Drug Information Bulletin

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&

Regulatory Affairs Division (RAD), IPA

1st India made COVID vaccine BBV152 got CDSCO approval for conducting clinical trial on 29th June 2020

Volume: 14 ***Number: 07*** ***5th July 2020***

Content

Editorial

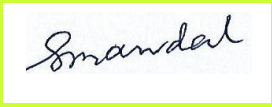
It is indeed a proud moment for Indians that DCGI has approved clinical trial of Whole-Virion Inactivated SARS-CoV-2 Vaccine (BBV152) of Bharat Biotech International Limited on 29 June 2020, the "first" India made novel corona virus vaccine. They also approved 12 sites for conducting clinical trial throughout India. This vaccine was developed by Hyderabad-based Bharat Biotech in Collaboration with Indian Council of Medical Research (ICMR) and National Institute of Virology (NIV).

Subsequently DCGI accorded approval for conducting clinical trial on another indigenously developed novel corona virus vaccine to Zydus Cadila Healthcare on 2nd July 2020. As per the company statement- "With ZyCoV-D, the company has successfully established the DNA vaccine platform in the country using non-replicating and non-integrating plasmid carrying the gene of interest, making it very safe."

Both the approval process was fast-tracked following a recommendation by the subject expert committee on COVID-19, considering the emergency and unmet medical need during the pandemic.

Now both the companies will conduct clinical trials following the "New Drugs and Clinical Trials Rules, 2019". This newly framed rule prescribed the detailed procedure for conducting clinical trial and the process of new drug approval. As per the experts the entire process takes considerable amount of time to complete the entire process.

Hope the result of clinical trial will be suitable for human use and will get approval from the DCGI for manufacturing and marketing in due course of time.



Dr. Subhash C. Mandal
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DCGI approved clinical trial of Whole-Virion Inactivated SARS-CoV-2 Vaccine (BBV152) of Bharat Biotech International Limited on 29 June 2020

File No: BIO/CT/20/000077

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Biological Division)

FORM CT-06

(See rules 22, 25, 26, 29 and 30)

PERMISSION TO CONDUCT CLINICAL TRIAL OF NEW DRUG OR INVESTIGATIONAL NEW DRUG

The Central Licencing Authority hereby permits M/s Bharat Biotech International Limited, Genome Valley, Shameerpet (India) -500078, Telephone No.: 9848887849, Fax: 04023480560, E-Mail: dra@bharatbiotech.com to conduct clinical trial of the new drug or investigational new drug, Whole-Virion Inactivated SARS-CoV-2 Vaccine (BBV152) as per **protocol no.:BBIL/BBV152-A/2020, Version No: 2.0, Date: 26-06-2020** in the below mentioned clinical trial sites.

CT No.: CT- 14/2020

2. Details of new drug or investigational new drug and clinical trial site [As per Annexure].

3. This permission is subject to the conditions prescribed in part A of Chapter V of the New Drugs and Clinical Trials Rules, 2019 under the Drugs and Cosmetics Act, 1940.

Place: New Delhi
Date: 29.06.2020

VENUGOPAL GIRDHARILAL SOMANI

(Dr. V. G. Somani)
Drugs Controller General (India)
Central Licencing Authority

Letter from DG, ICMR for expedited the process the process of clinical trial

सत्यमेव जयते

प्रोफेसर (डा.) बलराम भार्गव, पद्म श्री
एमडी, डीएम, एफआरसीपी (जी.), एफआरसीपी (ई.), एफएसीसी, एफएएचए, एफएएमएस, एफएनएएस, एफएएससी, एफ.एन.ए., डी.एस.सी.
सचिव, भारत सरकार
स्वास्थ्य अनुसंधान विभाग
स्वास्थ्य एवं परिवार कल्याण मंत्रालय एवं
महानिदेशक, आई सी एम आर

Prof. (Dr.) Balram Bhargava, Padma Shri
MD, DM, FRCP (Glasg.), FRCP (Edin.), FACC, FAHA, FAMS, FNASc, FASc, FNA, DSc
Secretary to the Government of India
Department of Health Research
Ministry of Health & Family Welfare &
Director-General, ICMR

भारतीय आयुर्विज्ञान अनुसंधान परिषद
स्वास्थ्य अनुसंधान विभाग
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
भारत सरकार
वी. रामलिंगस्वामी भवन, अंसारी नगर
नई दिल्ली - 110 029

Indian Council of Medical Research
Department of Health Research
Ministry of Health & Family Welfare
Government of India
V. Ramalingaswami Bhawan, Ansari Nagar
New Delhi - 110 029

D.O.No.ECD/COVID19/Misc./2020
2nd July, 2020

Dear Colleagues (As per list attached),

Greetings from the Indian Council of Medical Research (ICMR)!

This is to bring to your kind attention that ICMR has partnered with Bharat Biotech International Limited (BBIL) to fast-track clinical trials of the indigenous COVID-19 vaccine (BBV152 COVID Vaccine).

This is the first indigenous vaccine being developed by India and is one of the **top priority projects which is being monitored at the topmost level of the Government.** The vaccine is derived from a strain of SARS-CoV-2 isolated by ICMR-National Institute of Virology, Pune. ICMR and BBIL are jointly working for the preclinical as well as clinical development of this vaccine.

It is envisaged to launch the vaccine for public health use latest by 15th August2020 after completion of all clinical trials. BBIL is working expeditiously to meet the target, however final outcome will depend on the cooperation of all clinical trial sites involved in this project.

You have been chosen as a clinical trial site of the BBV152 COVID Vaccine. In view of the public health emergency due to COVID-19 pandemic and urgency to launch the vaccine, you are strictly advised to fast track all approvals related to initiation of the clinical trial and ensure that the subject enrollment is initiated no later than 7th July 2020.

Kindly note that **non-compliance will be viewed very seriously**. Therefore, you are advised to treat this project on highest priority and meet the given timelines without any lapse.

With regards

Yours sincerely

(Balram Bhargava)

Copy to:

1.Dr. Krishna Ella, CMD, Bhart Biotech, Hyderabad, AP
2.Dr. Krishna Mohan, Sr.Vice-President, Bharat Biotech, Hyderabad, AP

Tele.: 26588204, 26589620, Fax (Off.) : 91-11-26588662, E-mail: secy-dg@icmr.gov.in

Questions:

Following the letter by DG-ICMR to investigators of the clinical trial, questions were raised by experts over the launch date. Experts suggested that clinical trial of vaccine cannot be completed in 45 days then how did ICMR decide on the date of launch as August 15th.

Clarification:

"ICMR in their statement said that the letter by DG ICMR was meant to cut unnecessary red tape, without bypassing any necessary process, and speed up recruitment of participants. ICMR further clarifies that just as red tape was not allowed to become a hindrance in the fast track approval of new indigenous testing kits or for introducing the potential COVID-19 related drugs in the Indian market, the indigenous vaccine development process has also been sought to be insulated from slow file movement. The aim is to complete these phases at the earliest so that population-based trials for efficacy could be initiated without delay." TIMESNOWNEWS.COM

List of other COVID-19 candidate vaccines undergoing clinical trial as on 2nd July 2020

Developer	**Platform**	**Type of candidate vaccine**	**Current stage of clinical evaluation/regulatory status-Coronavirus candidate**
University of Oxford/AstraZeneca	NonReplicating Viral Vector	ChAdOx1-S	**Phase 3** ISRCTN89951424 Phase2b/3 2020-001228-32 Phase 1/2 PACTR202006922165132 2020-001072-15 MERS
CanSino Biological Inc./Beijing Institute of Biotechnology	NonReplicating Viral Vector	Adenovirus Type 5 Vector	**Phase 2** ChiCTR2000031781 Phase 1 ChiCTR2000030906
Moderna/NIAID	RNA	LNPencapsulated mRNA	Phase 2 NCT04405076 Phase 1 NCT04283461
Inovio Pharmaceuticals/ International Vaccine Institute	DNA	DNA plasmid vaccine with electroporation	**Phase 1/2** NCT04447781 NCT04336410
Wuhan Institute of Biological Products/Sinopharm	Inactivated	Inactivated	**Phase 1/2** ChiCTR2000031809
Beijing Institute of Biological Products/Sinopharm	Inactivated	Inactivated	**Phase 1/2** ChiCTR2000032459
Sinovac	Inactivated	Inactivated + alum	**Phase 1/2** NCT04383574 NCT04352608
BioNTech/Fosun Pharma/Pfizer	RNA	3 LNP-mRNAs	**Phase 1/2** 2020-001038-36 NCT04368728
Novavax	Protein Subunit	Full length recombinant SARS CoV-2 glycoprotein nanoparticle vaccine adjuvanted with Matrix M Novavax	**Phase 1/2** NCT04368988
Institute of Medical Biology	Inactivated	Inactivated	**Phase 1** NCT04412538

, Chinese Academy of Medical Sciences			
Genexine Consortium	DNA	DNA Vaccine (GX-19)	**Phase 1** NCT04445389
Gamaleya Research Institute	NonReplicating Viral Vector	Adeno-based	**Phase 1** NCT04436471 NCT04437875
Clover Biopharmaceuticals Inc./GSK/Dynavax	Protein Subunit	Native like Trimeric subunit Spike Protein vaccine	**Phase 1** NCT04405908
Anhui Zhifei Longcom Biopharmaceutical/ Institute of Microbiology, Chinese Academy of Sciences	Protein Subunit	Adjuvanted recombinant protein (RBDDimer)	**Phase 1** NCT04445194
Vaxine Pty Ltd/Medytox	Protein Subunit	Recombinant spike protein with Advax™ adjuvant	**Phase 1** NCT04453852
Imperial College London	RNA	mRNA	**Phase 1** NCT04449276
People's Liberation Army (PLA) Academy of Military Sciences/Walvax Biotech.	RNA	mRNA	**Phase 1** ChiCTR2000034112
Curevac	RNA	mRNA	**Phase 1** ChiCTR2000034112

Source: WHO

CSIR testing Patalgarudi to fight Against COVID-19

CSIR sought the permission of the Drug Controller General to test the medicinal herb Cocculus hirsutus in humans. Cocculus hirsutus is a tropical, invasive creeper with the common name broom creeper or *Patalgarudi* (Sanskrit). It is native to India, Pakistan, and tropical Africa.

Since 2016, there have been trials of developing a drug against dengue from the underworld. In addition to dengue, the drug is effective against viruses that cause chikungunya and encephalitis, the researchers said. The plant has been found to be effective against RNA viruses.

Dengue virus and coronavirus enter the human body in different ways, but they multiply within the body. Researchers predict that Covid-19 will have the same effect if the underworld is effective against dengue.

Scientists at CSIR hope that the antiviral feature contained in this plant helps prevent coronavirus. Scientists at CSIR hope that the antiviral feature contained in this plant helps prevent coronavirus.

Researchers are preparing to test whether the drug is effective in the early treatment of COVID. If approved, 50 of them will be tested in the first phase.

Source: KRISHI JAGRAN

Erratum: Drug Information Bulletin, 14 (06)- Price of a tablet of “Faviflu” is INR 103, which was misprinted as INR 1103.