



# NATIONAL INSTITUTE OF BIOLOGICALS NEWSLETTER

Issue I: January - March, 2021



*Visit of Dr. Shekhar C Mande, Secretary, DSIR & DG-CSIR on 25.03.2021*



*Visit of Dr. Ramesh K. Goyal, Vice Chancellor, DIPSAR University on 22.03.2021*

## Director's Desk



I feel privileged of taking over the responsibility as the Director of the National Institute of Biologicals from 19th February 2021.

NIB is climbing the ladder of success steadily in a highly competitive scientific fraternity and is coming into limelight on the national and international stage by maintaining the uniqueness in the Quality Control of Biologicals.

As director of NIB, I envision our Institute as part of a vital strategy to invest in and promote emerging research areas for improving the quality control testing methods of various biologicals.

To meet tomorrow's challenges and demand in the interest of public health we are ready to include more and more biologicals under NIB's umbrella.

Further to extend our support to indigenous manufacturers and researchers in the country we would like to add more to the national biological reference standards supplied by NIB.

We are making this newsletter a quarterly affair and it will also have columns from guests or NIB faculty.

I wish Good Luck to all.

**Anup Anvikar**  
Director

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## Monoclonal Antibodies and COVID-19



Harish Chander,  
Ph.D., Scientist Grade-I

Antibody is a protein produced naturally by immune system in response to an antigen of the invading pathogen. Monoclonal antibodies are the molecules that are developed with specificity towards a target of an invading pathogen, cancer cell or in arthritis. These molecules are created by an exposure of immune cells to a viral protein. These antibodies were developed to treat RSV (Respiratory Syncytial Virus), Influenza, MERS-CoV (Middle East Respiratory Syndrome coronavirus), Zika virus, Ebola and Rabies before COVID-19. Since the start of SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2) pandemic, which is also a causative agent of COVID-19, the spike protein on the virus surface caught the eye of clinicians and scientists as a potential target for designing anti-viral drug, vaccines or neutralizing monoclonal antibodies.

Although, clinicians and scientists are in the process of understanding the disease potential of COVID-19 and look for the patients that are most possibly be profited from the treatment of monoclonal antibodies, initial studies have suggested that the high-risk patients with co-morbidities such as high blood pressure, diabetes, kidney failure, suppressed immune system including the other medical conditions and age factor. These antibodies may be used for recently COVID-19 diagnosed patients who are not sick enough but having risk factors as mentioned above. Infusion of antibodies in these patients in the initial stages of infection is vital. The infusion of monoclonal antibodies may lead to allergic or non-allergic reaction in some patients because of the stimulation of the body's immune response. At present, three monoclonal antibodies are given the go-ahead signal by US Food and Drug Administration (FDA) Emergency Use Authorization are bamlanivimab, casirivimab and imdevimab that are directed specifically to target spike protein of the virus. Studies on COVID-19 virus have also suggested the use of antibody cocktails in severely sick patients.

A characteristic feature of COVID-19 is a cytokine storm induced by body's natural defence. The cytokine storm is the higher-than-usual concentrations of serum TNF, IL-6 and IL-8, but relatively low IL-1 or IL-2 concentrations. Cytokine storm in COVID-19 patients is a hyperinflammatory condition, which aggravates the patient's breathing complications that can lead to potentially fatal acute respiratory distress syndrome (ARDS). The learning from calming the cytokine storm in rheumatoid arthritis patients and also as advanced immunotherapy treatment of cancer worked even in the clinical management of COVID-19 patients with cytokine release syndrome. The infusion of intravenous tocilizumab (a recombinant humanized anti-interleukin-6 receptor monoclonal antibody) lowered the risk of death despite the fact that this treatment may render the patient with the double risk of additional infections. These comparing group of the patients were also given the standard treatment of anti-inflammatory modulators. Itolizumab is a monoclonal antibody that targets CD6 and had been suggested to reduce the worsening of COVID-19. The other monoclonal antibodies to calm the cytokine storm that are under trial include Sarilumab, Sirkumab, Clazakizumab, Olokizumab and various others. Out of these, maximum clinical studies have reported the use of tocilizumab and is considered as the best candidate for the management of cytokine storm in COVID-19.

The high rate of mutations in the viruses contribute to their increased virulence and ability to evolve. It is these mutations that provide the viruses an edge over their host. The new mutants of SARS-CoV-2 have recently been reported in South Africa, United Kingdom, Brazil. These variants may have changes in the spike protein that could restrict the use of monoclonal antibodies for neutralization of virus. Currently, due to the lack of effective anti-viral drugs or vaccine to treat COVID-19, the passive therapy of employment of monoclonal antibodies in the viral neutralization and inhibiting the cytokine storm is the need of the hour.

### References:

1. Lloyd EC, Gandhi TN, Petty LA. Monoclonal Antibodies for COVID-19. JAMA. 2021;325(10):1015. doi:10.1001/jama.2021.1225

2. Loganathan S, Athalye SN, Joshi SR. Itolizumab, an anti-CD6 monoclonal antibody, as a potential treatment for COVID-19 complications. *Expert Opin Biol Ther.* 2020 Sep;20(9):1025-1031. doi: 10.1080/14712598.2020.1798399. Epub 2020 Jul 29.
3. Patel S, Saxena B, Mehta P. Recent updates in the clinical trials of therapeutic monoclonal antibodies targeting cytokine storm for the management of COVID-19. *Heliyon.* Volume 7, Issue 2, February 2021, e06158
4. Marovich M, Mascola JR, Cohen MS. Monoclonal Antibodies for Prevention and Treatment of COVID-19. *JAMA.* 2020;324(2):131–132. doi:10.1001/jama.2020.10245

## **NIB WELCOMES THE NEW DIRECTOR**

Dr. Anupkumar Anvikar joined NIB as new Director on 19<sup>th</sup> February 2021. He holds MBBS and MD Microbiology from Government Medical College, Aurangabad, Maharashtra. Dr. Anvikar established the only South-East Asian WHO-recognized malaria RDT lot testing laboratory at ICMR-NIMR, New Delhi, which is one of the three such facilities globally. He has published 125 research articles in peer-reviewed journals and has seven patents to his name. He is also the recipient of two prestigious awards. The entire staff of NIB welcomes him and wishing him a bright future.



## **COLLABORATIONS:**

- The Scientists of Biochemical Kit Laboratory had imparted training to Department of Endocrinology, AIIMS, New Delhi, Research Staff on ‘Analysis of precision data and performance of system accuracy test for ‘Point of Care’ test devices for HbA1c using ‘human blood samples’ in the month of January to March 2021.
- NIB scientist from Vaccine Laboratory has carried out the remote assessment for accreditation of South African National Control Laboratory for Biological products (SANCL) for ISO17025:2017, as a Technical expert for Oral Polio, Measles and Yellow Fever vaccine in the team assessors of the South African National Accreditation System (SANAS) on 2<sup>nd</sup> February, 2021.

## Visit of Dr. Ramesh K. Goyal, Vice Chancellor DIPSAR University



Dr. Ramesh K. Goyal, Vice Chancellor DIPSAR University, Delhi visited NIB on 22<sup>nd</sup> March 2021 along with his team to interact with senior scientists of the institute. He along with his fellow team members presented their various ongoing projects and the area of research in which they are presently focusing.

Also discussed the opportunities of mutual collaborations in the area of Quality Control of Biologicals between NIB and DIPSARU.

## Visit of Dr. Shekhar C Mande, Secretary, DSIR & DG-CSIR

Dr. Shekhar C Mande, Secretary, DSIR & DG-CSIR visited NIB on 25<sup>th</sup> March, 2021 and interacted with senior scientists of Institute. He addressed the scientists emphasizing on the role of scientific research in the development of an organization.



## "Change your thoughts, change your life".... An introductory workshop based on the philosophy of Louise Hay.

An introductory workshop has been conducted at NIB, NOIDA by Dr. Hitu Khera, Heal your Life Trainer on 17<sup>th</sup> & 18<sup>th</sup> March 2021.



## One Day Seminar on COVID-19 Vaccine: Trends & Challenge"

Vaccine and Antisera laboratory of NIB conducted a one day seminar on "COVID-19 Vaccine: Trends & Challenges" on 19th March 2021. In the seminar speakers from industry/ academia were invited to deliver a talk on above topic.



## TRAININGS

The hands-on training for 56 Blood Bank officials (28 Blood Transfusion Officers and 28 Blood bank Lab Technicians) of Haryana state from the Haryana State Blood Transfusion Council, Panchkula, under National Health Mission (NHM) was held from 18th March to 7<sup>th</sup> April 2021.



## HINDI RAJBHASHA WORKSHOP

Two one day Workshops on Hindi Rajbhasha was conducted at NIB, NOIDA on 5<sup>th</sup> and 31<sup>st</sup> March 2021.



## Activities Undertaken By Quality Management Unit

Quality Management Unit of NIB organised following lectures for the scientific staff of laboratories and animal facility:



*Harmonization of bioassay on 07.01.2021 by Dr. Harish Chander, S-I & Divisional Head*



*Measurement of uncertainty in quantitative estimation on 21.01.2021 by Ms. Ajanta Sircar, S-II & Head Biochemical Kit Laboratory*



*SOP preparation, SOP Review & Amendments and Document Control on 02.02.2021 by Ms. Rashmi Shrivastava, Scientist - III*



*Internal quality checks for assuring the quality of test results on 10.02.2021 by Ms. Gurminder Bindra, Scientist - III*

- Conducted Internal Audit of 13 laboratories/ units from 15<sup>th</sup> to 19<sup>th</sup> February 2021 as per the requirement of ISO/ IEC 17025: 2017.
- Conducted Virtual Training on Effective Implementation of ISO 45001:2018 Occupation Health & Safety Management System (OH&SMS), Documentation review and Updating for transition to ISO 45001:2018 OH&SMS to NIB staff from 08<sup>th</sup> to 10<sup>th</sup> March 2021, facilitated by FICCI Quality Forum (FQF), New Delhi.

## PUBLICATIONS

- Suresh Kumar\* and Perumal Nagarajan, “A Journey of Coronaviruses from Sporadic Outbreaks to COVID-19 Pandemic”, Coronaviruses (2020) 1:1. (<https://doi.org/10.2174/2666796701999201116212306>).
- Shikha Yadav, Atish Ghaware, Nakul Dev S Yadav, VP Singh, Pankaj Sharma. “A1  $\beta$ -Casein Variant of Cow Milk Exacerbates House Dust Mite Induced Allergic Airway Disease in Murine Model” International Journal of Biology, Pharmacy and Biological Sciences IJBPAS), 10 (1) 326-345 (2021).
- Harsha Rohira, Sujithra Shankar, Shikha Yadav, Sushmita G. Shah, Archana Chugh. Enhanced in vivo antifungal activity of novel cell penetrating peptide natamycin conjugate for efficient fungal keratitis management. International Journal of Pharmaceutics Volume 600, 2021, 12048.

# SUPERANNUATION



*Mr. S.K. Sharma, Deputy Director (Admin),  
superannuated from his services on 28<sup>th</sup> Feb, 2021*



*Mr. Ravi Dutt, Driver, superannuated  
from his services on 31<sup>st</sup> Jan 2021.*

NIB wishes them a happy and healthy life



*International Women's Day Celebration at NIB, NOIDA on 08.03.2021*

## **ACKNOWLEDGEMENT:**

**Newsletter Editorial Team acknowledges the contribution of all the staff members of NIB.**



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