International Journal of Pharmaceutical Research and Applications
Volume 6, Issue 2 Mar-Apr 2021, pp: 703-707 www.ijprajournal.com ISSN: 2249-7781

A Rewiew of Lightening Towards Pfizer-Biontech Covid-19 Vaccine

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Date Of Submission: 01-05-2021 Date Of Acceptance: 10-05-2021

ABSTRACT: The most leading problem the whole country is facing is the "**Coronavirus**". Researcher mainly focuses on the idea of giving mRNA cellular machinery to make a protein that will create protecting Antibodies. Vaccines are a critical new tool in the battle against COVID-19 and many world's biggest pharmaceutical companies like – **PFIZER-BIONTECH, JOHNSON &JOHNSON, ASTRAZENACE, BHARAT BIOTECH, ZYDASCADILA, SERUM INSTITUTES** and so many companies are competing for COVID-19 vaccine. The main purpose of a review is to focus on the origin of the vaccine and its immunogenicity activity against COVID-19 SARS-COV-2. This paper highlights the efforts of the PFIZER-BIONTECH vaccine and deals with the course of treatment for the disease.

KEYWORDS: Human coronavirus, structural proteins, BNT162b, mRNA, immune system, antibody, clinical trials.

I. INTRODUCTION

In December, 2019 SARS-COV-2 virus was detected in china 'Wuhan'. On 8 January, 2019 these infectious agent causing breakouts were identified as a novel coronavirus 2019. On 11 March, 2020 WHO upgrade status of COVID-19 outbreak from epidemic – pandemic. COVID -19 pandemic is manifested and interconnected nature of our world. So many vaccines manifest successfully and going into development. Generally, for the formulation of any vaccine against newly identifying disease, it takes 10 to 15 years of duration. But in this pandemic situation, researchers have successfully developed a vaccine within a year. The Pfizer is one of the world's largest U.S. Bio-Pharma-Company and a German-Bio-technology company creates a vaccine-BNT162b. According to the research, people having age 16 & above having high efficacy. In May, 2020, Pfizer dose initial batch of healthy American volunteers in Baltimol. With an experimental COVID-19 vaccine. Ugur-Sahin, the brilliant immunologist founder of BioNTech and Kathrin Jansen, who heads vaccine research & development for Pfizer comes together with an idea of using mRNA, the genetic molecules that gives cells protein making instruction, to develop medicine for cancer, heart disease & even infectious viruses transforming human cell into drug factories. The director of Pfizer is Scott Gottlieb, the Pfizer chief Albert Bourla and Pfizer chief scientific Officer Mikael Dalster challenges the team to have millions of doses of vaccine in hand of population before the end of the year. The Food & Drug Administration,Pfizer-BioNTech COVID-19 vaccine has not been accepted or permit, but has been authorized for emergency use. The two SARS-COV-2 vaccines are- BNT162b1 and BNT162b2.

II. MATERIALS

Development Process,Contents, Formulation:The ingredients use of Pfizer-BioNTech vaccines are, Active Ingredients and Inactive ingredients. Active Ingredient:- Nucleoside-modified mRNA encoding the virus spike glycoprotein of SARS-COV-2. Inactive Ingredients :- 2[(polyethylene glycol)-2000]-N, N-ditetradecylacetamide, 1, 2-distearoyl-sn-glycero 3-phosphocholine, Cholesterol, (4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), Sodium chloride, Monobasic potassium phosphate, Potassium chloride, Dibasic sodium phosphate dehydrate, sucrose, water for injection. The vaccines do not contain gelatin, eggs, preservatives and latex.

III. DOSE PREPARATION

The vaccine contains a frozen suspension of multiple dose vial, which do not contain preservative and should be thawed and dilute before administer. Thawed vial should be refrigerated or at room temp [up to 25*C (77*F)]

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before dilution the thaw suspension contains white to off-white opaque amorphous particles. Dilution of the vial is made with 1.8 ml of sterile 0.9% sodium chloride injection, USP to from the vaccine.The vial contains 5 doses of 0.3ml, after dilution. The packaging of vaccine is not done with 0.9% sodium chloride injection, USP and must be stored separately. Bacteriostatic 0.9% sodium chloride injection or any other diluents should not use. The appearance of vaccine is an off-white suspension, after dilution. There are no particulate and no discoloration is observed and this confirms during inspection of vials. During this process aseptic techniques must follow strictly.

IV. PRE-CLINICAL STUDIES

In preclinical trials, Pfizer-BioNTech scientist select immunization of non-human-primates such as rhesus macaques, mice with BNT162b2 which are a nucleoside modified messenger RNA (mod RNA) participants expressing the SARS-COV-2 spike glycoprotein, which develop strong anti-viral effect against an infectious SARS-COV-2. A single vaccination of BNT162b2 obtains high neutralizing antibody titers in mice. Vaccination of mice leads to strong the T helper 1 and T follicular helper type $CD4^+$ response and IFN¥$^+$IL-2$^+$CD8$^+$T-Cell response. This mRNA vaccine is given in two doses containing 100mg at 0 day and 21 day. It observes that after seven days of the second dose, the 50% of virus neutralize titre of antibodies which reach up to 18 times that of human SARS-COV-2 convalescent serum panel, remain 3.3 times higher than this standard five weeks after second immunization, while the absolute titres decay from 1689 to 310. The T_H1-based $CD4^+$ response and the IFN¥$^+$CD8+T-Cell response matches the cellular immunogenicity profile report in mice. In a three week interval two doses of 100 mg of BNT162b2 are set apart and protect 2-4 years old rhesus macaques against viral infection when administering intra nasally and intra tracheally with $1x10^6$ plaque-forming units of SARS-COV-2, 55 days after second vaccination. Reverse transcription quantitative polymerase chain reaction (RT-qPCR) is measured by viral RNA in, the broncho alveolar lavage fluid (BAL) and nasopharyngeal (NP) and oropharyngeal (OP) swabs, is lower in the vaccinated animals than in the unvaccinated. The virus is absent on day 3 and day 6 after administration. Overall, these preclinical data show that the BNT162b2 is an immunogenic vaccine which is very effective and shows as antiviral activity in the lower and upper respiratory tract of rhesus macaques three days after administration.

V. CLINICAL TRIALS

According to WHO, around the world wide 7 countries currently are in clinical trials of COVID-19 vaccines. The Pfizer-BioNTech researchers report the safety, availability tolerability and immunogenicity data from ongoing placebo-controlled, observer-blind, dose-advance study.

Study Design: This is the multicenter, multinational phase I, II, III random, placebo-control, observer-blind, dose find, vaccine volunteer selection and efficacy study in the healthy volunteers is consisting of two phases-PHASE I & PHASE II/III. This study is conducted in the age group of 18-55 years in healthy volunteers (not for pregnant women) to access the safety, tolerability and immunogenicity of two different SARS-COV-2 mRNA vaccine candidates against COVID-19 and efficacy of the candidates

[1]. As a 2 dose schedule (separated by 21 days)

[2]. At various different dose levels in phase I

[3]. In 3 age groups (PHASE I : 18-55 years of age; 65-85 years of age)

(PHASE II& III: greater than and equal to 16 years of age)

[4]. Phase I: To identify preferred vaccine volunteer and dose level

Each group (vaccine candidates/dose level/ age group) comprises of 15 volunteers in this 12 volunteers is randomize to receive the active vaccine and another 3 receive placebo. For each vaccine volunteer/ dose level/ age group is following-

[1]. Additional safety assessments

[2].Control enrollment (require only for 1st volunteer and/ or dose level study)

[3].Not more than 5 volunteers in which 4 active and 1 placebo can administer the vaccine on 1st day.

[4]. For acute reactions, the 1st 5 volunteers is observed by blind site staff for at least 4 hours after the vaccination.

[5]. Vaccination of remaining volunteers is commenced no sooner than 24 hours after 5 volunteers receive his/ her vaccine.

1. Phase II/III- An expand cohort and efficacy part

On the basis of safety, immunogenicity data generate during the course of the study is select for proceeding in to phase 2/3. Volunteer in

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this phase is less than and equal to 16 years of age, stratify as follow: 16-55 years or less than 55 years. The commencement of each age stratum be based upon the satisfactory post. Dose 2 safety & immunogenicity data from 18 -55 years and 65 to 85 years in phase I. Vaccine volunteers is select for phase 2/3 evaluation is BNT162b2 at the dose 30 mg. The first 360 volunteers enroll (180 to active vaccine and 180 to placebo, stratify equally between 18-55 years and less than 55 to 85 years) is comprise phase II portion. Safety data through 7 days after dose 2 & immunogenicity data through one month after dose 2 from these 360 volunteers is analyzed. Volunteer expects to participate for up to maximum 26 months.

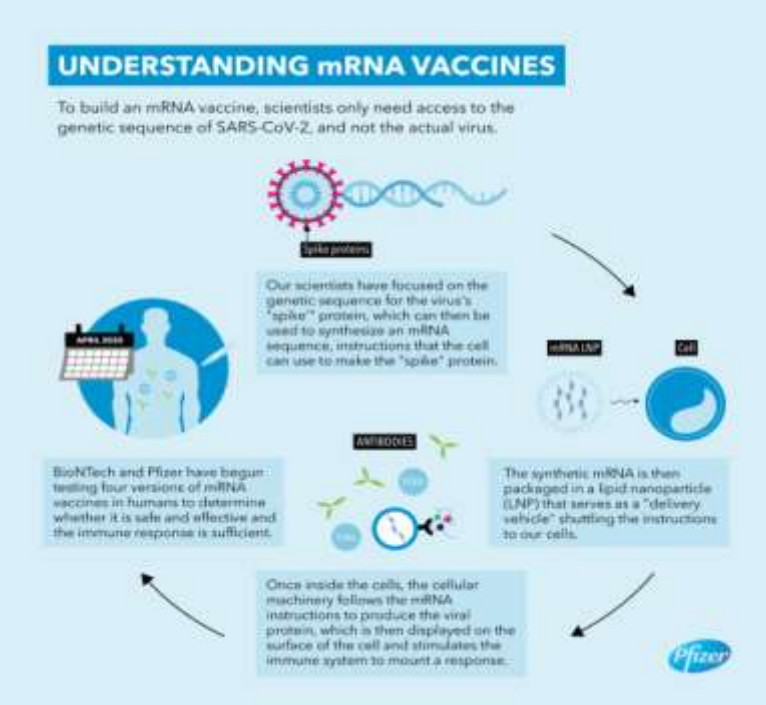
It is observed that effectiveness of vaccine is 52% between time for 1st and 2nd dose which is 21 days. The researcher want to examine effectiveness of vaccine after 15 days of 1st dose receive. After 15 days of 1st dose efficacy of vaccine is approximately 89%-91%. After the second dose of vaccine, level of immunity is increase to 95%. Strong antibody response follows to second dose is observed by researchers. The antibody levels start to decrease been inactive slowly at 63 days it still remain high.

Common Side Effects:1. In the arm where you got the shot- Pain, Redness, Swelling.

Throughout the rest of your body- Tiredness, Headache, Muscle pain, Chills, Fever, Nausea.

These side effects usually start within a day or two after vaccination. Side effects may affect your ability to do daily activities, but should go away in a few days.

VI. MECHANISM OF ACTION OF PFIZER-BIONTECH VACCINE: (HOW IT WORK)



VII. DOSING AND SCHEDULE

According to Pfizer-BioNTech, 2 doses (0.3ml each) of COVID-19 vaccine is administered intramuscularly within 3 weeks. 1st boost to prime immune system. Introducing to spike protein & allow to generate small immune response precious to 2nd dose. These period is need to allow this process to grow properly.

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1st dose-

1. Prime immune system
2. Remember virus
3. Develops antibodies within 14 days.

2nd dose-

1. Strengthens immune response.
2. Develop more antibodies.

VIII. FUNDING

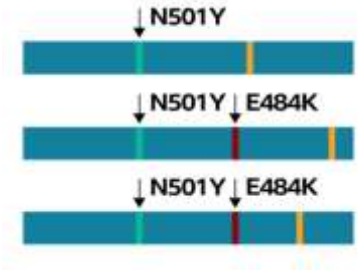
In March 2020, from FOSUN US$135 million expenditure is received by BioNTech, in the interchange of 1.58 million shares. The 100 million (US$119 million) fund from the European commission and European investment Bank is receive by BioNTech. In September 2020, German government finances 375 million (US$445 million) BioNTech for the development COVID-19 vaccine program.

IX. STORAGE CONDITIONS

The temperature of the vaccine is maintained between -60* & -80*C (-112* &-76*F) for 5 days before vaccination. It can be maintained at 2* to 8*C (36 to 46*F) up to 2 hours temperature up to 25*C (77*F) or 30*C (86*F).According to US Food and drug administration (FDA) bring up to date Emergency Use Authorization (EUA) to grant undiluted frozen vials of the vaccine and maintain the temperature between -25* and -15*C (-13 and 5*C) up to two weeks before use.

X. VARIANTS

Variants like **N501Y and E484K mutation. N501Y** is spread widely in the UK, South Africa and Brazil. In South Africa, Brazil and some UK E484K affect the response of antibody.



XI. CONCLUSION

This is not the first pandemic or nor a last in the history of humankind. Ongoing pandemic corona is spreading vigorously. Various vaccines is being developed and many more to go. After various clinical trial the Pfizer BioNTech is the 1st vaccine to be developed. In this 8 month journey the study arises an important step in the development of vaccine, which help to end this destructive pandemic. Administration of two doses of BNT16b2 confers 95% protection against COVID-19 in volunteers 16 years of age or above. Pfizer-BioNTech vaccine cannot immediately return back to normality from the preCOVID-19 world nor it affirm, but it is a step to make new normal world where COVID-19 left its mark.

XII. ACKNOWLEDGEMENT

We take this opportunity to express our heart-felt gratitude and deep regard to our guide, MRS. SHARMILA WAGH MADAM for her guidance, monitoring and constant encouragement. Supported by IDEAL INSTITUTE OF PHARMACY and an extended gratitude to my colleagues.

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