1 Das kationische Lipid ALC- 0315

1. Das Lipid wurde nicht separat auf seine Toxizität hin untersucht, statt dessen verglich man mit einem komplett anderen, strukturell unterschiedlichen Lipid. [1]

N I x i i n

The toxicity of LNP formulation or the novel excipients alone was not specifically studied. In the repeat dose toxicity studies with the clinical candidate vaccine (BNT162b2 V9) and BNT162b2 VB,

Safetybfthe novelexcipienfs was noeassessed m a secondsÉeciesÄIo further data wouldDél Submitted as stated by the Sponsor. In response to the TGA enquiry regarding the toxicity assessmene Of the novel excipients in the LNP formulation, the Sponsor referred to the evaluation of the siRN& broduct Onpattro™ (patisiran) administered as a LNP formulation, which is approved in the US/ Europe and Canada (not reviewed by TGA) for the treatment of hereditary transthyretin-mediatedj amyloidosis (hATTR amyloidosis) by IV infusion every 3 weeks„The LNP in Onpattrqyyjscomposedj

of DLin-MC3-DMA, PEG2000-C-DMG, DSPC, and cholesterol. No nonclinical safety concerns regarding excipients, impurities, or degradation products were identified in the FDA and EMA evaluations. The

primary toxicity o serve m ot rats an mon eys was ane evaüon m Iver enzymes, WI hepatocyte vacuolation. Therefore, the Sponsor argued that ALC-0315 and ALC-0159 would have

Nonclinical Evaluation of BNTI 62b2 [mRNA] COVID-19 vaccine (COMIRNATY) Submission No. PM-2020-05461-1-2

---

similar toxicity profile to the lipids DLin-MC3-DMA and PEG2000-C DMG, respectively, as they were structurally and functionally similar (See Section 1.4). However, while the pegylated lipids (ALC-0159 and PEG2000-C DMG) are structurally similar, the structures of ALC-0315 and DLin-MC3-DMA are not similar. Nonetheless, given that both the novel excipients are amino or amino/PEG lipids and the potential lifetime exposure is expected to be low (see discussion below), the Sponsor's justification for not conducting repeat dose toxicity studies with the novel excipients in a second animal species is acceptable.

2. Man belog die EMA bei der Eignung des pKs von ALC-0315 [2] [3]

tween 1M ana 1 v perrormance coma oe mat tne optimal pnysrcal

Assessment report or chemical properties differ between the two routes. One strong

Comirnaty determinant of immunogenicity was the lipid pKa, with a

COVID•19 range of

m«'ified) 6.6-6.9 being optimal for 1M immunogenicity (Figure 2C). This EUROPEAN M AGE-WY m«edweNo difand

19 February 2021 from the optimal pKa range for IV delivery Of siRNAs Human (CHMP) s, which has been psulafrom

reported as 6.2—6.6. [11 23] mRNA 'reen

by RNA tion fficiencies and I,NP sizes ranged from 69% to and

(RNA 50 to 42 run, respectively. While there was no relationship

c•ns Th•

• RhA 201

2019:

1) DI' C3-DMA

Appare Ka: 6.44

Intrilü Ka: 9.4

PATISIRA (Onpratto)

Figure 6. E„NLA Assessment Repott on Cornirnaty by Pfizer/ BioNTech, dated 19 February 2021, page • 2) sw 2

Apparent p 6.75

Intrinsic p 8.9

Apparent pKa MODERNA (

—Instability Potency —Toxicity

3) ALC.0315

Apparent pKa. 6.09

Intrinsic pKa: 9.6

0-8 FIZER BIONTECH (Comárnaty)

J.M. optimal pKa range ture 4. Structure and pKa values of amin€Elipids: 1) DI-in-MC3-DMA

ALC-0315 LNP

pKa = 6.09 (Hassett 6.6 et - al., 6.92019) I-1 02 by Pfiier bv MCKlerna): Alnylam):

BioNTech): apparent apparent aplXirent pKa pKa 6.44, 6.75, pKa 6.09, intrinsic

intrinsic intrinsic pKa pKa 9.4 8.9 pKa 2),3) 9.6,Alc15 by

0

3 4 5 6 7 8 10

Less positive charges More positive charges

Less stable More stable More aggregations

Less aggregations Less transfectant More transtectant

Less tox More to

Figure S. Lipid PK.a of Al—C-0315 with regards to instability, potency and toxicity. Modified from Trends in Pharmacological Sciences, Vol. 42(6), 448—460, Patel et al. 2021 Tbe Importance of-4ppare"tpKa in the Development of Nanopartides Em-apsn/ahng "RN-A and mRNA, page No. 458, copyright C 2021 , with permission from Elsevier Ltd.

2 Das PEGylierte Lipid ALC- 0159

1. BioNTech weiß, dass die PEG-Kettenlänge einen unterschiedlichen bei den Nebenwirkungen macht [4]

thus improving the effectivity of LNP-siRNA drug [80]. This study is in agreement with the previous study by Judge et al. where the authors found less formed anti-PEG antibodies and a substantial reduction of side effects upon repetitive dosing in mice when PEGylated liposomes containing a shorter alkyl chain (C14) PEG-lipid versus a longer alkyl chain C16 PEG-lipid were used [151]. Studies directly examining the effects of anti-PEG antibodies on the efficacy and safety of LNP-mRNA drugs containing PEG lipids are

2. Man hat die PEG-Kettenlänge NICHT per Massenspektrometrie geprüft. [5]

▪ *Table·P.4-4.·Specification·for·ALC-0159[a].¶*

Quality Attribute	Analytical Procedure	Acceptance Criteria
Appearance	Visual examination	White powder which contains no foreign matter
Identity	Infrared spectroscopy	IR spectrum of the sample corresponds to the reference spectrum
Microbial contamination	Ph. Eur. 2.6.12	TAMC NMT 100 CFU/g

a. In order to release a batch for use in the manufacture of LNP drug product, results from the supplier are also required for the following tests. For details regarding the specification and methods for these tests performed at the supplier, refer to Section 3.2.A.3.4 Control of Excipients [ALC-0159]. The drug product manufacturer intends to implement these tests as part of incoming materials testing following qualification of the methods.

1. Assay
2. Impurities
3. Residual solvents

Abbreviations: IR = infrared; NMT = not more than; LNP = lipid nanoparticle; TAMC = Total aerobic microbial count; Ph. Eur. = European Pharmacopeia

¶

3. Das hat die AG-Impfstoffe des Expertcouncils gemacht und massive Unterschiede in der PEG-Kettenlänge festgestellt [6]

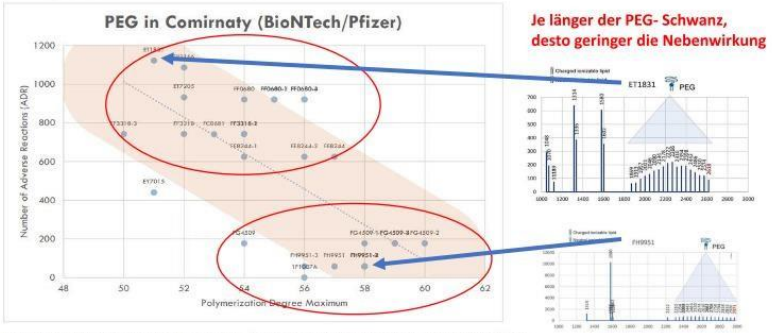


Figure 7: From the mass spectra of samples from different batches of Comirnaty vaccine (BioNTech/Pfizer), the maximum chain lengths were compared with the number of reported vaccination complications. A clear correlation can be seen. The blue dots are associated with the BioNTech/Pfizer batch numbers analysed.

3 PAM und GMP wurde nicht bestanden und BNT162B2 ist mit DNA verunreinigt.

1. Sowohl EMA als auch BioNTech wissen, dass BNT162B2 die PAM (Post-authorization measure = Maßnahme nach der Zulassung) am 20. Mai 2021 NICHT ERFÜLLT waren [7]

4. Overall conclusion

The ecommendation number 7 is only considered as partly fulfilled.

C] PAM fulfilled (all commitments fulfilled) - No further action required

E PAM not fulnlled (not all commitments fulfilled) and further action, as specified be10W, required by the end Of second quarter 2021

Recommendatjon n 7 to provide the results o' the Studies performed to enhance the robustness Of DNase Step has fulfilled. Further are to fulfil Recommendation 7 induding submission of a detailed Summary of the results from the Studies and indusion Of data in Module the dossier by the end Of 2021. It also that Recommendations 3 end 7 are grouped.

2. GMP NICHT bestanden wurde [8]:

		Yes	No	N/A
GMP	GMP-inspection check is satisfactory		X	
ASMF	ASMF Holder has submitted the applicant's and/or		X	

3. BNT162B2 mit DNA verunreinigt ist [8]

2.1.3. Post Authorisation Measure

Recomnnendation #7 to provide the results of the studies performed to enhance the robustness of the DNase digestion Step has only been partly fulfilled. Further actior.S are required to fulfil Recommendation #7 including submission of a detailed summary of the results from the studies and inclusion of these data in Module of the dossier by the end of second quarter 2021. It also recommended that Recommendations 3 and 7 are grouped

Response to Post Authorisation Measure

Following the increase in residual DNA observed during the ACMF PPQcampaign, small scale experiments were initiated to enhance the robustness of the DNase I digestion step. Studies were conducted to better understand the impact of reaction components, process parameters, and operation parameters on levels of residual DNA template. The small-scale studies are inconclusive and no adjustments to the DNase step are recommended, therefore the data from these studies are not provided.

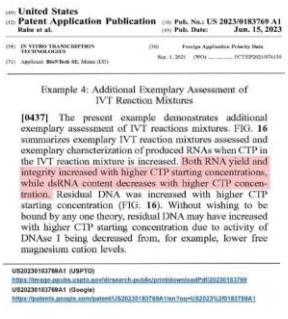
Type IB variation report
EMA/CHMP/429590/2021 Page 6/9

The root cause analysis is supported by the data previously shown in EMEA/H/C/005735/PAM-ANX REC027 [redacted]

Pfizer has implemented an activity assay for incoming enzymes to monitor and identify outliers that trend with drug substance product quality until acceptance criteria for the new assay can be established. This includes [redacted]

Assessor's comments:

4. Die Verringerung der dsRNA-Kontaminationen im Produkt führten zu einer Erhöhung der DNAKontamination. Das wurde der EMA verschwiegen. [9]



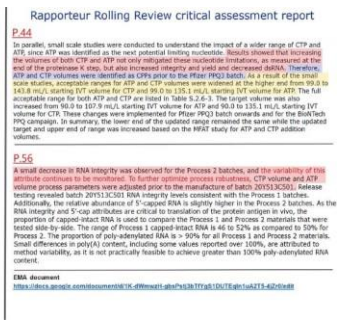
(19) United States
(12) Patent Application Publication
Rabe et al.
(10) Pub. No.: US 2023/0183769 A1
(43) Pub. Date: Jun. 15, 2023

(54) IN VITRO TRANSCRIPTION TECHNOLOGIES
(71) Applicant: BioNTech SE, Mainz (DE)
(30) Foreign Application Priority Data
Sep. 1, 2021 (WO) PCT/EP2021/074134

Example 4: Additional Exemplary Assessment of IVT Reaction Mixtures

[0437] The present example demonstrates additional exemplary assessment of IVT reactions mixtures. FIG. 16 summarizes exemplary IVT reaction mixtures assessed and exemplary charcterization of produced RNAs when CTP in the IVT reaction mixture is increased. Both RNA yield and integrity increased with higher CTP starting concentrations, while dsRNA content decreases with higher CTP concentration. Residual DNA was increased with higher CTP starting concentration (FIG. 16). Without wishing to be bound by any one theory, residual DNA may have increased with higher CTP starting concentration due to activity of DNAse I being decreased from, for example, lower free magnesium cation levels.

US20230183769A1 (USPTO)
US20230183769A1 (Google)



Rapporteur Rolling Review critical assessment report

P.44

In parallel, small scale studies were conducted to understand the impact of a wider range of CTP and ATP, since ATP was identified as the next potential limiting nucleotide. Results showed that increasing the volumes of both CTP and ATP not only mitigated these nucleotide limitations, as measured at the end of the proteinase K step, but also increased integrity and yield and decreased dsRNA. Therefore, ATP and CTP volumes were identified as CPPs prior to the Pfizer PPQ batch. As a result of the small scale studies, acceptable ranges for ATP and CTP volumes were widened at the higher end from 99.0 to 143.8 mL/L starting IVT volume for CTP and 99.0 to 135.1 mL/L starting IVT volume for ATP. The full acceptable range for both ATP and CTP are listed in Table 5.2.6-3. The target volume was also increased from 90.0 to 107.9 mL/L starting IVT volume for ATP and 90.0 to 135.1 mL/L starting IVT volume for CTP. These changes were implemented for Pfizer PPQ3 batch onwards and for the BioNTech PPQ campaign. In summary, the lower end of the updated range remained the same while the updated target and upper end of range was increased based on the RPAT study for ATP and CTP addition volumes.

P.56

A small decrease in RNA integrity was observed for the Process 2 batches, and the variability of this attribute continues to be monitored. To further optimize process robustness, CTP volume and ATP volume process parameters were adjusted prior to the manufacture of batch 201513C501. Release testing revealed batch 201513C501 RNA integrity levels consistent with the Process 1 batches. Additionally, the relative abundance of 5'-capped RNA is slightly higher in the Process 2 batches. As the RNA integrity and 5'-cap attributes are critical to translation of the protein antigen in vivo, the proportion of capped-intact RNA is used to compare the Process 1 and Process 2 materials that were tested side-by-side. The range of Process 1 capped-intact RNA is 46 to 52% as compared to 50% for Process 2. The proportion of poly-adenylated RNA is > 90% for all Process 1 and Process 2 materials. Small differences in poly(A) content, including some values reported over 100%, are attributed to method variability, as it is not practically feasible to achieve greater than 100% poly-adenylated RNA content.

EMA document

5. Warum DNA Verunreinigung schlecht ist: https://drbine.substack.com/p/integriert-die-plorre-nun-oder-nicht.pdf

tga.gov.au/sites/default/files/foi-2389-06.pdf

Quellen:

[1] https://www.tga.gov.au/sites/default/files/foi-2389-06.pdf

[2] Apparent Cytotoxicity and Intrinsic Cytotoxicity of Lipid Nanomaterials Contained in a COVID-19 mRNA Vaccine. (2023). International Journal of Vaccine Theory, Practice, and Research , 3(1), 957-972. https://doi.org/10.56098/iivtpr.v3i1.84 [3] Hassett KJ, Benenato KE, Jacquinet E, Lee A, Woods A, Yuzhakov O, Himansu S, Deterling J, Geilich BM, Ketova T, Mihai C, Lynn A, McFadyen l, Moore MJ, Senn JJ, Stanton MG, Almarsson Ö, Ciaramella G, Brito LA. Optimization of Lipid Nanoparticles for Intramuscular Administration of mRNA Vaccines. Mol Ther Nucleic Acids. 2019 Apr 15;15:1-11. doi: 10.1016/j.omtn.2019.01.013. Epub 2019 Feb 7. PMID: 30785039; PMCID: PMC6383180. https://pubmed.ncbi.nlm.nih.gov/30785039/

[4] Vlatkovic l. Non-Immunotherapy Application of LNP-mRNA: Maximizing Efficacy and Safety. Biomedicines. 2021 May (5):530.doi: 10.3390/biomedicines9050530. PMID: 34068715; PMCID: PMC8151051. https://pubmed.ncbi.nlm.nih.gov/34068715/

[5] Rapporteur's Rolling Review Report Quality - COVID-19 mRNA Vaccine BioNTec S. 160

[6] SAMMLUNG ERSTER ERGEBNISSE https://expertcouncil.one/wp-content/uploads/2023/03/AG-Impfstoffe-erste-ErgebnisseJuli-2022 expertcouncil one.pdf

[7] 1251-Assessment-Report-for-the-Post-Authorization-Measure-REC-027.pdf Seite 5 https://postvac.org/community/rechtliche-fragen/neue-erkenntnisse-starke-verunreinigung-des-biontech-mrna-impfstoffscomirnatv/paged/4/#post-39818

[8] Type 1B variation report S. 3 https://mega.nz/file/eloSvQvS#Y2g4VtSCUlDXg9JSTY32BQlM8 Up918xtrkgOSMxlFw

[9] Sun, P. (2024, February 1). Masterpiece of BioNTech & Pfizer. Patent's Substack. https://patentsun.substack.com/p/masterpiece-of-craftsmanship-and

Autor: Dr. Sabine C. Stebel — Einmal mit Profis arbeiten (ISBN: 978-3943413434) https://drbine.substack.com/

4 Sicherheitseinstufung des Produktes seitens BioNTech/Pfizer

Weltweite OEB Anforderungen

um die weltweiten OEB-Anforderungen in der pharmazeutischen Industrie verständlicher darzustellen, vergleichen wir in dieser Tabelle die maximal erlaubte Kontaminationsmenge eines Produktes (Gewicht pro Tag) mit der Anzahl von Zuckerkristallen denen ein Operator ausgesetzt werden darf.

https://www.containment-technolow.com/oeb-stufen/

	Maximale Belastung Gewicht / m^3	Maximale Belastung Gewicht/ Tag	Toxisches potential	Max. Kontamination / Tag im Vergleich mit Zuckerkristallen Zuckerkristall e 3 mg
	e 200 ng	0.01 mg	es Potential	0,003
	1 pg	O, 1 mg	ntial	0,03
	1 - 10	-I mg	oxisches Potential	0.03 -0,3
	10-	1 — 10 mg	ittleres toxisches potential	0,3-
	100- 1.000 pg	10 — 100 mg	Geringes toxisches Potential	- 33,3
	1.000-5000 pg	100	kein toxisches Potential	33,3 Sicher und Effektiv?

1. Sicherheitseinstufung ALC-0315 [1]

ALC-0315

Pfizer Occupational Exposure Band (OEE3): OEB 3 • Contact Hazards Unknown (control 100ug'm2) to the ot 10ug\ma to

2. Sicherheitseinstufung ALC-0159 [1]

ALC-OI 59

Pfizer Occupational Exposure to Band OEB 3 • Contact Hazards Unknown (control exposure to the range of l

3. Sicherheitseinstufung BNT162B2 (Comirnaty) [1] [2] e pfzer SAFETY DATA SHEET

date 2 Page

ection 1 : IDENTIFICATION OF THE SUBSTANCE,'UIXTURE AND OF THE OMPANWUNDERTAKING

Product identitier

Ptizer•8ioNTech Covid•19 vaccine Tris•Sucroæ

Synonyms

'J ':3ü204 ortaining PF•D730S88S (BNV16202): Covid19 Read' to Uso Formwation; h Covid•19 vaccine for ages 5 through Il: 5 to Il. Dilute to use Orange p: Ptizer-BioNTech Covid•lg vaccine tor ages 12 and older: 12 years and older. Ready use Grey Cap: PF-07302048 containing PF-D730588S (BNT162b2): corVAC Containing -07305885 (BNT162b2) COWAC Containing PF-07305885 [BNT162b2)) cov10 ine Containir,g PF.073C5885 (BNT162b2); COVID.19 Vacene Containing .0730sges (BNTt62b2)

Trade t applcable P .07302048

H 00024713; »•000024/14; H000024864; H000024E6S; H 8000025768; OC025769:

Farn" Manoparticles containing PF-07305885 (BNTt62b2) and Lipids

Pharmaceutical Sciences
Worldwide Research & Development

P zer

STAPOARO

PF_07302C48

Lot PFM302CAs-OP-RM

F.pimtim Date

O atj.ml OEB S

TESTS AND RESULTS	
Fluorescence assay	
RNA Content	[redacted] mg/mL

FOOTNOTES
Parent drug product lot (b) (4)
[redacted] C for up to [redacted] days if sampled aseptically

09-Jul-2021 13:15 (GMT)

4. Dosierung laut Fachinformation [3]

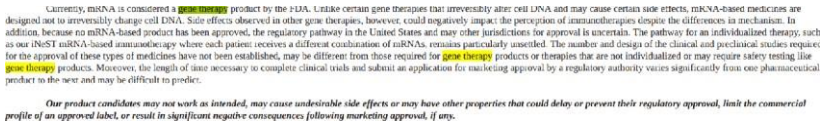
1. BEZEICHNUNG DES ARZNEIMITTELS

Comirnaty 30 Mikrogramm/Dosis Injektionsdispersion
COVID-19-mRNA-Impfstoff (Nukleosid-modifiziert)

5	< 1 µg	< 0,1 mg	Hohes toxisches Potential

5 BioNTechs (Börsen-)Geständnisse

1. 31. März 2020 [4]

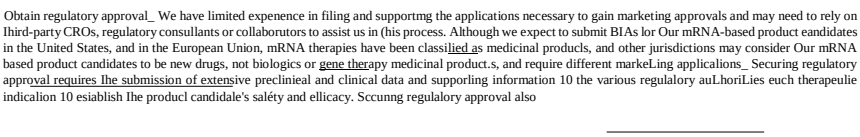


Currently, mRNA is considered a gene therapy product by the FDA. Unlike certain gene therapies that irreversibly alter cell DNA and may cause certain side effects, mRNA-based medicines are designed not to irreversibly change cell DNA. Side effects observed in other gene therapies, however, could negatively impact the perception of immunotherapies despite the differences in mechanism. In addition, because no mRNA-based product has been approved, the regulatory pathway in the United States and may other jurisdictions for approval is uncertain. The pathway for an individualized therapy, such as our iNeST mRNA-based immunotherapy where each patient receives a different combination of mRNAs, remains particularly unsettled. The number and design of the clinical and preclinical studies required for the approval of these types of medicines have not been established, may be different from those required for gene therapy products or therapies that are not individualized or may require safety testing like gene therapy products. Moreover, the length of time necessary to complete clinical trials and submit an application for marketing approval by a regulatory authority varies significantly from one pharmaceutical product to the next and may be difficult to predict.

Our product candidates may not work as intended, may cause undesirable side effects or may have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

Derzeit wird die mRNA von der FDA als Gentherapieprodukt betrachtet. Im Gegensatz zu bestimmten Gentherapien, die die Zell-DNA irreversibel verändern und bestimmte Nebenwirkungen verursachen können, sind mRNA-basierte Arzneimittel so konzipiert, dass sie die Zell-DNA nicht irreversibel verändern. Die bei anderen Gentherapien beobachteten Nebenwirkungen könnten sich jedoch trotz der Unterschiede im Mechanismus negativ auf die Wahrnehmung von Immuntherapien auswirken. Unter Da bisher kein mRNA-basiertes Produkt zugelassen wurde, ist der Zulassungsweg in den Vereinigten Staaten und möglicherweise auch in anderen Ländern ungewiss. Der Weg für eine individualisierte Therapie, wie wie unsere mRNA-basierte Immuntherapie iNeST, bei der jeder Patient eine andere Kombination von mRNAs erhält, ist noch besonders unsicher. Die Anzahl und das Design der klinischen und präklinischen Studien, die für die Die Anzahl und das Design der klinischen und präklinischen Studien, die für die Zulassung dieser Art von Arzneimitteln erforderlich sind, stehen noch nicht fest und können sich von denen unterscheiden, die für gentherapeutische Produkte oder Therapien erforderlich sind, die nicht individualisiert sind, oder Sicherheitstests erfordern wie Gentherapieprodukte. Darüber hinaus ist die Dauer der klinischen Studien und der Einreichung eines Antrags auf Marktzulassung bei einer Aufsichtsbehörde von einem Arzneimittel zum anderen sehr unterschiedlich und kann schwierig sein. von einem Pharmaprodukt zum nächsten und kann schwer vorhersehbar sein.

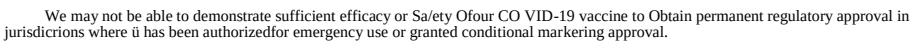
2. 26. Oktober 2022 [5]



Obtain regulatory approval_ We have limited expenence in filing and supportmg the applications necessary to gain marketing approvals and may need to rely on Ihird-party CROs, regulatory consullants or collaborutors to assist us in (his process. Although we expect to submit BIAs lor Our mRNA-based product eandidates in the United States, and in the European Union, mRNA therapies have been classilied as medicinal producls, and other jurisdictions may consider Our mRNA based product candidates to be new drugs, not biologics or gene therapy medicinal product.s, and require different markeLing applicalions_ Securing regulatory approval requires Ihe submission of extensive preclinieal and clinical data and supporling information 10 the various regulalory auLhoriLies euch therapeulie indicalion 10 esiablish Ihe producl candidale's saléty and ellicacy. Sccunng regulalory approval also

Obwohl wir davon ausgehen, dass wir BLAS für unsere mRNA-basierten Produktkandidaten in den Vereinigten Staaten und in der Europäischen Union einreichen werden, wurden mRNA-Therapien als Gentherapeutika eingestuft, und andere Gerichtsbarkeiten könnten unsere mRNA-basierten Produktkandidaten als neue Arzneimittel und nicht als Biologika oder Gentherapeutika betrachten und andere Zulassungsanträge erfordern.

3. 27. März 2023 [6]



We may not be able to demonstrate sufficient efficacy or Sa/ety Ofour CO VID-19 vaccine to Obtain permanent regulatory approval in jurisdicrions where ü has been authorizedfor emergency use or granted conditional markering approval.

Es kann sein, dass wir nicht in der Lage sind, eine ausreichende Wirksamkeit oder Sicherheit unseres Impfstoffs COVID-19 nachzuweisen, um eine dauerhafte behördliche Zulassung in Ländern zu erlangen, in denen der Impfstoff für den Notfalleinsatz zugelassen ist oder eine bedingte Zulassung erhalten hat.

4. BioNTech wusste, 2021 bereits dass die natürliche Immunität besser/breiter aufgestellt ist [7]

„Während sich bei Geimpften nur Antikörper gegen das Spike-Protein detektieren lassen, sind im Serum von Genesen auch Antikörper gegen andere Proteine des SARS-CoV-2-Virus zu finden, zum Beispiel das Nukleokapsid-Protein (N-Protein)."

5. Es gibt keine Grenzwerte für viele der verwendeten Chemikalien [8]

Quelle:
[1] Sicherheitsdatenblatt BNT162B2: https://fragdenstaat.de/dokumente/_236331-104a-pf00161-mtr-pfem-en-0021
[2] Reference Standard Certificate https://phmpt.org/wp-content/uploads/2023/11/125742 Sll M3 32r pf-07302048-dprm-coa.pdf
[3] Fachinformation: https://www.forumimpfen.de/images/Fachinfo/BNT COM Fl COMIRNATY 30g 12Jahre Fertiglsung 230309.pdf [4] NASDAQ_BNTX_2019.pdf (annualreports.com)
https://www.annualreports.com/HostedData/AnnualReportArchive/b/NASDAQ BNTX 2019.pdf
[5] Form 20-F/A for Biontech SE filed 10/26/2022 https://investors.biontech.de/static-files/4c20d743-ad34-4d12-808e15f103d52831
[6] Form 20-F for Biontech SE filed 03/27/2023 https://investors.biontech.de/static-files/5491aad7-4833-4938-b67303c906344eb5
[7] BionTech-lnfobrief: https://tkp.at/wp-content/uploads/2022/09/BionTech-lnfobrief.pdf
[8] Oude Blenke E, Örnskov E, Schöneich C, Nilsson GA, Volkin DB, Mastrobattista E, Almarsson Ö, Crommelin DJA. The Storage and In-Use Stability of mRNA Vaccines and Therapeutics: Not A Cold Case. J Pharm Sci. 2023 Feb;112(2):386-403. doi:
10.1016/j.xphs.2022.11.001. Epub 2022 Nov 16. PMID: 36351479; PMCID: PMC9637289. https://pubmed.ncbi.nlm.nih.gov/36351479/

Autor: Dr. Sabine C. Stebel — Einmal mit Profis arbeiten (ISBN: 978-3943413434) https://drbine.substack.com/