BioNTech and Pfizer

modRNA-Based COVID-19 Vaccine BNT162b2

BioNTech and Pfizer

BioNTech – Phase 2/3 July 27, 30 µg dose level in a 2 dose regime, 30,000 volunteers, 18 – 85 years. Proposed to be ready October 2020

modRNA-Based COVID-19 Vaccine BNT162b2 Selected for a **Pivotal Efficacy Study**. 2 **lipid nanoparticle–formulated, nucleoside-modified RNA (modRNA) vaccine** candidates were evaluated in the **US Phase 1** portion of the trial which **encodes an optimized SARS--CoV--2 full--length spike glycoprotein,**

The RNA is optimized for high stability and translation efficiency [13,14] and incorporates 1-methyl-pseudouridine instead of uridine to dampen innate immune sensing and to increase mRNA translation in vivo (**Toll-Like Receptors 7/8**)

Sponsors: **Pfizer**, **Fosun** (**China**)
Collaborations: **Genmab**, **Sanofi**, **Bayer Animal Health**, **Genentech**, a member of the **Roche Group**, **Genevant**,

Target: **SARS-CoV-2 full-length 'S' spike glycoprotein, spike T cell epitopes**

Measuring: CD4+ and IL-2 induced CD8+ T cell response. Transient increase in C-reactive protein (CRP) and temporary reduction of blood lymphocyte counts, indicator of vaccine adjuvant activity
(**lymphocytes** into **lymphoid tissues – See Adenovirus and collective immunity, but not in children**)
Interleukins monitored: **IL-2, IL-4**

Special Note: IL-2 induces regulatory T-Cells (Tregs) for cell mediated immunity, not adaptive immunity or humoral"

[1]Non-peer reviewed study: **RNA-Based COVID-19 Vaccine BNT162b2** Selected for a Pivotal Efficacy Study

[2]Pfizer and BioNTech Choose Lead **mRNA Vaccine Candidate Against COVID-19** and Commence Pivotal Phase 2/3 Global Study

Phase 1/2 Study to Describe the Safety and Immunogenicity of a **COVID-19 RNA Vaccine Candidate** (**BNT162b1**) in Adults **18 to 55** Years of Age: **Interim Report** (**not certified** by peer review) – **July 1**, **2020**
45 participants were randomized and **vaccinated**

Twelve participants per dose level (**10 µg and 30 µg**), were **vaccinated** with **BNT162b1** on Days **1** and **21** and **12 participants** received a **100 µg** dose on Day **1**. **Nine participants received placebo**

Vaccine RNA can be modified by incorporating 1-methyl-pseudouridine which dampens innate immune sensing and increases mRNA translation in vivo [**10**]. The **BNT162b1 vaccine candidate** now being studied **clinically incorporates such nucleoside modified RNA** (**modRNA**) and **encodes the receptor binding domain** (***RBD***) **of the SARS-CoV-2 spike protein**, a **key target** of virus **neutralizing antibodies** [**11**]

The **vaccine RNA** is formulated in **lipid nanoparticles** (**LNPs**) for more **efficient delivery into cells** after **intramuscular injection** [**14**].

In the **7 days** following either Dose **1** or **2**, **pain at the injection site was the most frequent prompted local reaction**, reported after Dose **1** by **58.3%** (**7/12**) in the **10 µg**, **100.0%** (**12/12** each) in the **30 µg and 100 µg BNT162b1** groups, and by **22.2%** (**2/9**) of **placebo recipients**. After Dose **2**, **pain was reported by 83.3% and 100.0% of BNT162b1 recipients at the 10 µg and 30 µg dose levels**, respectively, and by **16.7 % of placebo recipients**.

One participant each in the **10 µg** group (**8.3%** [**1/12**]) and **30 µg** group (**9.1%** [**1/11**]) dose levels and **4 participants** at the **100 µg** group (**33.3%** [**4/12**]) had **Grade 3 decreases in lymphocytes**. These **post Dose 1 decreases in lymphocyte count**, were transient and **returned to normal 6-8 days after vaccination**. In addition, **Grade 2 neutropenia** was noted **6-8 days** after the **second dose of 10 µg** or **30 µg BNT162b1**, in **1 participant each**.

RNA vaccines are known to induce **type I interferon** which has been **associated with transient migration of lymphocytes into tissues** [**15**, **16**, **17**,**18**]

Since the **100 µg** dose level cohort was **not boosted**, no corresponding data for immunogenicity **after a second vaccination** are available however there **were no substantial differences in immunogenicity between the 30 µg and 100 µg dose** levels after Dose **1**. This observation suggests that a well-tolerated and immunogenic **dose level may be between 10 µg and 30 µg** for **this vaccine candidate**

Our study had **several limitations**. While we used convalescent sera as a comparator, the kind of immunity (**T cells versus B cells or both**) and **level of immunity needed** to protect from **COVID-19 are unknown**. Further, this analysis of available data **did not assess immune responses or safety beyond 2 weeks after the second dose of vaccine**. **Both are important to inform the public health use of this vaccine**.

Later phases of this study will prioritize enrolment of **more diverse populations**, including those with chronic underlying health conditions and **from racial/ethnic groups** adversely affected by **COVID-19** [**19**]

Role of the funding source: **BioNTech is the Sponsor of the study**. **Pfizer** was **responsible for the design**, **data collection**, **data analysis**, **data interpretation**, and **writing of the report**.

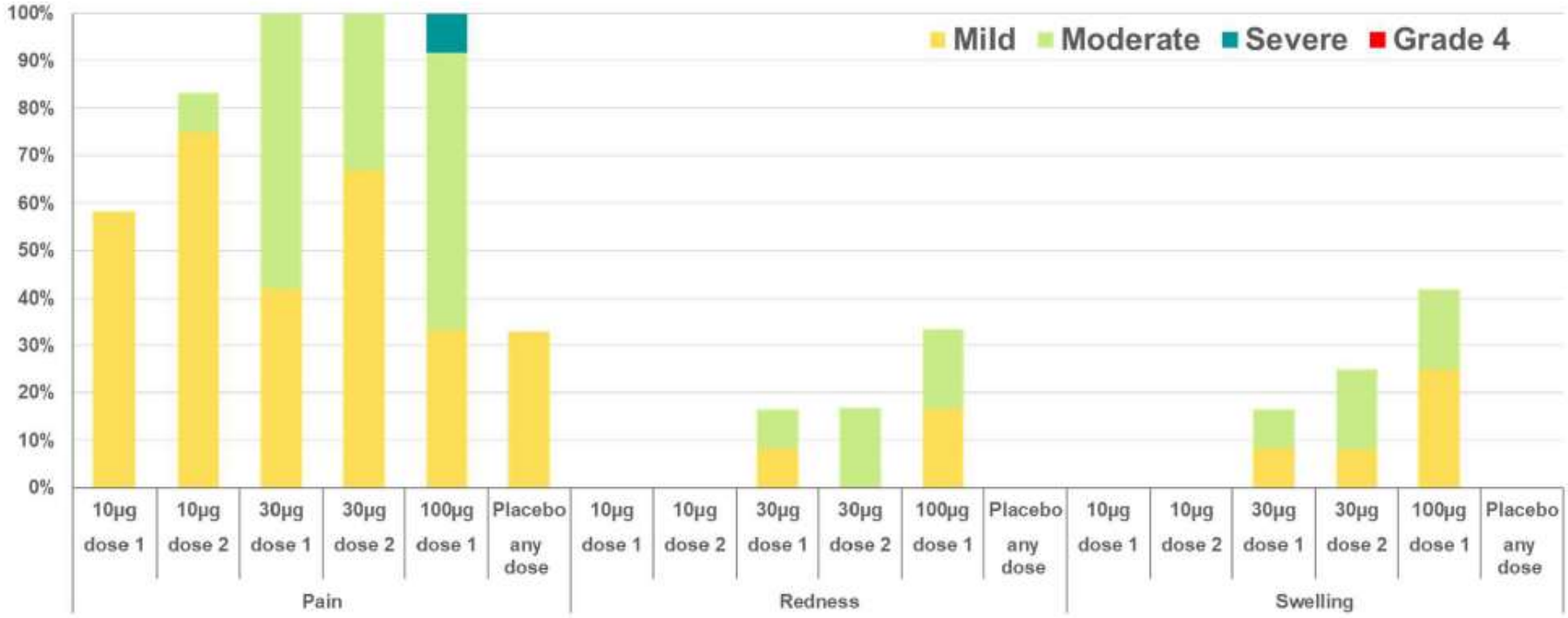
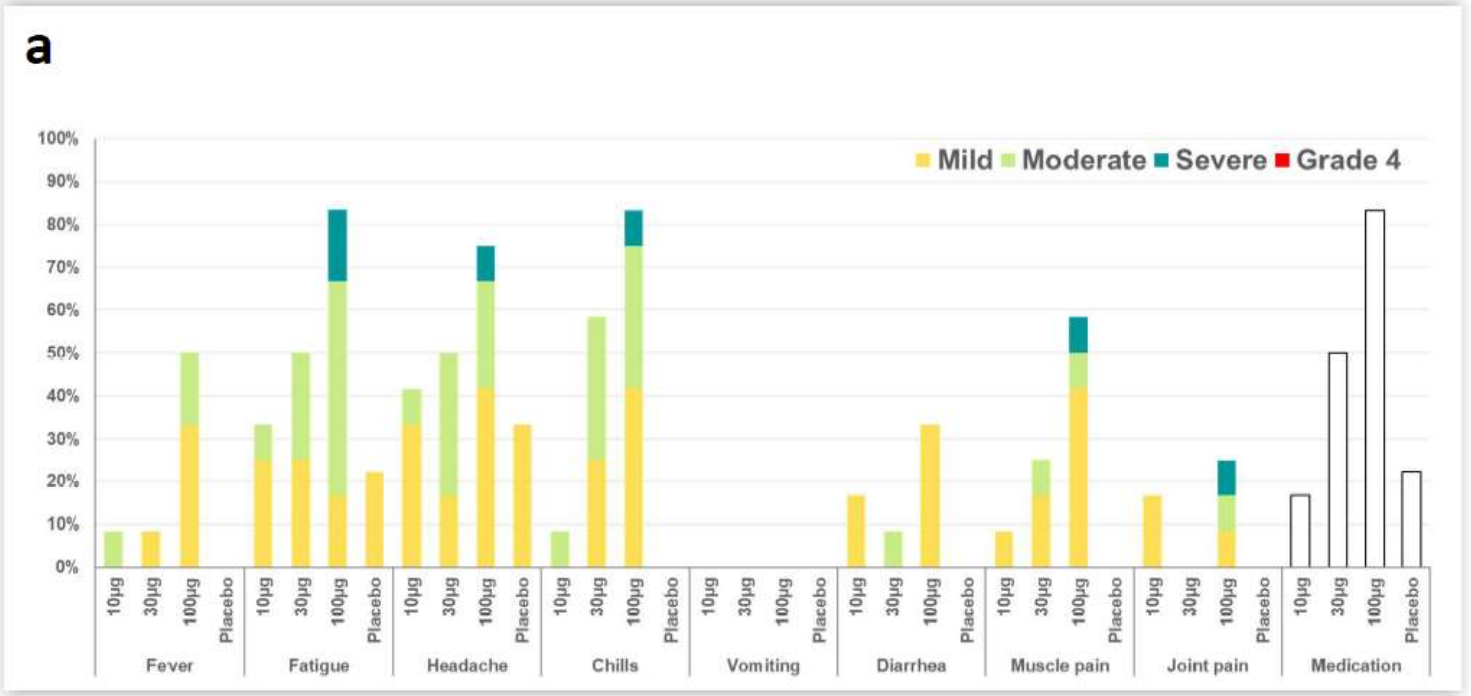


Figure 2 | Local reactions reported within 7 days of vaccination, all dose levels. Solicited injection-site (local) reactions were: pain at injection site (mild: does not interfere with activity; moderate: interferes with activity; severe: prevents daily activity; Grade 4: emergency room visit or hospitalization) and redness and swelling (mild: 2.0 to 5.0 cm in diameter; moderate: >5.0 to 10.0 cm in diameter; severe: >10.0 cm in diameter; Grade 4: necrosis or exfoliative dermatitis for redness, and necrosis for swelling). Data were collected with the use of electronic diaries for 7 days after each vaccination.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Muscle pain
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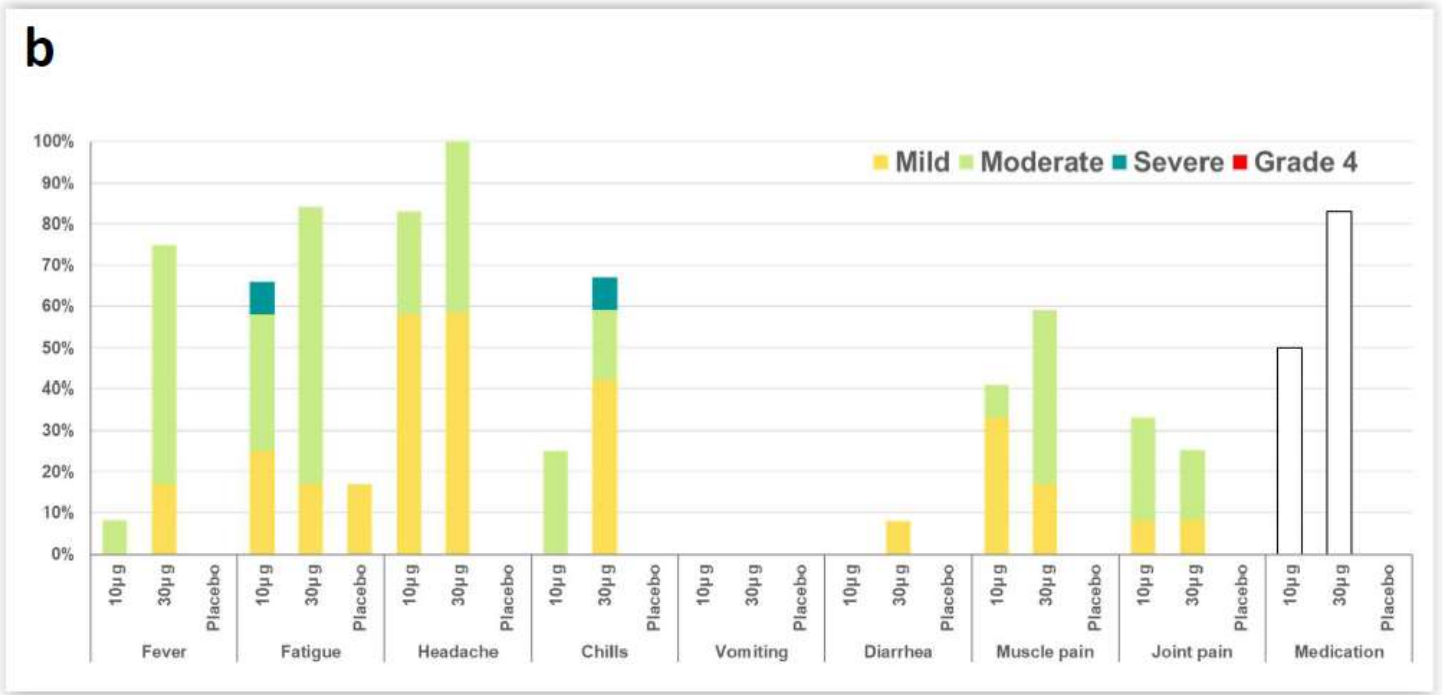
Medication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Fatigue
Headache
Chills
Vomiting
Diarrhea
Muscle pain
Joint pain
Medication

Concurrent human antibody and T_H1 type T-cell responses elicited by a COVID-19 RNA vaccine (**not certified by peer review**) – **July 20**, **2020 (**27 pages)

On **11 March 2020**, the **World Health Organization** (**WHO**) declared the **SARS-CoV-2** outbreak a **pandemi**c.

Recently, **we reported** safety, tolerability and antibody response data from an on-going **placebo-controlled**, **observer-blinded phase 1/2 COVID-19 vaccine trial** with **BNT162b1**, **a lipid nanoparticle** (**LNP**) **formulated nucleoside modified messenger RNA encoding the receptor binding domain** (**RBD**) of the **SARS-CoV-2 spike protein**

Two doses of **1 to 50 µg** of **BNT162b1** elicited robust **CD4+ and CD8+ T cell responses** and strong antibody responses, with RBD binding **IgG concentrations** clearly above those in a **COVID-19** convalescent human serum panel (**HCS**).

Two Phase 1/2 umbrella trials in **Germany** and the **US investigate several LNP-encapsulated RNA vaccine** candidates developed in `**Project Lightspeed**`. **Recently**, **we have reported interim data obtained in the US trial** (**NCT04368728**) for the **most advanced candidate BNT162b11** [1]
(See next slide)

The **RNA** is optimized for high stability and translation efficiency [**13**,**14**] and **incorporates 1-methyl-pseudouridine instead of uridine to dampen innate immune sensing** and to **increase mRNA translation *in vivo*** [**15**]

RBD-binding IgG concentrations and **SARS-CoV-2** neutralising titers in sera **increased with dose level** and **after a second dose**. **This study now complements our previous report** with **available data from the German trial** (**NCT04380701**, EudraCT: 2020-001038-36), **providing a detailed characterisation** of **antibody and T cell immune responses** elicited by **BNT162b1 vaccination**.

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Trial record 2 of 2 for: BNT162b2

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Study to Describe the Safety, Tolerability, Immunogenicity, and Efficacy of RNA Vaccine Candidates Against COVID-19 in Healthy Adults

The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Know the risks and potential benefits of clinical studies and talk to your health care provider before participating. Read our disclaimer for details.

ClinicalTrials.gov Identifier: NCT04368728

Recruitment Status: Recruiting
First Posted: April 30, 2020
Last Update Posted: September 4, 2020

See Contacts and Locations

Sponsor:
BioNTech SE

Collaborator:
Pfizer

Information provided by (Responsible Party):
BioNTech SE

Actual Study Start Date: **April 29**, 2020
Estimated Primary Completion Date: **April 19, 2021**
Estimated Study Completion Date: **November 14, 2022**
29,481 participants – **2 dose** regimen

Between 23 April 2020 and 22 May 2020, **60 participants** were **vaccinated with BNT162b1** in **Germany**. **Twelve participants** per **1 µg**, **10 µg**, **30 µg,** and **50 µg dose level groups** received a first dose on Day **1** and were **boosted** on Day **22**

The **study population** consisted of healthy males and non-pregnant females with a mean age of 41 years (range **18 to 55 years**) with equal gender distribution. **Most participants were Caucasian** (**96.7%**) with **one African American** and **one Asian participant** (**1.7%** each).

Whereas no relevant change in routine clinical laboratory values occurred after **BNT162b1 vaccination**, **a transient increase in C-reactive protein** (**CRP**) and **temporary reduction of blood lymphocyte counts were observed in a dose-dependent manner in vaccinated participants**

CRP is a well-known inflammatory serum protein previously described **as biomarker for various infectious disease vaccines** and **an indicator of vaccine adjuvant activity** [**16**–**19**]. **Based on our previous clinical experience** with **RNA vaccines** the **transient decrease in lymphocytes** is **likely attributable** to **innate immune stimulation-related redistribution of lymphocytes into lymphoid tissues** [**20**]. **Both parameters are considered pharmacodynamics markers** for the **mode-of-action of RNA vaccines**

To demonstrate the breadth of the neutralising response, a panel of **16 SARS-CoV-2 RBD variants** identified through publicly available information [21] and **the dominant** (**non-RBD**) **spike variant D614G** [**22**] was evaluated in **pseudovirion neutralisation assays**. Sera collected **7 days** after the **second dose** of **BNT162b1** showed high neutralising titers to ***each of the SARS-CoV-2 spike variants*** (Figure 2c).

(Note: **mutant D614G** is **apparently the more dominant mutation** since **June, 2020** with a **few amino** acid substitutions which studies suggest **promotes more ACE2 cell expression**) with the **help of furin cleavage which allows infectivity and binding to more cell types**).

CD4+ and CD8+ T cell responses in **BNT162b1 immunised participants** were characterised prior to priming vaccination (Day **1**) and **7 days after boost vaccination** (on Day **29**) using direct ***ex vivo*** **IFN-γ** ELISpot with **peripheral blood mononuclear cells** (**PBMCs**) from **36 participants** across the **1 µg** to **50 µg dose-level cohorts**

The **strength** of **RBD-specific CD4+ T cell responses** **correlated positively** with both **RBD-binding IgG** and with **SARS-CoV-2** neutralising antibody titers, ***in line with the concept of intramolecular help*** [**23**]

The **strength** of **RBD-specific CD8+ T cell responses** correlated positively with **vaccine-induced CD4+ T cell responses**, but **did not significantly correlate with SARS-CoV-2 neutralising antibody titers**

(Note**: CD8+ Cells** are not the **dominant immune cell** as much as the **CD4+ is the driving engine**. More on this in another presentation and **CD4+ and CD8+** in **pathogen immunity concerning Regulatory Cells or Tregs and IL-2R**)

To assess functionality and polarisation of **RBD-specific T cells**, **cytokines secreted in response to stimulation** with overlapping peptides representing the full length sequence of the vaccine encoded RBD were determined by **intracellular staining** (**ICS**) for **IFNγ**, **IL-2** and **IL-4 specific responses** in pre- and post-**vaccination PBMCs** of 18 **BNT162b1** immunised participants. **RBD-specific CD4+ T cells secreted IFN-γ**, **IL-2**, or **both**, but **did not secrete IL-4**. Similarly, fractions of **RBD-specific CD8+ T cells secreted IFN-γ + and IL-2**.

Fractions of **RBD-specific IFNγ+ CD8+ T cells** reached up to **several percent** of **total peripheral blood CD8+ T cells**. **Analysis** of **supernatants** of **PBMCs** stimulated ***ex vivo*** with overlapping RBD peptides from a **subgroup of five vaccinated participants detected pro-inflammatory cytokines TNF**, **IL-1β** and **IL-12p70**, **but neither IL-4 nor IL-5**

In **summary, these findings** indicate that **BNT162b1 induces functional and pro-inflammatory CD4+/CD8+ T cell responses in almost all participants**, with **T_H1 polarisation** of the **helper response**.

We observed concurrent production of neutralising antibodies, **activation** of **virus-specific CD4+ and CD8+ T cells**, and robust **release of immune-modulatory cytokines** such as **IFN-γ**, which **represents** a **coordinated immune response to counter a viral intrusion** (for review 24). **IFN-γ is a key cytokine** for **several antiviral responses**. **It acts in synergy with type I interferons** to inhibit replication of **SARS-CoV-2** [**25**]

The **detection of IFN-γ**, **IL-2** and **IL-12p70** but not **IL-4** **indicates a favourable T_H1 profile** and the **absence of a potentially deleterious T_H2 immune response**. **CD4+ and CD8+ T cells may confer long-lasting immunity** against **corona viruses** as indicated in **SARS-CoV-1** survivors, where **CD8+ T-cell immunity *persisted for 6-11* years** [**24**,**27**].

A **notable observation** is that **two injections of BNT162b1** at a **dose level as low as 1 µg** are **capable of inducing RBD-binding IgG levels** **higher than those observed in convalescent sera**, and **serum neutralising antibody titers that were still increasing up to Day 43**. **Considering that it is not known which neutralising antibody titer would be protective,** and **given the substantial T-cell responses** **we observed** for **some participants** in the **1 µg cohort**, a **considerable fraction of individuals** may benefit **even from this lowest tested dose level**

Here's a hypothetical. Imagine if, **instead of conferring protection** for up to **43 days**, imagine if **this was reversed** and **became a serious biological reaction or rejection that lasted 43 days** as the **body fights itself rather than healing itself**. And **as this is an unknown**, **treatments** for it would also be **considerably unknown** if the **system** becomes **imbalanced by cytoxocity**

The neutralisation assay used a **previously described strain of SARS-CoV-2** (**USA_WA1/2020**) **that had been rescued by reverse genetics and engineered by the insertion of an mNeonGreen** (**mNG**) **gene into open reading frame 7 of the viral genome** [**29**]

Vero cells (**ATCC CCL-81**) and **Vero E6 cells** (**ATCC CRL-1586**) were **cultured** in Dulbecco's modified Eagle's medium (DMEM) with GlutaMAX™ (Gibco) **supplemented with 10% fetal bovine serum** (**FBS**) (Sigma-Aldrich). **Cell lines were tested for mycoplasma contamination** after receipt and before expansion and cryopreservation.

VSV-SARS-CoV-2 spike variant pseudovirus neutralisation assay.

Vesicular stomatitis virus (**VSV**)-**SARS-CoV-2-S pseudoparticle generation** and neutralisation assays were performed as previously described [21]. Briefly, **human codon optimized SARS-CoV-2 spike** (**GenBank**: **MN908947.3**) **was synthesised** (**Genscript**) **and cloned into an expression plasmid.**

Amino acid substitutions were cloned into the spike expression plasmid using site-directed mutagenesis. **HEK293T cells** (**ATCC CRL-364 3216**) were **seeded and transfected** the following day with **spike expression**. At **24 hours post-transfection** at **37 °C**, **cells were infected with the VSVΔG:mNeon/VSV-G virus; the supernatant containing VSV-SARS-CoV-2-S pseudoparticles was collected, centrifuged at 3000xg for 5 minutes to clarify and stored at -80 °C until further use.**

July 27,, 2020

Pfizer and BioNTech Choose Lead mRNA Vaccine Candidate Against COVID-19 and Commence Pivotal Phase 2/3 Global Study

- *Companies advance nucleoside-modified messenger RNA (modRNA) candidate BNT162b2, which encodes an optimized SARS-CoV-2 full-length spike glycoprotein, at a 30 µg dose level in a 2 dose regimen into Phase 2/3 Study*
- *Candidate and dose level selection informed by preclinical and clinical data obtained in Phase 1/2 studies conducted in the U.S. (C4591001) and Germany (BNT162-01)*
- *The Phase 2/3 study protocol follows all the U.S. Food and Drug Administration (FDA) guidance on clinical trial design for COVID-19 vaccine studies.*
- *Phase 2/3 study of up to 30,000 participants aged 18 – 85 years started in the U.S. and expected to include approximately 120 sites globally*
- *Trial regions to include areas with significant expected SARS-CoV-2 transmission to assess whether investigational vaccine candidate, BNT162b2, is effective in preventing COVID-19*
- *Assuming clinical success, Pfizer and BioNTech on track to seek regulatory review as early as October 2020 and, if regulatory authorization or approval is obtained, plan to supply up to 100 million doses by the end of 2020 and approximately 1.3 billion doses by the end of 2021*

Pfizer BIONTECH

PFIZER INC.
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Trial record 1 of 2 for: BNT162b2

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A Trial Investigating the Safety and Effects of Four BNT162 Vaccines Against COVID-2019 in Healthy Adults

ClinicalTrials.gov Identifier: NCT04380701

Recruitment Status : Recruiting
First Posted : May 8, 2020
Last Update Posted : August 18, 2020

See Contacts and Locations

Actual Study Start Date: **April 23**, 2020
Estimated Primary Completion Date: **November 2020**
Estimated Study Completion Date: **November 2020**
456 participants
Four Prophylactic **SARS-CoV-2 RNA Vaccines** Against **COVID-2019** Using Different Dosing Regimens

Sponsor:
BioNTech RNA Pharmaceuticals GmbH

Information provided by (Responsible Party):
BioNTech SE (BioNTech RNA Pharmaceuticals GmbH)

July 27, 2020 05:15 PM Eastern Daylight Time

NEW YORK & MAINZ, Germany--(BUSINESS WIRE)--Pfizer Inc. (NYSE: PFE) and BioNTech SE (Nasdaq: BNTX) today announced the start of a global (except for China) Phase 2/3 safety and efficacy clinical study to evaluate a single nucleoside-modified messenger RNA (modRNA) candidate from their BNT162 mRNA-based vaccine program against SARS-CoV-2.

"Forward-Looking Information and Factors That May Affect Future Results"

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After extensive review of preclinical and clinical data from Phase 1/2 clinical trials, and in consultation with the U.S. Food and Drug Administration's Center for Biologics Evaluation and Research (CBER) and other global regulators, Pfizer and BioNTech have chosen to advance their BNT162b2 vaccine candidate into the Phase 2/3 study, at a 30 μg dose level in a 2 dose regimen. BNT162b2, which recently received U.S. Food and Drug Administration (FDA) Fast Track designation, encodes an optimized SARS-CoV-2 full length spike glycoprotein (S), which is the target of virus neutralizing antibodies.

RNA-Based COVID-19 Vaccine BNT162b2 Selected for a **Pivotal Efficacy Study**

(**not certified by peer review**)

Healthy adults **18–55** and **65–85** years of age

We now present additional safety and immunogenicity data from the **US Phase 1 trial** that supported selection of the **vaccine candidate** advanced to a **pivotal Phase 2/3 safety and efficacy evaluation**. These results **support selection** of the **BNT162b2 vaccine candidate** for **Phase 2/3** large-scale safety and efficacy evaluation, **currently underway**

BioNTech and **Pfizer** launched an unprecedented and **coordinated program to compare 4 RNA-based COVID-19 pandemic vaccine candidates** in umbrella-type clinical studies conducted in **Germany** (**BNT162-01**) and the **US** (**C4591001**). The program was designed to **support the selection of a single vaccine candidate and dose level** for a **pivotal global safety and efficacy trial**.

Here we report the full set of safety and immunogenicity **data from the Phase 1** portion of an **on-going randomized**, **placebo-controlled**, **observer-blinded dose-escalation US trial** that was used to select the final **vaccine candidate**, **BNT162b2**, as well as comparison of the safety and immunogenicity of both vaccine candidates (**ClinicalTrials.gov identifier**: **NCT04368728**). These **data** include evaluation of **10-µg**, **20-µg**, and **30-µg dose levels of BNT162b1** in **65–85 year old adults** and of an additional **20-µg** dose level in **18–55 year old adults**.

The neutralization assay used a **previously described strain of SARS-CoV-2** (**USA_WA1/2020**) **that had been rescued by reverse genetics and engineered by the insertion of an mNeonGreen gene into open reading frame 7 of the viral genome** [**11**,**12**]. **Both vaccines** elicited **lower antigen-binding IgG** and **neutralizing responses** in **65–85 year olds** compared to **18–55 year olds**

The **data set presented here guided our decision** to **advance BNT162b2** (which **expresses the full-length spike**) at the **30-µg dose level** into the **Phase 2/3**, **global safety and efficacy evaluation** in participants **18–85 years of age**

Short-lived declines in **post-vaccination lymphocyte counts** were without evidence of associated clinical impact, were observed across age groups, and **likely reflect temporary redistribution of lymphocytes from the bloodstream to lymphoid tissues** as a **functional response to the immune stimulation of immunization** [**13**,14,**15**,**16**]

The **reason** for the **lower reactogenicity of BNT162b2** compared to **BNT162b1 is not certain**, given that **BNT162b1** and **BNT162b2** share the **same modRNA platform**, **RNA production** and **purification processes**, **and LNP formulation**.

RNA vaccines require vaccine RNA translation in the host to express antigen, thus **higher reactogenicity may be associated with an innate immune shutdown of host cell translation that can result in suboptimal antigen presentation and lower immunogenicity**.

This study and interim report have **several limitations**. First, **at the time of publication**, **data** on **immune responses or safety beyond 7 days after Dose 2 were not available**. **Second**, **we do not yet know the relative importance** of **humoral** and **cellular immunity** in protection from **COVID-19.. cellular immune responses elicited by BNT162b2 are still being studied and will be reported separately.**

Third, although the **serum neutralizing responses elicited by the vaccine candidates relative to those elicited by natural infection** are highly encouraging, the **degree of protection** against **COVID-19 provided by this or any other benchmark is unknown**.

Many of the limitations to this study are **now being addressed in the global Phase 2/3 portion of this study**, **while we expand our RNA vaccine manufacturing and distribution capacity**. In this **pivotal study**, we are assessing the safety and efficacy of **2 doses** of **30 µg BNT162b2** in up to **30,000 participants** (randomized 1:1 **with placebo**) from **diverse backgrounds** and **individuals from racial and ethnic backgrounds** at **higher risk** for **severe COVID-19** [**22**]

Role of the funding source

BioNTech is the **sponsor of the study**. **Pfizer** was **responsible for the design**, **data collection**, **data analysis**, **data interpretation**, and **writing of the report**. The corresponding **authors** had full access to all the data in the study and **had final responsibility for the decision to submit the data for publication**. All study data were available to all authors

BNT162b2	10 µg (n=12)	20 µg (n=12)	30 µg (n=12)	100 µg (n=0)	Placebo (n=9)	Total (n=45)	10 µg (n=12)	20 µg (n=12)	30 µg (n=12)	Placebo (n=9)	Total (n=45)
Sex, n (%)											
Male	5 (41.7)	6 (50.0)	3 (25.0)	–	5 (55.6)	19 (42.2)	2 (16.7)	5 (41.7)	6 (50.0)	4 (44.4)	17 (37.8)
Female	7 (58.3)	6 (50.0)	9 (75.0)	–	4 (44.4)	26 (57.8)	10 (83.3)	7 (58.3)	6 (50.0)	5 (55.6)	28 (62.2)
Race, n (%)											
White	11 (91.7)	10 (83.3)	9 (75.0)	–	9 (100.0)	39 (86.7)	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Black or African American	0	2 (16.7)	1 (8.3)	–	0	3 (6.7)	0	0	0	0	0
Asian	1 (8.3)	0	2 (16.7)	–	0	3 (6.7)	0	0	0	0	0
Ethnicity, n (%)											
Non-Hispanic/ Latinx	11 (91.7)	11 (91.7)	12 (100.0)		9 (100.0)	43 (95.6)	12 (100.0)	12 (100.0)	12 (100.0)	9 (100.0)	45 (100.0)
Age at Vaccination, y											
Mean ± SD	36.8 ± 12.20	37.6 ± 10.07	37.3 ± 9.85	–	34.4 ± 13.22	36.7 ± 10.95	68.0 ± 2.89	71.0 ± 5.82	68.5 ± 2.81	70.0 ± 3.84	69.3 ± 4.09
Median (range)	37.0 (21–53)	38.0 (23–53)	36.5 (23–54)	–	30.0 (19–53)	37.0 (19–54)	67.0 (65–73)	68.5 (65–81)	68.0 (65–74)	69.0 (65–77)	68.0 (65–81)

Table 1 | Participant demographics for BNT162b1 and BNT162b2

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Trial record 2 of 2 for: BNT162b2

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Study to Describe the Safety, Tolerability, Immunogenicity, and Efficacy of RNA Vaccine Candidates Against COVID-19 in Healthy Adults

The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Know the risks and potential benefits of clinical studies and talk to your health care provider before participating. Read our disclaimer for details.

ClinicalTrials.gov Identifier: NCT04368728

Recruitment Status: Recruiting
First Posted: April 30, 2020
Last Update Posted: September 4, 2020

See Contacts and Locations

Sponsor:
BioNTech SE

Collaborator:
Pfizer

Information provided by (Responsible Party):
BioNTech SE

Actual Study Start Date: **April 29**, 2020
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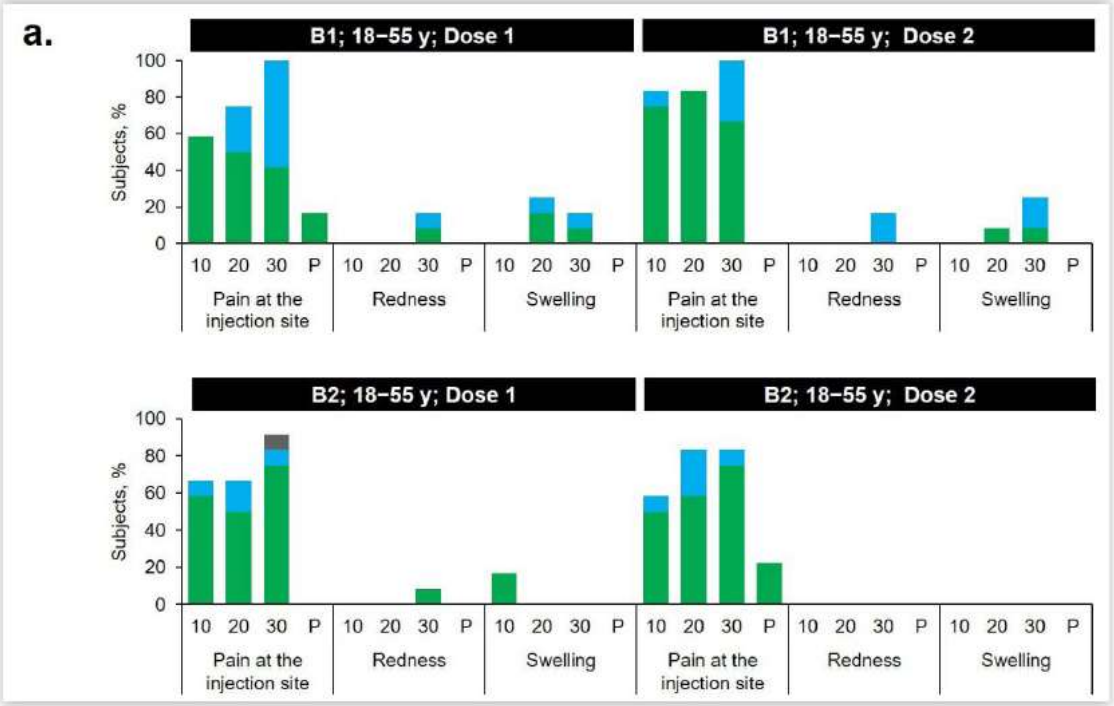
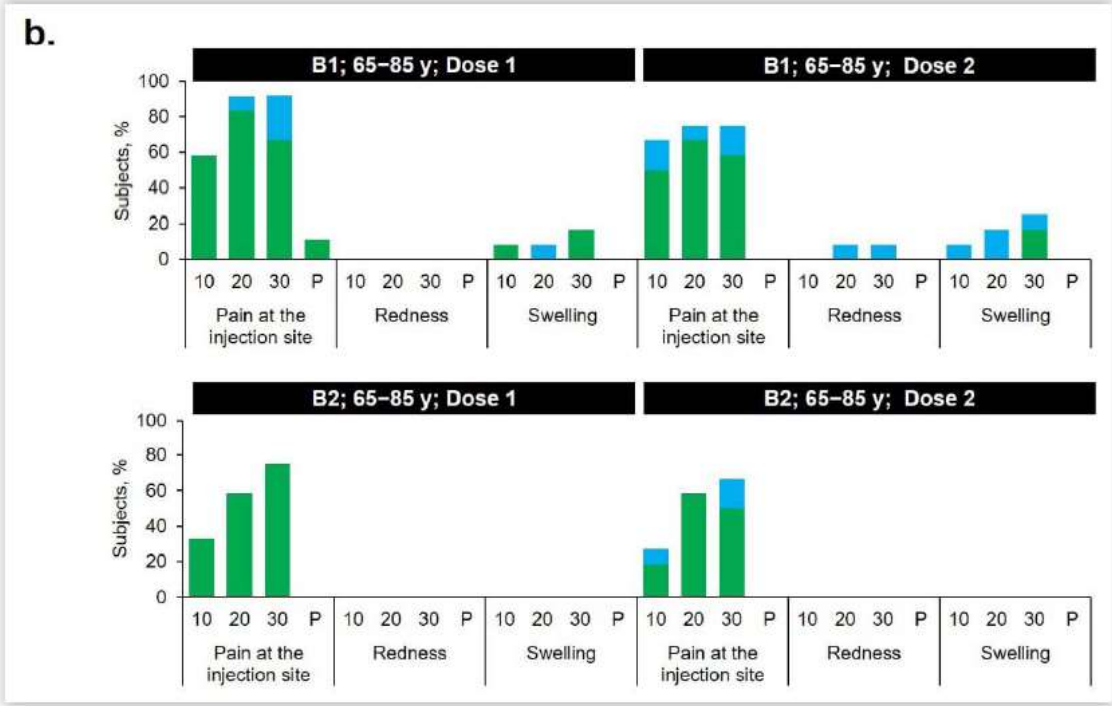
29,481 participants – **2 dose** regimen

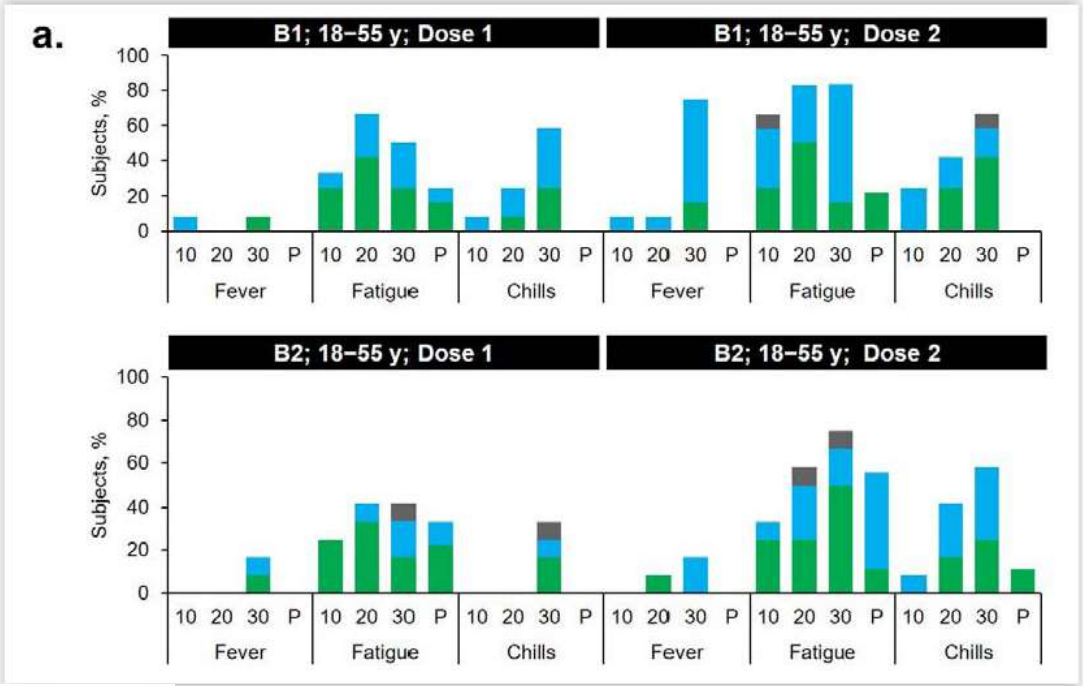


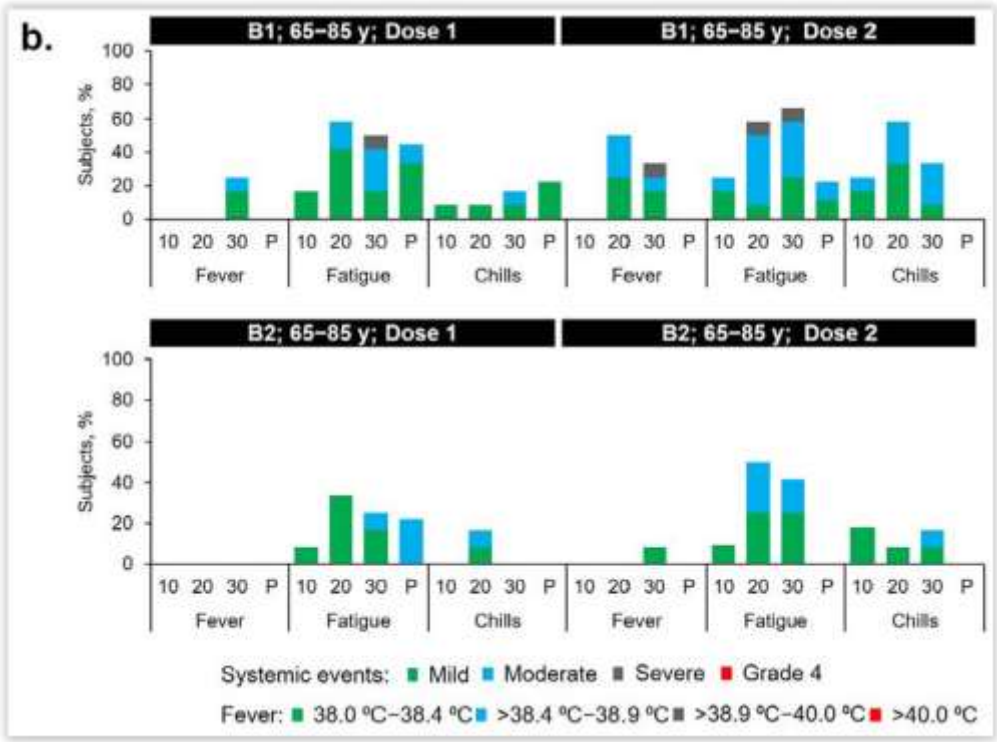
B1 – BNT162b1; B2 – BNT162b2

10 = **10 µg**; 20 = **20 µg**; 30 = **30 µg**;
P = **placebo**;

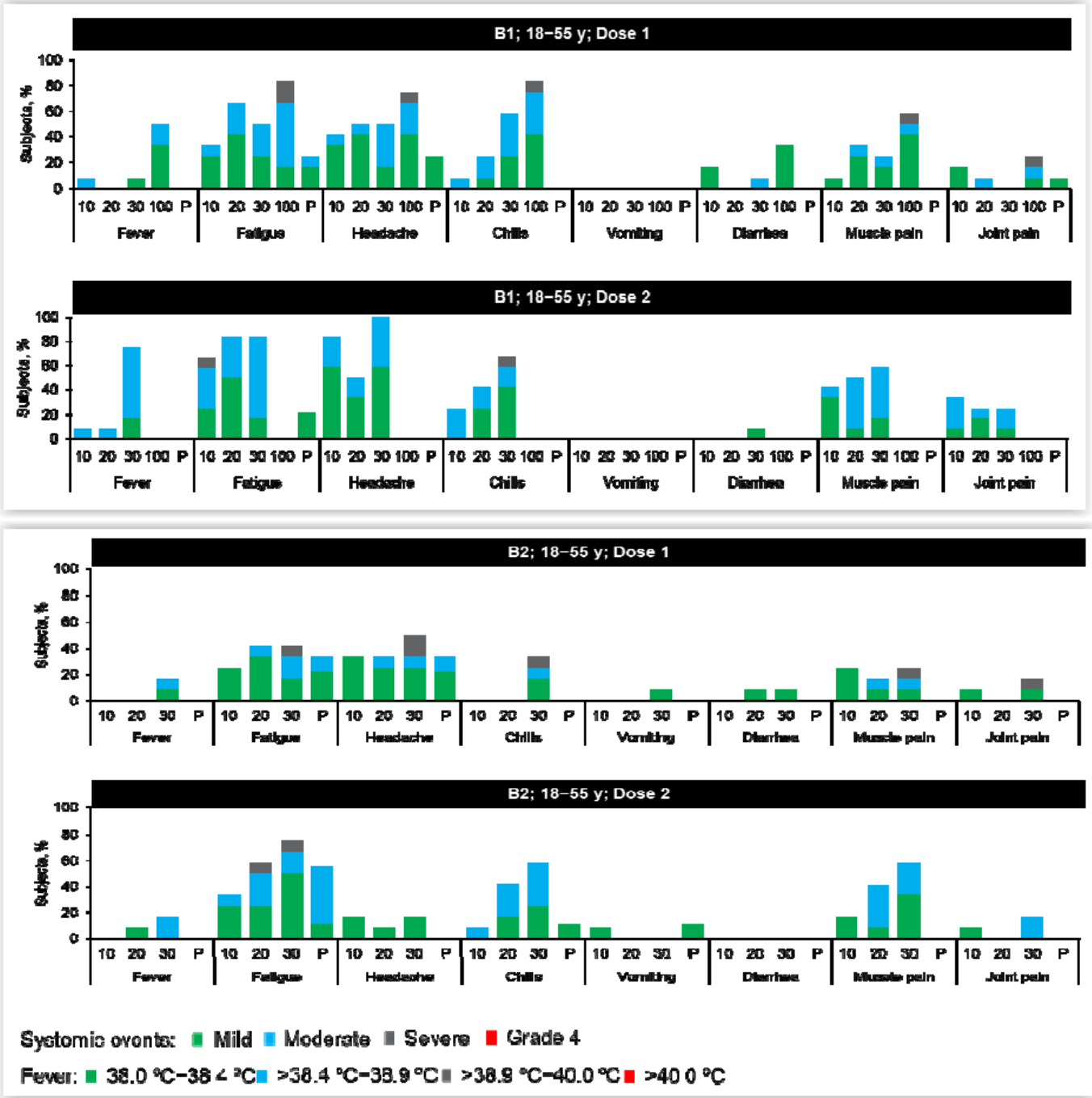


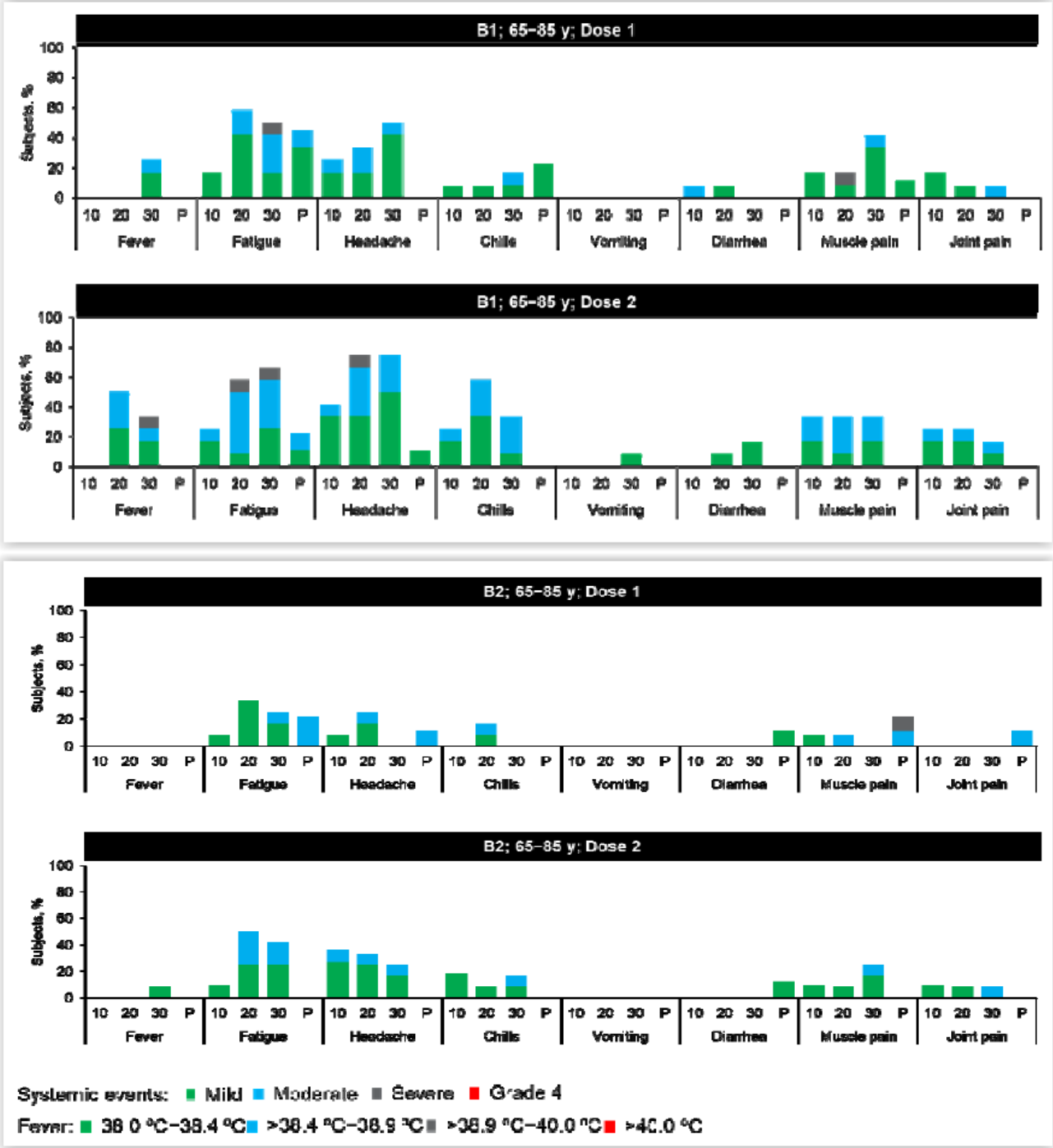
BNT162b1; B2 – BNT162b2





10 = **10 µg**; 20 = **20 µg**; 30 = **30 µg**;
P = **placebo**;


B1; 18–55 y; Dose 1
B1; 18–55 y; Dose 2
B2; 18–55 y; Dose 1
B2; 18–55 y; Dose 2
Subjects, %
100
80
60
40
20
0
10 20 30 100 P
Fever
Fatigue
Headache
Chills
Vomiting
Diarrhea
Muscle pain
Joint pain
10 20 30 P
Systemic events: Mild Moderate Severe Grade 4
Fever: 38.0 °C–38.4 °C >38.4 °C–38.9 °C >38.9 °C–40.0 °C >40.0 °C


B1; 65–85 y; Dose 1
B1; 65–85 y; Dose 2
B2; 65–85 y; Dose 1
B2; 65–85 y; Dose 2
Subjects, %
100
80
60
40
20
0
10 20 30 P
Fever
Fatigue
Headache
Chills
Vomiting
Diarrhea
Muscle pain
Joint pain
Systemic events: Mild Moderate Severe Grade 4
Fever: 38.0 °C–38.4 °C >38.4 °C–38.9 °C >38.9 °C–40.0 °C >40.0 °C