] See *"HIV prevention is making progress. And a breakthrough vaccine appears within reach"* LA Times, 06/09/2019 attached to this response.

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applicants' vaccine would result in a delay in availability of an HIV vaccine for the populations that would benefit from it.

Janssen is expected to be first to enter the market with an RSV Senior vaccine for the prevention of RSV in older adults. Based on the applicants' limited knowledge of the development status of other major vaccine players. In a highly competitive environment, the applicants expect that those competitors will follow very closely after Janssen. Therefore, market entrance timing will be key for commercial viability of the program and any delay could result in significant loss of market share.

5. Please explain the consequences of the decision granting you the authorisation for a period shorter than requested. On page 63 of the SEA it is stated that "A shorter substitution period (12 years for example) would place the applicant under the obligation to re-apply even if they are optimistic about the chances of achieving the realistic scenario." Would it affect, and if so in what way, for example your business plan, potential investments etc?

The applicants have committed to substitute the substance in 15 years.

By definition this process will not be complete 18 months before the expiry of the 12 years authorisation. The resubmission would therefore simply entail a statement that the substitution process is on track and implementation is ongoing. This is inefficient from a regulatory perspective as this information could also be obtained through the regular supervision by enforcement authorities of the ongoing authorisation.

The applicants have shown that the substitution cannot – for practical reasons – be fully completed in 12 years. The challenge is that the technical substitution process ***might***[3] possibly be complete but certainly not the regulatory one. The substitution plan and the substitution review period requested ensure that the applicants can finalise the process in all jurisdictions.

In some complex jurisdictions the applicants can show that the 12 years would never suffice. Therefore the most logical business decision would be to simply delay market launch in those jurisdictions. These markets are predominantly in the more vulnerable and less affluent parts of the world which would then suffer as a consequence of the shorter review period.

The financial and resource burden for a reapplication in the midst of a substitution process is substantial and would almost certainly delay the substitution process itself. The subject matter experts involved in the substitution would be forced move their efforts from the substitution to the reapplication.

[3] This will not be certain 18 months before the expiry of a 12 year review period.

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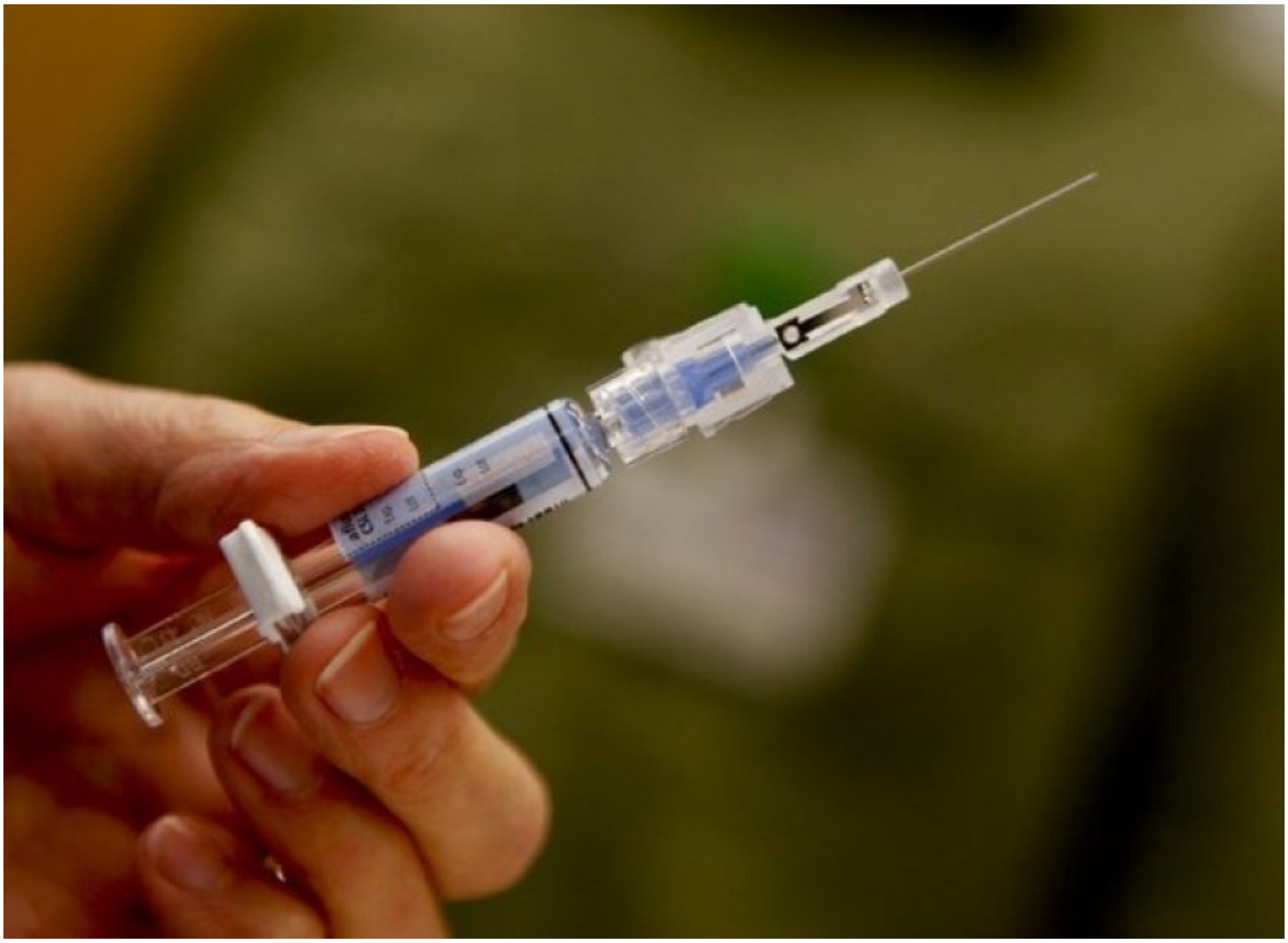
SCIENCE

HIV prevention is making progress. And a breakthrough vaccine appears within reach



After decades of research, scientists are cautiously optimistic about the prospects for an HIV vaccine. (Mark Boster / Los Angeles Times)

By EMILY BAUMGAERTNER
STAFF WRITER

SEP. 6, 2019
6 AM

First there were the drugs that could knock back HIV to undetectable levels, and the virus

was no longer synonymous with a death sentence. Then came a treatment that allowed people who were HIV-negative to remain that way, even if their partners weren't.

But to truly defeat the virus that causes AIDS, doctors need a vaccine. And after decades of dead ends and dashed hopes, they may finally be on the verge of having one.

With a large-scale clinical trial launching this fall and several others already underway, scientists say they are cautiously optimistic that they'll soon have a way to fight HIV long before a person is ever exposed.

"When you have a disease that is transmitted without symptoms, you're going to acquire it when you least expect it," said Dr. Larry Corey, principal investigator of the HIV Vaccine Trials Network. In such situations, "the only base control measure ever proven to be effective is a vaccine."

Researchers and public health experts agree that the surest way to eliminate a disease for good is by deploying a vaccine. It worked for smallpox. It worked for polio. And, if combined with antiretroviral therapy and pre-exposure prophylaxis, it could work for HIV too.

A vaccine would mean "the end of the AIDS story as we know it," said Dr. Robert C. Gallo, director of the Institute of Human Virology at the University of Maryland School of Medicine.

More than 37 million people around the world are living with HIV, and they spread it to about 5,000 others every day, Corey said. There are also about 180,000 transmissions to newborns each year.

"This virus is unfortunately doing very well," he said.

The human immunodeficiency virus (HIV) attacks a specific type of white blood cell the body relies on to fight off infections. If left untreated for several years, a patient's white blood cell count becomes critically low, leading to acquired immunodeficiency syndrome (AIDS). That makes the body vulnerable to bacteria and fungi that can cause tuberculosis, meningitis,

certain types of cancer and other serious diseases that can lead to death.

Once Gallo and other scientists identified HIV as the cause of AIDS in 1984, it didn't take long for them to recognize the need for a way to inoculate people against the virus. Even back then, he said, "We were already planning for a vaccine."

Vaccines prime the immune system for a dangerous invader by introducing a dead or weakened version of it. That way, if the real threat comes along later, the body is already equipped to recognize it and beat it back.

With classic threats like measles or polio, the vast majority of people are already able to suppress the virus and eradicate it from their bodies. In those cases, developing a vaccine is as simple as finding a safe way to mimic a natural infection — perhaps by introducing a modified version that has been stripped of its weaponry.

But HIV is different, because no patient has ever been known to overcome the virus on his or her own.

That means scientists working on a vaccine don't have a natural cheat sheet at their disposal. It also means that a successful vaccine will have to work extra hard to achieve its goal.

"If we want to make a durable vaccine, we have to be even more clever than the natural infection. We've never had that challenge with any other virus," said Dr. Anthony S. Fauci, director of the National Institute of Allergy and Infectious Diseases. "I don't think it's going to be impossible. But we need to understand the relationship between the pathogen and the immune system in a way we've never had to before."

HIV is a wily opponent. The virus doesn't just defend itself against attacking immune cells, it invades them, integrating itself into the victim's DNA. It can also envelop itself in sugar molecules to keep antibodies from latching onto its shell.

Then there are genetic complications. HIV has more genetic diversity than any other known virus. It makes frequent mistakes as it replicates, and it can survive without correcting them. This ability to rapidly mutate makes it a moving target — no match for a vaccine designed to

protect against a single strain.

On top of that, there are different HIV subtypes in different parts of the world. (Subtype B is common in North America and Europe, for example, while subtype C is found in southern and eastern Africa.) An effective vaccine must be based on components drawn from a mosaic of HIV variants in order to work against many strains.

“You have to protect against all that variability,” said Dr. Susan Buchbinder, director of Bridge HIV, a prevention research unit in the San Francisco Department of Public Health.

That strategy will be tested this fall in a large-scale efficacy trial called Mosaico. The experimental vaccine, made by Johnson & Johnson, contains an array of genetic sequences from various HIV strains.

In preclinical trials, the vaccine effectively protected about 66% of nonhuman primates against HIV-like viruses. Follow-up studies in people helped finalize its makeup.

Now scientists plan to enroll some 3,800 healthy participants at more than 50 trial sites across North and South America and Europe. All of them will be drawn from groups that are at high risk of contracting HIV, including men who have sex with men and transgender people. They will receive four vaccinations over the course of a year.

The study will be double-blind, meaning that neither the participants nor the researchers will know who has been randomly selected to receive the experimental vaccine and who is getting a placebo. If the vaccine proves successful, researchers hope it will be used around the world.

“We’re really excited about this one,” said Buchbinder, the protocol chair for the Mosaico trial.

Focusing on high-risk populations is paramount, researchers say. Men who have sex with men constitute almost two-thirds of new HIV infections in the United States. And the world‘s approximately 25 million transgender people are almost 50 times more likely to be living with HIV than the general population.

As part of the study enrollment process, the researchers will educate volunteers on the benefits of pre-exposure prophylaxis (PrEP) and urge them to take that drug in lieu of joining the study. Only those who say they still want to forgo the treatment will be able to participate.

Other trials are already underway. In sub-Saharan Africa, a similar vaccine is being tested on 2,600 women, the group that's most at risk in that region. That trial began in 2017, and results won't be available until 2021 at the earliest.

Two parallel studies that began in 2016 are intended to test whether infusions of a broadly neutralizing antibody can prevent a person from acquiring HIV and, if so, what levels are needed to sustain that protection. Lab studies showed that these antibodies stop up to 90% of HIV strains from infecting human cells. These trials are taking place in sub-Saharan Africa and North and South America.

Another clinical trial underway in South Africa is testing an enhanced version of a vaccine that was the first to show even limited effectiveness against HIV. That vaccine provided sustained protection in about one-third of those tested in a 2009 landmark study in Thailand.

"It wasn't good enough for prime time, but it helped us," Fauci said. He said experts decided not to deploy the vaccine, in part because it might make people think they were immune to HIV when in reality they were only partially protected.

No vaccine is foolproof, and scientists say they don't have to be. Researchers with the International AIDS Vaccine Initiative determined that a vaccine that's 70% effective would do more to prevent new infections than PrEP.

The Mosaico trial is pushing for 65% effectiveness, Buchbinder said. "Even a more modestly effective vaccine could alter the course of the epidemic," she said.

Many other vaccine candidates are in the pipeline. Gallo and his colleagues are working on their own HIV vaccine that they expect will enter a Phase II trial to test its efficacy in the near future.

“We’ve clearly had our ups and downs, but science is all about testing our hypotheses, even if the outcome is, ‘Nope, definitely not working,’” Buchbinder said. “The only failed experiment is one in which you don’t find an answer to your question.”

SCIENCE MEDICINE HEALTH

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Emily Baumgaertner is a science and medicine reporter at the Los Angeles Times. She previously worked in the New York Times’ Washington bureau, where she broke stories on the FDA and the CDC under the Trump administration. Baumgaertner reported from the Ebola outbreak in Sierra Leone and a yellow fever epidemic in Congo. At age 16, she sequenced and analyzed an original gene implicated in breast cancer. After finishing her graduate degree in global health metrics at the George Washington University, Baumgaertner had planned to become a researcher but decided to pursue storytelling.

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