mRNA and Drugs: A Fistful of Million Dollar Questions

This is the English translation of the talk I gave as part of a pharmaceutical-medical-legal conference called “Lo Strappo nel Cielo di Carta: Farmaci a mRNA e L’Imprevisto Che Svela L’Illusione”, The Rip in the Paper Sky: mRNA Drugs and the Unexpected That Unveils the Illusion, that took place the 28th of April 2023 in Perugia, Italy.

One must have very specific requirements to create an advanced therapy drug such as mRNA drugs. If those requirements fail, the therapy is useless and potentially harmful.

Hence my questions.

1. The COVID-19 Syndrome

Let us start from the very beginning—the COVID-19 Syndrome.

Are the symptoms of COVID-19 syndrome unmistakable?

If I see COVID-19 symptoms, can I say with absolute observational certainty that it can only be COVID-19 syndrome?

It doesn't seem so because other diseases and syndromes can have the same symptoms that COVID-19 syndrome has.

2. COVID-19 Syndrome Causative Agent

Do we know beyond the shadow of a doubt what the causative agent of COVID-19 syndrome is?

When we have symptoms, modern medicine first looks for the aetiological agent.

This agent can be:

a. Toxin

b. Pathogen

Somehow during the narrative, it was never allowed to investigate the above two possibilities.

We went directly with the pathogen hypothesis, which then became an established certainty that no one could question or doubt.

Always assuming it is a pathogen, we need to find out whether it is:

a. Infectious

b. Non-infectious

It has been assumed from the outset that it is infectious.

If it is infectious, then the pathogen must follow an epidemiological pattern fairly well defined by modern medicine as described by the contagion theory.

Did this happen in the COVID-19 syndrome 'pandemic'?

Doesn't seem so.

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3. Infectious Pathogen

Once we have established that COVID-19 syndrome is caused by an infectious pathogen, then we must isolate this pathogen.

Has the infectious pathogen ever been isolated?

I don't think so.

I want to clarify the difference between isolating and sequencing.

a. Isolate

   Definition from Cambridge Dictionary

   To separate something from other things with which it is connected or mixed.

   For example:

   When a prisoner is placed in solitary confinement, the prisoner is placed in an environment where he/she has no way of communicating or contacting others.

b. Sequencing

   Definition from Cambridge Dictionary specifically for biology

   The process of discovering the order in which nucleotides (=chemical substances) are combined within DNA

   Therefore, I can have all the nucleotide sequences ever imagined in the world strung together without ever having detected or isolated a virus, bacterium, or any living thing with those nucleotide molecules within it.

4. Cause and Effect

After we have, in theory, 'isolated' the pathogen, have we established beyond doubt that the it causes COVID-19 syndrome?

I don't think so.

I want to point out that even if a pathogen or nucleotide sequence is found in the fluids or tissues of a sick patient, this does not prove that that pathogen or sequence causes the disease.

For example:

Suppose a person has a car accident and, during hospitalisation, Candida infection is found. In that case, we cannot say that Candida caused the car accident and neither that the car accident caused the Candidiasis.

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5. Laboratory Analysis

Polymerase Chain Reaction, PCR, has been chosen as the primary diagnostic test for the pathogen.

Here I have two observations and two questions.

a. Has the PCR test ever been validated as the golden standard test of diagnostic excellence?

   When using PCR, is the result that it produces beyond doubt?

   I don't think so.

b. Polymerase Chain Reaction consists of taking a DNA fragment, placing this string of nucleotides into a chemical cocktail, and copying the same sequence several times per cycle to obtain multiple copies of the same initial DNA fragment.

   But where does this nucleotide string we place on this platform come from, since the pathogen has never been isolated and is only, perhaps, chemically sequenced?

6. Creation of mRNA Drugs

Creating mRNA drugs entails that a nucleotide sequence is used for therapeutic purposes.

My question is as follows:

Which nucleotide sequence are we using if we have never isolated and, only then, chemically sequenced the COVID-19 syndrome pathogen?

7. What is mRNA

To understand mRNA drugs, one should realise what mRNA is and its function.

According to modern genetic theory:

a. We have chromosomes in the nucleus of our cells.
b. These chromosomes are sequences of 4 nucleotides that alternate on a strand and form what we call the DNA double helix.
c. DNA always remains in the cell's nucleus and is jealously guarded by the body by various mechanisms, like a fortress.

So how does DNA issue its commands?

This is where the class of RNAs comes in. There are various types, but the one we are interested in is Messenger RNA.

When proteins need to be made for the body, this is what is supposed to happen:

a. The DNA, in a highly twisted and condensed format, opens at the specific location that codes for the required protein.
b. Specific chemical sequences begin transcription of the DNA strand information, and a complementary string called mRNA is synthesised.
c. When all the information has been encoded, the mRNA molecule detaches from the DNA, exits the nucleus and is ferried to the cell's cytoplasm.

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d. In the cytoplasm, the mRNA is flagged and docked very specifically to a 'machinery' (ribosome) that reads the mRNA information strand and translates it into the relevant protein.

Thus, the role of mRNA is to carry information from the DNA in the nucleus to the cytoplasm of the cell to synthesise proteins.

8. Characteristics of mRNA

a. It is a molecule with a strong electrical charge. It cannot enter and leave the cell of its own accord.
b. It is only found near the nucleus in the cell's cytoplasm.
c. It is a transient molecule; it is immediately destroyed after it has done its job.
d. It is kept under constant scrutiny. You do not find any mRNA lazying around because it is destroyed immediately.
e. If any non-native mRNA is suddenly found, the alarm is triggered, alerting that the cell has been compromised and it is immediately destroyed, without even giving the mRNA time to reach the ribosome.
f. If by chance there is an mRNA molecule lying around in the body outside a cell, it is immediately attacked by the immune system.
g. mRNA out of place, in quantities not regulated by the body and of a foreign entity causes inflammation.

9. Lipid Nano Particles (LNP)

To overcome the above-mentioned mRNA's characteristics, which greatly diminish its possibility of being used as a therapeutic agent, pharmaceutical companies have developed synthetic lipids.

In other words, synthetic lipids act like Trojan Horses.

This is because:

a. They will cover the electronic charge of the mRNA so that it can cross cell membranes.
b. They will theoretically not be recognised by the body's enzymes, which would immediately destroy them, as they, too, are foreign material to the body.

Being able to do this requires an ultra-microscopic delivery mechanism, i.e. at the nanometre level.

10. Hypothetical Suggested Structure

a. Tiny beads of about 80-100nm made of various synthetic lipids.
b. Contained inside is mRNA. Theoretically, about 100 mRNA molecules per bead.

The size is crucial for mRNA delivery. If they are over 100nm, the body immediately detects and destroys the beads.

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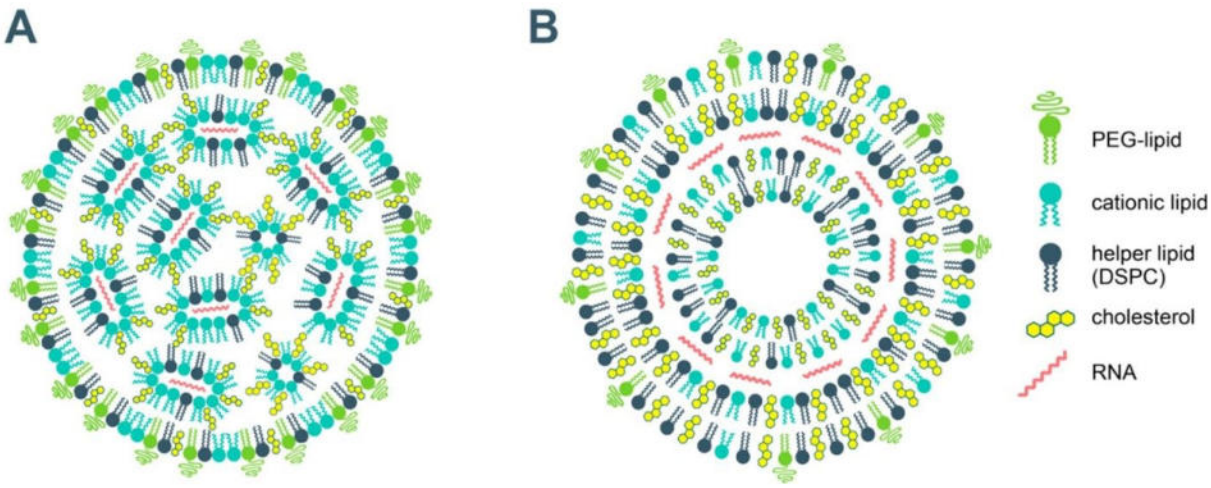
Figure 1:



A Comprehensive Review of the Global Efforts on COVID-19 Vaccine Development

Yingzhu Li, Rumiana Tenchov, Jeffrey Smoot, Cynthia Liu, Steven Watkins, and Qiongqiong Zhou

ACS Central Science 2021 7 (4), 512-533

DOI: 10.1021/acscentsci.1c00120

On the left is the suggested structure of the nano-lipid beads found in BioNTech's advanced drug therapy. On the right is the proposed structure of the nano-lipid beads in Moderna's advanced therapy drug.

Cationic lipid is a positively charged lipid.

PEG-lipid is a synthetic lipid chemically bound to PEG.

Helper lipid is a lipid that helps in holding up the whole framework.

Cholesterol is used to increase the rigidity of the hypothetical bubble structure.

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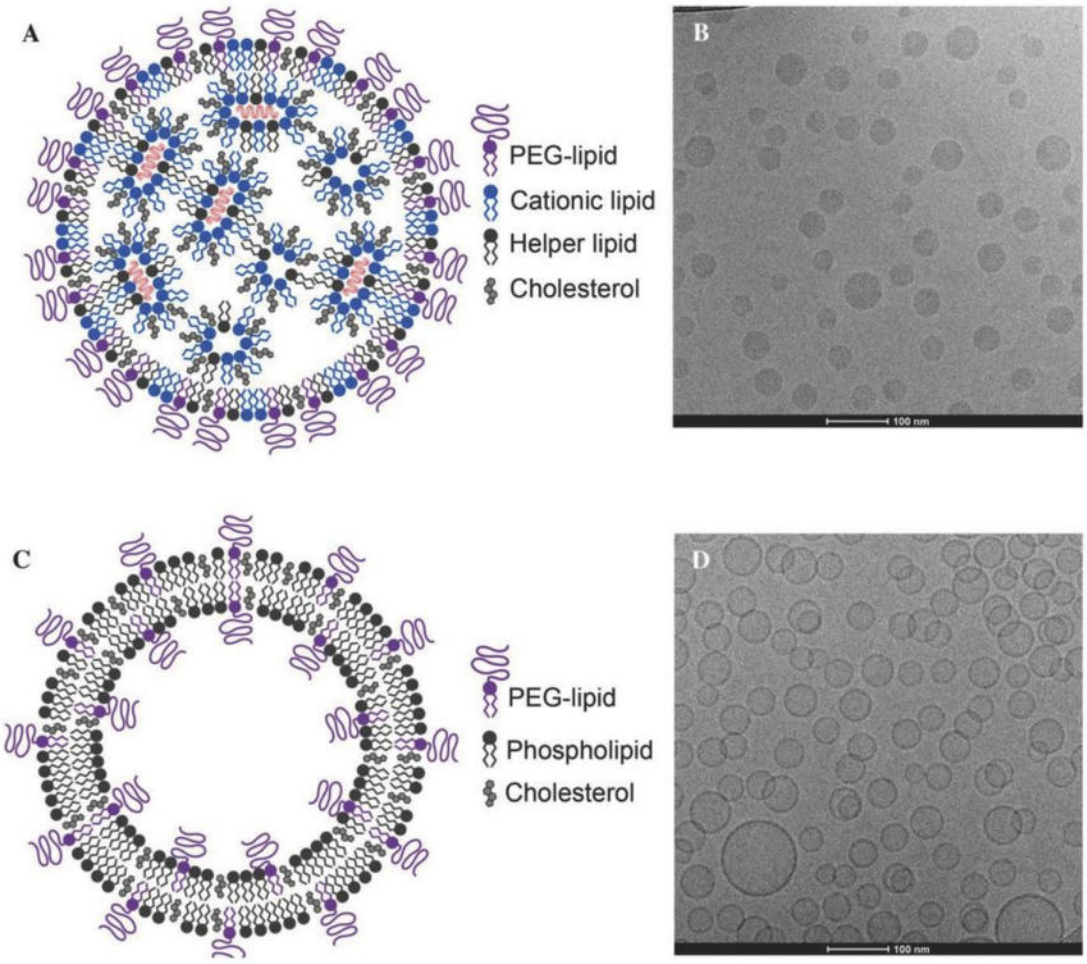
Figure 2:



Structure of LNP–siRNA as compared to liposomes. A, B) The proposed structure of LNP–siRNA formulations containing ionizable amino-lipids within A) inverted micellar structures surrounding siRNA (in red), and B) the corresponding cryo-TEM image. The electron-dense core structure observed in the LNP–siRNA is likely to be the result of electron diffraction from lipid and nucleic acid within the particle. C, D) In contrast, liposomal formulations (depicted in panel (C)) contain an aqueous core with electron densities consistent with the exterior of the liposome.

Small Methods, Volume: 2, Issue: 9, First published: 26 April 2018, DOI: (10.1002/smtd.201700375)

How was the suggested ball structure determined?

Through the cryo-TEM imaging technique.

Transmission electron microscopy (CryoTEM), commonly known as cryo-EM, is a form of cryogenic electron microscopy, more specifically, a type of transmission electron microscopy (TEM) in which the sample is studied at cryogenic temperatures (usually liquid nitrogen temperatures).

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The US National Institute of Standards and Technology considers the field of cryogenics to be that involving temperatures at least below -153 Celsius.

Translated: the hypothetical structure can only be 'seen' at temperatures at least below -153 Celsius. (However, it is still my understanding that the human body fluctuates between 34-37 degrees Celsius, so, provided the suggested structure exists in reality, I have profound doubts that it can actually exist in the human body)

In addition, so-called photos are always a computer processing of what is assumed to be. This is true in all electron microscopy techniques but especially in the one used here, i.e. CryoTEM.

Wikipedia excellently explains the process:

"Even though in the majority of approaches in electron microscopy one tries to get the best resolution image of the material, it is not always the case in cryo-TEM. Besides all the benefits of high-resolution images, the signal to noise ratio remains the main hurdle that prevents assigning orientation to each particle. For example, in macromolecule complexes, there are several different structures that are being projected from 3D to 2D during imaging and if they are not distinguished the result of image processing will be a blur. That is why the probabilistic approaches become more powerful in this type of investigation.[18] There are two popular approaches that are widely used nowadays in cryo-EM image processing, the maximum likelihood approach that was discovered in 1998[19] and relatively recently adapted Bayesian approach.[20]"

The keyword is probabilistic approaches.

https://en.wikipedia.org/wiki/Transmission_electron_cryomicroscopy

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How is the image processed?

Figure 3:

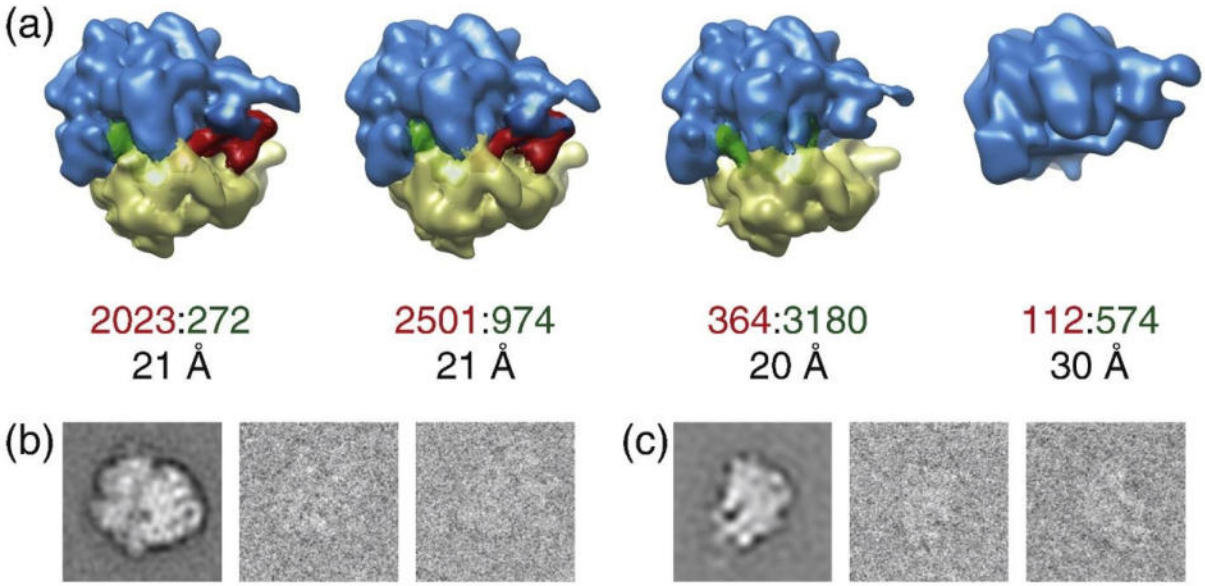

Fig. 4. Ribosome test case. (1 A = 0.1 nm 1 nm = 10 A)

Sjors H.W. Scheres, A Bayesian View on Cryo-EM Structure Determination, Journal of Molecular Biology, Volume 415, Issue 2, 2012,

Pages 406-418, SSN 0022-2836, https://doi.org/10.1016/j.jmb.2011.11.010. (https://www.sciencedirect.com/science/article/pii/S0022283611012290)

This is an example of the Bayesian approach used in the cryo-EM technique on a ribosome, which is much larger than an mRNA molecule.

Above are the images the computer creates, but it makes them because the human has given it parameters to build on.

The grainy figures below are what you see after the tissue has been utterly minced and destroyed in preparation for electron microscopy and then frozen to at least -153 degrees Celsius.

Drawing (a) is obtained from Figure (b). As you can see, it is a drawing of what scientists think they see.

To arrive at the complete picture of how a ribosome is depicted in scientific studies and texts, further modifications are added that are elaborated by complex mathematical and probabilistic methods based on assumptions that scientists have in mind and not what is actually seen.

That said, the stability of the structure is crucial. If the assembly breaks down, the drug (mRNA) delivery to the body does not occur.

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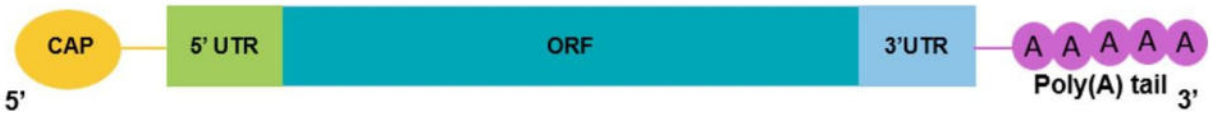
Given that we are talking of dimensions that are not visible under an optical microscope and given that we are talking about a drug that has stringent requirements in order to work:

- How can we be sure that the beads are that size?
- How can we be sure that each bead has that number of mRNA molecules?
- How can we be sure that the stability of the structure is maintained throughout the manufacturing, transport, pre- and post-administration process until the mRNA is released inside the cell?

Figure 4:



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A schematic illustration of an mRNA molecule with structural elements

mRNA: open reading frame (ORF) flanked by 5′ and 3′ untranslated regions (UTRs), a 5′ cap and a 3′ poly(A) tail, as shown.

The cap, poly(A) tail and UTRs are crucial for ribosome-mediated translation and mRNA stability.

The elongated poly(A) tail at the 3′ end is important for mRNA's stability and subsequent translation.

Here is what the European Medicines Agency (EMA) had to say about this mRNA structure that is the active ingredient of the advanced therapy drug.

"Electropherograms were presented demonstrating similarities in the peak pattern of RNA species, but some differences between Process 1 and 2 were also noted. It can therefore not be concluded that identical species are obtained by the processes. It is likely that the fragmented species will not result in expressed proteins, due to their expected poor stability and poor translational efficiency (see below). <u>However, the lack of experimental data on the truncated RNA and expressed proteins does not permit a definitive conclusion and needs further characterisation</u>. Therefore, additional characterisation data remain to be provided as a specific obligation".

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EMA is telling us that they have found pieces of mRNA that are not intact. That is to say: they don't have the structure they should have to function as per the schematic illustration in Figure 4.

Once again, EMA:

"According to the Applicant, the majority of fragments are expected to be comprised of truncated transcripts including the 5' region but lacking the 3' region and poly(A)tail. However, the results indicating a substantial proportion of shorter/truncated mRNA with both cap and poly(A)tail are not in agreement with this statement."

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EMA is stating here that the Applicant (BioNTech) claims that the mRNA fragments (i.e. non-intact mRNA) only have the 5' region, so, in theory, the fragments are not translated by the ribosome.

But according to EMA, from their analysis, they found truncated pieces of mRNA that also have the 3' and poly(A) part that serves for the recognition and attachment of the mRNA to the ribosome to be then transcribed into protein.

So what EMA is saying here is that there are pieces of mRNA that are not intact, are not of the original sequence that was manufactured, but still have all the required traits to be attached to the protein production machinery, and in so doing there is a risk that the wrong proteins will be produced.

Once again, from EMA:

"The Applicant explains that the redistribution is probably due to the use of a linearised DNA plasmid template in Process 2 instead of a PCR-derived DNA template in Process 1. For both processes, the poly(A)tail is anticipated to be sufficiently long to guarantee stability of the RNA and function in translation. This explanation is considered reasonable by the CHMP."

What EMA is saying here is that it takes BioNTech's word at face value and assumes that the structure of the mRNA strand will be long enough to guarantee stability and function for translation into the desired protein.

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Once again, from EMA

"The Applicant should provide additional data to further characterise the truncated and modified mRNA species present in the finished product. Relevant protein/peptide characterization data for predominant species should be provided."

EMA is asking BioNTech to provide further studies to have more information about the shredded and modified pieces of mRNA in the finished product. Basically, EMA is admitting that inside the finished drug for human use, there are pieces of mRNA that are not the original sequence and that there is no information about what these RNA pieces will ultimately do in the body.

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Yet again, from EMA:

"The technical procedure for the quantification of the poly (A) tail is considered, in general, sufficiently described but the suitability of this method of the intended purpose remains to be confirmed"

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Bearing in mind that this is a drug intended for parenteral use, EMA has no idea whether the method described by BioNTech actually does what BioNTech says it does.

11. Synthetic Nano Lipids

Characteristics:

a. Synthetic nano lipids are very long, chemically modified hydrocarbon chains. They are huge polymers.
b. Their synthesis is exceptionally complicated; they require organic solvents and precise requirements for storage to hold them up altogether.
c. Some of the synthetic nano-lipids used have a positive charge that allows them to clump around the negatively charged mRNA. (ALC-0315)
d. Some of the synthetic nano lipids are chemically bound to PEG (polyethene glycol) so that the synthetic nano lipid complex is made invisible to phagocytes (the body's scavengers). (ALC-0315)

Below are the technical data sheets of the synthetic lipids from Echelon, used in BioNTech's mRNA drugs. Please read the highlighted parts carefully.

It says:

"The product is for research use only and not for human use."

"The toxicological and pharmacological properties of this compound are not fully known."

These are the substances being injected in millions of people, including children.

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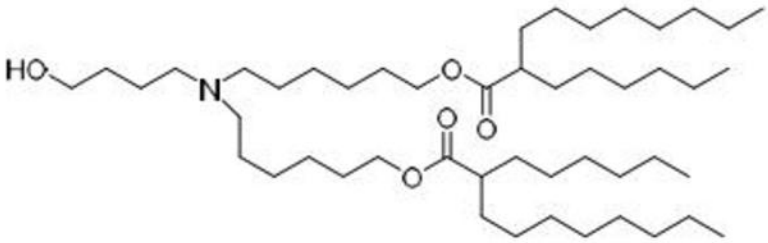
Echelon Biosciences Inc.

ALC-0315

Catalog number: N-1020



Molecular Formula: $C_{48}H_{95}NO_5$

MW: 766.29

CAS: 2036272-55-4

Alternative Names: ((4-Hydroxybutyl)azanediyl)bis(hexane-6,1-diyl) bis(2-hexyldecanoate)

Solubility: Chloroform (>10mg/mL), Ethanol (>10mg/mL)

Storage and Handling: Store dry at 4 °C. Stock solutions should be stored frozen (-20 °C or below).

Background: ALC-0315 is an ionizable lipid which has been used to form lipid nanoparticles for delivery of RNA. ALC-0315 is one of the components in the BNT162b2 vaccine against SARS-CoV-2 in addition to ALC-0159, DSPC, and cholesterol. This product is for research use only and not for human use.

References: 1) R. Tenchov, R. Bird, A. E. Curtze, Q. Zhou (2021) "Lipid Nanoparticles—From Liposomes to mRNA Vaccine Delivery, a Landscape of Research Diversity and Advancement" ACS Nano, DOI: 10.1021/acsnano.1c04996.
2) K.H. Moss, P. Popova, *et al.* (2019) "Lipid Nanoparticles for Delivery of Therapeutic RNA Oligonucleotides" *Mol. Pharmaceutics* 16, 2265–2277, DOI: 10.1021/acs.molpharmaceut.8b01290.
3) Y. Duan, A. Dhar, et al. (2020) "A brief review on solid lipid nanoparticles: part and parcel of contemporary drug delivery systems" RSC Adv.,10, 26777-26791.

Echelon Biosciences Inc.

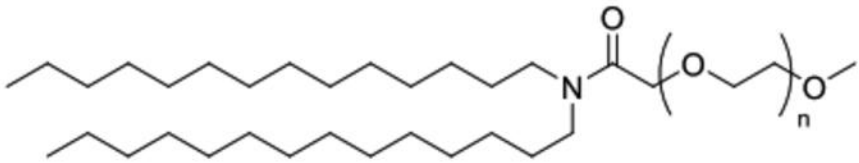
Ph: 866-588-0455
Fax: 801-588-0497

Echelon-inc.com

Echelon Biosciences Inc.

ALC-0159

Catalog number: N-2010



Molecular Formula: $(C_2H_4O)_nC_{31}H_{63}NO_2$

MW: ~2330

CAS: 1849616-42-7

Alternative Names:

Solubility: Chloroform (>10mg/mL), Ethanol (>10mg/mL)

Storage and Handling: Store dry at -20 °C. Stock solutions should be stored frozen (-20 °C or below).

Background: ALC-0159 is a PEGylated lipid which has been used to form lipid nanoparticles for delivery of RNA. ALC-0159 is one of the components in the BNT162b2 vaccine against SARS-CoV-2 in addition to ALC-0315, DSPC, and cholesterol. This product is for research use only and not for human use.

References: 1) R. Tenchov, R. Bird, A. E. Curtze, Q. Zhou (2021) "Lipid Nanoparticles—From Liposomes to mRNA Vaccine Delivery, a Landscape of Research Diversity and Advancement" ACS Nano, DOI: 10.1021/acsnano.1c04996.
2) K.H. Moss, P. Popova, *et al.* (2019) "Lipid Nanoparticles for Delivery of Therapeutic RNA Oligonucleotides" *Mol. Pharmaceutics* 16, 2265–2277, DOI: 10.1021/acs.molpharmaceut.8b01290.
3) Y. Duan, A. Dhar, et al. (2020) "A brief review on solid lipid nanoparticles: part and parcel of contemporary drug delivery systems" RSC Adv.,10, 26777-26791.

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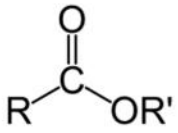
The following questions arise:

a. Have the toxicological profiles of these synthetic nano-lipids been studied for repeated and continuous use over time? Have they been studied for pharmaceutical use, particularly parenteral administration?
b. Are these huge polymers biologically degraded?
c. Do they accumulate in the body? If so, where? And what toxicity does it cause in the immediate, medium and long term?
d. If they are degraded, what are they degraded into?
e. Do we have toxicological profiles of the degraded molecules?

- Do they accumulate in the body? If so, where? And what toxicity does it cause in the immediate, medium and long term?

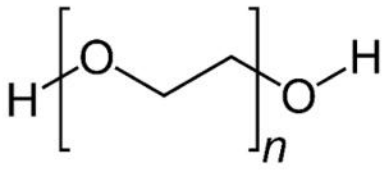
f. Since solvents of documented toxicity are needed to hold the whole thing together, are these solvents present in the dose given to the patient?
g. Has the toxicological profile of positively charged synthetic nano-lipids been studied? What is the effect on the cell membranes with which they interact?
h. The chemical structure, particularly regarding the ester bonds attached to very different units, is very dependent on what type of environment it finds in the body and dramatically influences its biodegradability. Have these variations been taken into account?
   The following is a schematic representation of an Ester bond:



i. There are studies indicating that the positive charge of these synthetic nano-lipids disturbs the natural structure of cell membranes. If so, would they then cause auto-immune reactions? Would cellular membranes become sort of like sieves, with all the pathological ramifications this implies?
j. Has the toxicological profile of chemically bound PEG nano-lipids been worked out for pharmaceutical use and, in particular, parenteral administration?

- PEG has well-known hypersensitivity characteristics
- Creates erroneous changes in pharmacokinetics
- Produces degradation products that are very toxic to the body
- PEG polymer is easily degraded by mechanical stress

The following is the schematic structure of PEG polyethene glycol. It is a polymer prepared by polymerisation of ethylene oxide. N represents how many times the structure in between brackets is repeated (polymerised)



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This is what EMA has to say about these nano lipids:

"Lipid-related impurities have been identified in the finished product and have been characterized. An investigation has been initiated and is ongoing to assess and review potential root causes. The outcome of the investigation shall be provided."

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In layman's language, in the final product, the one that is being injected into millions of people worldwide, repeatedly, EMA has found impurities linked to the presence of nano-lipids. But in this day and age, this is no problem at all for EMA.

Back to EMA again:

"In order to confirm the purity profile and ensure comprehensive quality control and batch-to-bath consistency throughout the lifecycle of the finished product, the applicant should provide additional information about the synthetic process and control strategy for the excipient ALC-0315)"

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BioNTech has to provide EMA with further information and pharmaceutical studies on the process involved in synthesising these nano-lipids and how BioNTech is actually checking that the infrastructure of the hypothetical beads with the mRNA inside them arrive safe and sound until it is injected in the patient.

And here we go again from EMA:

"Lipid related impurities have been observed in some recently manufactured finished product batches, correlated with ALC-0315 lipid batches. The quality of ALC-0315 excipient is considered acceptable based on the available data on condition that specific impurities in the finished product will be further evaluated"

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Ultimately, EMA is telling us that impurities were observed in the final product, but EMA knows nothing about these impurities. However, EMA still considers these impurities acceptable based on the available data (which data?) on the condition that BioNTech gives EMA further data on the impurities found in the final product.

In the meantime, please continue injecting it into people.

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12. Hypothetical Mechanism of Action

a. The small ball with the mRNA molecules embedded in it circulates the body until it decides to enter a cell.
b. The lipids attach themselves to the cell membrane through endocytosis. The cell decides it likes the bead and eats it whole.
c. Inside the cell's cytoplasm, the lipids decide to leave the mRNA free to roam.
d. The mRNA decides it would like to go to the protein production factory. It goes to the ribosome, the ribosome recognises it as valid, accepts it, attaches it to the machinery and begins the synthesis of the complementary string of amino acids that will form the 'spike' protein.
e. The 'spike' protein at this point is regurgitated through the cell membrane and placed like a flag on the cellular membrane telling the whole body, "Here I am folks! Come and get me".
f. This event, in theory, triggers:
    - Cell-mediated immunity, including macrophage-like cells, cytotoxic T lymphocytes, and Natural Killer cells that cause cell degeneration and death (apoptosis)
    - Neutralising antibodies that attach to the 'spike' protein, which supposedly inhibit or neutralise any biological effect it may have. Protein-antibody complexes can further induce and amplify the effects of the immune system.

My queries are as follows:

a. These small balls do not have a targeting ligand. That is, a chemical sequence on the outer surface that directs them towards a particular type of cell and not others and through which they can enter only specific cells and not others.
    - Does this mean that the little balls can penetrate all the cells in the body, even those we would like to protect at all costs?
    - Does this mean that the 'spike' protein flag can be expressed on any cell in the body?
    - Have studies been done to see how the expression of this chemical sequence on the surface of cells alters the functionality of the cells themselves, tissues and organs?
b. What happens if cell-mediated immunity causes apoptosis in tissues that in modern medicine are considered non-regenerable as they mature?
c. What happens if antibodies attack the 'spike' protein flag on the cell surface?
d. What happens if the flag of the 'spike' protein induces the process of opsonisation, i.e. macrophages and neutrophils come in droves to eat the cell?
e. What happens if the antibody-protein complex wanders around all over the body?

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13. Pharmacokinetics Studies

So far, I have asked questions mainly involving what is called pharmacodynamics. That is, what the drug does to the body.

But there is also the question of what the body does to the body, which depends very much on the makeup of the person who is taking the drug. This is called pharmacokinetics.

The four phases are:

a. Absorption

b. Distribution

c. Metabolism

d. Excretion

Some of it has already been mentioned, but I would like to focus the questions on individual variability here.

These processes can vary depending on the following:

a. Concomitant diseases
b. Disorders of any kind, such as genetic mutations, obesity, malnutrition, dehydration etc.
c. Changes in the management of drug metabolism. The function and efficiency of the excretory organs.
d. Other concomitant drugs.
e. Variations depending on whether male or female
f. Variations according to age
g. Variation according to body weight
h. In women, whether they are of childbearing age or not, whether pregnant or not.
i. Race
j. Diet

The questions I ask are the following:

- Have studies been done on people with concomitant diseases?
- Have studies been done on people with any disorders, diseases or disorders of metabolism and excretion?
- Have studies been done according to biological sex, race, and body weight? And on different diets?
- Have studies been done according to age group? Infants, children, adolescents, elderly etc.
  - Have studies been done on fertility? Both male and female?
  - Have studies been done on pregnant women? On foetuses? Does the drug pass to unborn children? Both male and female?
- Have studies been done on women who are breastfeeding? What about infants receiving breast milk?
- Has it been investigated whether the drug and/or its metabolites are transmitted through contact or exposure (sexual intercourse, urine, faeces, breathing, sweating, hair, etc.)?
- Have any studies been done on the effects of metabolites on the environment after it leaves the body?

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As you can see, many questions still need to be answered. Too many to even imagine giving this chemical concoction to any being.

Personally and professionally, I think these mRNA drugs (not that the other so-called viral DNA vector vaccines are any better) are another crime against humanity.

Ora et Labora

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Rome, Italy, on the 23rd of May 2023