

Details of the Technologies Developed

Keeping into consideration, recent COVID-19 crisis, the nominee's group has developed a novel herbal formulation Flunorm^R for successful treatment of this dreadful disease. The clinical trial of the Flunorm^R, against COVID-19 disease, highlights that beside helping the main drug therapy module, the newly developed formulation successfully helps in curtailing the complications associated with the SARS-CoV-2 delta strain infection. In fact, the nominee has been working in collaboration with several Indian pharmaceutical industries such as **Cadilla Pharmaceutical Ltd, Ahmedabad, Life Care Inc., New Delhi** and **Gennova Biopharmaceuticals Limited, Pune** to develop nano-particle based drug formulations. He has used not only liposomes as drug carriers but also exploited polymers (e.g. fibrin, PLGA etc) based-nano-particles to overcome the problems that are encountered by the liposomes in blood circulation. A number of patents with these companies are currently in the process of filing.

For the last thirty years, Dr. Owais is actively involved in the development of liposome-based formulations for the treatment of a range of infectious diseases such as fungal (candidiasis, cryptococcosis, aspergillosis), bacterial (tuberculosis, leprosy, salmonellosis), protozoal (leishmaniasis, malaria) nematodes (filariasis) and HIV infections (Owais *et. al*, 1993, Owais *et. al*, 1995, Owais *et. al* 1999, Khan *et. al* 2002, Khan, *et. al* 2003, Deeba *et. al*. 2005, Sharma, *et al* 2006, Sharad, *et al* 2006). He worked in collaboration with one of the world repute multi national Pharmaceutical Company, **Cadilla Pharmaceutical Ltd.**, Ahmedabad to develop Nano particle based drug formulation for treatment of opportunistic fungal infections under PRDSF program of Department of Science & Technology, Govt. of India. He has also developed liposome based antigen delivery vehicles, which can elicit strong immune response against model antigens in the animals (Owais & Gupta 2000, Nadeem *et. al* 2001, Nadeem *et. al* 2001, Owais *et. al*. 2001, Faisal *et. al* 2003, Farah *et. al*, 2005, Atif *et. al*, 2006, Sharad *et. al*, 2006].

The experience of applicant's research group in developing liposome/microsphere/niosomes based drug and antigen delivery systems is being currently exploited by some of the leading pharmaceutical and biotechnology companies to develop some novel drug formulations. **The nominee also promulgates the idea of**

administering suitable drug formulation along with immunomodulators to combat infectious diseases. In this regard, various liposome/microsphere/niosomes based antifungal formulations of Amp B, nystatin and azole have been developed. The coadministration of such drugs along with immunomodulators tuftsin, protein A, muramyl peptide *etc* has been found to exert tremendous increase in efficacy of antifungal drugs.

The RD antigen based vaccine against tuberculosis developed in applicant's lab is being evaluated by **Gennova, Pune** for its prophylactic potential. In another such project that is being run in collaboration with one of the renowned biotechnology company, Life Care, New Delhi, the nominee has developed liposome based formulations of some essential oils as well as other natural herbal products and in process of patenting these formulations.

Dr. Owais is also actively collaborating with some industries of **USA** to develop **nanoparticles based mouth fresheners**. The formulation is in final stage of trial and is likely to be launched in the market soon.

CLINICAL TRIAL ON FLUNORM, AN IN-HOUSE NOVEL FORMULATION, DEVELOPED BY NOMINEE'S RESEARCH GROUP, AT JN MEDICAL COLLEGE ALIGARH

F.No.-2-28015/26/2020-HPC (EMR)-AYUSH
Government of India
Ministry of AYUSH

2nd Floor, Office Block No. 3,
NBCC Office Complex,
Midway Nazim, New Delhi 110
Dated: 23rd June, 2020

To

Dr. Muhammad Owais, Professor, PhD (Biotechnology)
Department of TB and Chest Diseases,
JMMC, AMU, Aligarh-2
Email ID:

Sub: Project proposal submitted under EMR scheme of Ministry of AYUSH reg.

Sir/Madam,

The undersigned is directed to convey that your proposal titled "A Herbal composition named Flunorm™ for treating viral infections" was taken up in the 2nd Special Meeting of the Project Approval Committee (PAC) for SARS-CoV-2 Infection and COVID-19 held on 15th & 16th June, 2020 under EMR scheme. A copy of the minutes of the said PAC has already been sent to you vide mail dated 23.06.2020.

2. The decision of the above PAC is reproduced as under:

"Approved the project proposal to be completed in six months" since from the day of commencing just could subject to appropriate revision of the budget with details of contingency amount, submission of the IPC Clearance certificate and fulfillment of the conditions for proprietary formulation within 7 days."

3. You are therefore requested to submit the above mentioned information/documents to CMR Sectional the earliest.

Yours faithfully,


K.B. Shrivastava

Under Secretary to the Government of India
Emr@ayush.gov.in@gmail.com
Emr_ayush@yahoo.com

D.No.16/IEC
13-16



Institutional Ethics Committee (Regd.)
(Under Central Drugs Standard Control (CDSCO) Ministry of Health & Family Welfare, Govt. of India)
Jawaharlal Nehru Medical College & Hospital, Faculty of Medicine
Aligarh Muslim University, Aligarh U.P. India - 202 002

Prof. Mohammad Shameem
as, M.P.P (Gen.)
Member Secretary

Prof. (Retd.) M.R. Ajmal
as
Chairman

CERTIFICATE

A HERBAL COMPOSITION NAMED FLUNORM™ FOR TREATING
VIRAL INFECTIONS.

Members of Institutional Ethics Committee examined & approved the Project
proposal submitted by Dr. Mohammad Owais, Professor & Principal Investigator,
Interdisciplinary Biotechnology Unit AMU, and Co-Principal Investigators, Prof.
Zuber Ahmad, Department of TB and Chest Diseases, J.N. Medical College,
Faculty of Medicine AMU,


(Prof. Mohammad Shameem)
Member Secretary, IEC


(Prof. M.R. Ajmal)
Chairperson

MEMBER SECRETARY
Institutional Ethics Committee
Faculty of Medicine
AMU, Aligarh

CHAIRPERSON
Institutional Ethics Committee
Faculty of Medicine
AMU, Aligarh

Contact Details:
Prof. Mohammad Shameem (Member Secretary)
Department of Tuberculosis and Respiratory Diseases, J.N. Medical College, Aligarh Muslim University, Aligarh
Ph: 0571-272113 (01) Ext. 7084, Mob: 9422313253, Email: se@iec@amu.ac.in

Organizers: Theresa M Allen (terry.allen@ualberta.ca; Pieter R Cullis (pieterc@interchange.ubc.ca)

[illegible]

THE INFORMATION CONTAINED HEREIN IS UNCLASSIFIED DATE 08-19-2006 BY 60322 UCBAW

Dr. M. Owais
Professor, Interdisciplinary Biotechnology Unit
Aligarh Muslim University, Aligarh



सत्यमेव जयते

**Government of India
Ministry of Science and Technology
Department of Biotechnology**

PRESENTS

**NATIONAL BIOSCIENCE AWARD FOR
CAREER DEVELOPMENT 2007**

TO

**DR. OWAIS MOHAMMAD
ALIGARH MUSLIM UNIVERSITY, ALIGARH**

in recognition of his pioneering work in development of nano-particles based delivery systems such as virosomes for gene packaging, liposomes and microspheres for vaccine development, gene therapy vectors and drug delivery systems. He has developed liposome based antigen delivery vehicles, which can elicit strong immune response against model antigens in animals.

Given this Day, the 17th of March 2008 at the function organized in connection with the Foundation Day of the Department.

KAPIL SIBAL
MINISTER OF SCIENCE & TECHNOLOGY
AND EARTH SCIENCES



To Whom it may concern

This letter is my personal recommendation for Dr. Mohammed Owais. I have seen the profile of Dr. Owais very closely who holds a distinguished record from his Ph.D. days till today specifically in the area of development of liposome-based formulations for the treatment of a range of infectious diseases. His pioneering work in development of nano-particle based delivery systems such as virosomes for gene packaging, liposomes and microspheres for vaccine development, gene therapy vectors and drug delivery systems are being currently exploited by some of the leading pharmaceutical and biotechnology companies to develop some novel drug formulations. Dr Owais work in the area of liposomes technology and nanoparticle has been featured as a cover page by reputed International journals (Molecular Medicine & FEMS-Immunology and Medical Microbiology). He has also developed liposome based antigen delivery vehicles, which can elicit strong immune response against model antigens in animals. Dr. Owais is also currently propagating idea of administering suitable drug formulation along with immunomodulators to combat infectious diseases.

Cadila Pharmaceuticals Ltd., India has sought help of Dr. Mohammed Owais in development of nanoparticle based novel antifungal formulations for treatment of opportunistic fungal infections under the PRDSF program of DST, Govt of India. This product is likely to have great market value and the formulations have been found to impart tremendous increase in efficacy of the drugs. Presently Gennova is evaluating liposome based vaccine delivery options for human phase I clinical trial which have been developed at Dr. Owais lab.

On a personal note, I would like to mention that it has been a pleasure to know a scientist like Dr. Owais, who has developed applied science area so well within academic environment. I wish him all the success in his endeavors and he may add more laurels to his illustrious career.

Yours Sincerely,

A handwritten signature in blue ink, appearing to read "Sanjay Singh".

Sanjay Singh, Ph.D.

Chief Executive Officer

Gennova Biopharmaceuticals Limited

Plot No.: P-1, I.T. – B.T.Park, Phase – II, M.I.D.C., Hinjwadi, Pune – 411 057 (India) Phone Nos.: + 91 20 39821300 Fax: 91 20 – 39821441

Agreement for (re-)use of an illustration



June 10, 2005

Dr. Mohammad Owais
A.M. University - Int. Biotech. Unit
Int. Biotech. Unit,
AMU, Aligarh,
India Aligarh
U.P. 202002

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E fems@fems-microbiology.org
I www.fems-microbiology.org

Dear Dr. Mohammad Owais

Co-administration of Immunomodulator tuftsin and Liposomalised nystatin can combat less susceptible *C. albicans* infection in temporarily neutropenic mice / FEMSIM 41 (2004) 249-258

Your above-detailed article was recently published in FEMS Immunology and Medical Microbiology.

FEMS Publications Office is presently preparing the new cover for the Journal FEMS Immunology and Medical Microbiology for 2006 and would like to use Figure 1b from your article on the cover. The image accompanied by the legend would be used for all issues of FEMS Immunology and Medical Microbiology in 2006 and appear in miniature on the FEMS website and publisher's website. In addition, our publisher may use the cover for marketing purposes.

We understand that you are the copyright holder for this image. If you allow us to use the image, possibly with alterations to complement the cover design, could you please sign a copy of this agreement letter and send it to my attention, confirming that we may use the illustration as indicated, in both print and electronic versions of the Journal.

Please return the signed original of this letter by mail or fax, retaining a copy for your own files, to:

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Tel: +31-15-269 3931
Fax: +31-15-269 3921

Thank you for your assistance.
Yours sincerely,

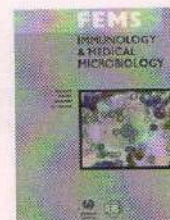
Dr Alenka Princić
FEMS Editorial Coordinator



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Signed.....

Date.....



Aligarh Muslim University, Aligarh



Republic Day Celebrations – 2009

Certificate of Outstanding Merit

This is to certify that Prof./Dr/Mr./Ms. *Mohd Qwais Lecture*
Department of *Inter. Biotech Unit* is awarded *Outstanding* Certificate
of Honour for bringing laurels to the University and is felicitated in a Public Meeting held on the
auspicious occasion of the 60th Republic Day.

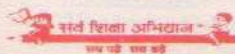
V.K.
Prof. V.K. Abdul Jaleel
Registrar, AMU Aligarh

Date: 26 January 2009



भारत सरकार
विज्ञान और प्रौद्योगिकी मंत्रालय
विज्ञान और प्रौद्योगिकी विभाग
टेक्नोलॉजी भवन, महरौली रोड
नई दिल्ली 110016

GOVERNMENT OF INDIA
MINISTRY OF SCIENCE AND TECHNOLOGY
DEPARTMENT OF SCIENCE AND TECHNOLOGY
TECHNOLOGY BHAWAN, NEW MEHRAULI ROAD
NEW DELHI-110016



Dr. G.J. SAMATHANAM
Advisor/Scientist-G
06/TDT
Telefax : 011-26862512
Phone : 011-26590367
Email : samathan@nic.in

D O No.

VII-PRDSF/103/05-

Date:

22.06.2007

Dear Dr. Owais,

I am forwarding herewith the minutes of the first year monitoring committee meeting of the project titled "Evaluation of Tuftsin-bearing polyene nanoparticles in combating some systemic murine fungal infections" among Aligarh Muslim University, Aligarh / M/s Cadila Pharmaceuticals Ltd., Ahmedabad held on 18.06.2007 at Ahmedabad for favour of your information & compliance. As and when you receive the industry contribution the same may be communicated to us for taking action to release DST share. Please ensure the observations of the monitoring committee during the second year so that you are able to contribute still more.

With kind regards,

Yours sincerely,

(G.J. Samathanam)

✓ Dr. Owais Mohammed,
Senior Lecturer,
Interdisciplinary Biotechnology Unit,
Aligarh Muslim University,
Aligarh-202002

Copy to:

1. Dr. Rajiv I. Modi, Managing Director, M/s Cadila Pharmaceuticals Ltd., "Cadila Corporate Campus", Sarkhej - Dholka Road, Bhat, Ahmedabad - 382 210.
2. Dr. Bakulesh M. Khamar, Executive Director - Research, M/s Cadila Pharmaceuticals Ltd., "Cadila Corporate Campus", Sarkhej - Dholka Road, Bhat, Ahmedabad - 382 210 - with a request to consider the release of Cadila's second year contribution to AMU as recorded in the minutes. Please take action on the issues industry has to provide information to DST.
3. Shri V.K. Sharma, Advisor (Corporate Affairs), Cadila Pharmaceuticals Ltd., D-1011, New Friends Colony, New Delhi - 110 065

(G.J. Samathanam)

डॉ. जी.जे. समथानम/Dr.G.J.SAMATHANAM
वैज्ञानिक 'जी' / Scientist 'G'
विज्ञान और प्रौद्योगिकी विभाग / Deptt. of Science & Tech
टेक्नोलॉजी भवन / Technology Bhawan
नया महरौली रोड, नई दिल्ली-110016
New Mehrauli Road, New Delhi-110016

Biotechnology in the Service of Humanity

Message

Biotechnology is a frontier area of science with a high promise for the welfare of humanity. New generation of biotechnology developed as a result of intensive work in India has opened up a vast area of research and development. I am confident that fruits of biotechnology would be harvested for the benefit of millions of our poor people as we move into the next millennium.

Atal Bihari Vajpayee
(Atal Bihari Vajpayee)
Prime Minister



Message

India is well poised to leaping towards a bio-industrial development by conserving and using the precious biodiversity of the country on a sustainable basis with the application of biotechnological tools.

Dr. M. M. Manohar Joshi
Minister for HRD & Science and Technology

Significant Achievements

- A novel targeted gene delivery system dedicated for liver cells developed and patented in U.S.
- Identification of a mutation conferring resistance to HIV infection in Indian population.
- Cloning and sequencing of atleast six genes achieved, specially the seed storage, amino acids, biosynthetics and genes for plant defence, for enhancing the nutritional quality. A US patent granted for the seed storage protein gene.
- Plant tissue culture established as an industrial activity. 45 lakh plants of forest and horticulture species field planted in 4000 ha.; 40% increase in yield achieved in tissue cultured cardamom plants.
- Bioremediation and desulphurisation technologies perfected and transferred to industry, bioremediation field tested for wastewater recovery.
- Transgenic silkworm with luciferous genes can act as a bio-factor for producing proteins of agricultural and therapeutic importance.
- Biofertilizers and biopesticides formulations demonstrated on large scale in farmers' field; production units set up.
- 1000 genetically superior calves born through Embryo Transfer Technology (ETT), including 100 buffalo calves.
- Specific primers developed for sex determination of embryos; being used as a customised service for farmers.
- Record production of over 10 tonnes/ha/year in two crops of pawns through semi-intensive aquaculture attained.
- Through intensive carp farming production level of 18 tonnes/ha/year achieved.
- First indigenous recombinant vaccine strain for oral cholera, VA 1.3 and Rotaviral diarrhoea enter clinical trials.
- Three indigenous test systems perfected for detection of HIV-1 and II, and Streptococcal infections, transferred to industry.
- Low cost nutritious food supplement for the school children being produced.
- Liposome incorporated Amphotericin B, a drug for curing systemic fungal infections and leishmaniasis commercialised.
- Skin culture technology for burn, new vitiligo, cord blood and bone marrow preservation technologies transferred to hospitals.
- Centres for DNA Fingerprinting, Plant Genome, Brain Research, a Golden Jubilee Women's Biotechnology Park and a Biowillage being established.
- Human resource development in 17 States and UTs; produced about 4000 trained students.
- A wide spread bioinformatics network with INTERNET based Biotechnology Service Provider established.
- Large number of biotechnology based programmes to benefit rural population, SC/ST and women successfully conducted.

Department of Biotechnology, Ministry of Science and Technology

Various nanoparticle based novel formulations

developed by nominee's group

1. Immunoliposomes: Chloroquine bearing immunoliposomes decorated with Mab specific for surface of infected erythrocyte (Antimicrob Agents & Chemother 1995)
2. DNA delivery vehicle: The Brucella SOD protein expressing DNA was encapsulated in liposome and used as DNA vaccine for prophylaxis against brucellosis (Microbes & Infection 2009, Plos One 2014)
3. Tuftsin bearing Amphotericin B liposome: Immunomodulator tuftsin bearing Amp B liposomes for treatment of aspergillosis, candidiasis and cryptococcosis (FEMS 2005, JDT 2004).
4. pH sensitive liposomes: pH sensitive liposome for treatment of fibrosarcoma (Molecular Medicine 2007)
5. **Tuftsin bearing Amphotericin B niosomes**: Tetrapeptide tuftsin was intercalated in the bilayer of AM B containing niosomes. The formulation was used for treatment of fungal infection (Cadila Pharmaceuticals, Ahmedabad).
6. Tuftsin bearing Amphotericin B microspheres: The PLGA microspheres were grafted with tuftsin to activate macrophages. The formulation was used in treatment of fungal infections (Cadila Pharmaceuticals, Ahmedabad).
7. Non PC liposomes: Various liposome using non PC phospholipid were develop to develop novel antigen delivery system (Vaccine 2006).
8. **Saccharosome**: Lipid isolated from *Saccharomyces cerevisiae* were used to develop antigen delivery system (Vaccine 2009).
9. **Escheriosome**: The fusogenic lipids abundant in *Escherichia coli* were used to develop escheriosome based antigen delivery system the formulation was used to develop vaccine against murine malaria in model animal (Vaccine 2003, Nanomedicine 2014).
10. **Erythrosome**: The lipid isolated from human erythrocytes were used for development of antigen delivery system. Both inside out as well right side out vesicles were also exploited for homing of entrapped antigen to the antigen presenting cells (BBA 2005).

11. Subtilosme: The lipid isolated from *Bacillus subtilis* was used in development of novel vaccines (BBA 2005).
12. Spermatosome: The potential of sperm to transfer encapsulated genetic material was further exploited to deliver encapsulated antigen to the target cells (Febs Letters 2006, Vaccine 2008).
13. Archaeosome: The lipid isolated from archae-bacteria was used in development of antigen delivery system. The formulation was used in prophylaxis against listeriosis and experimental tuberculosis.
14. Fibrin microbeads: Autologous plasma was used to fabricated plasma beads that were used in prophylaxis and chemotherapy of fungal infections (JDT 2012, Therapeutic Delivery 2011, Vaccine 2013, IJMM; 2015).
15. 5-FU nanoassemblage: Biomimetic synthesis of 5-FU nano-particles (Plos One 2013)
16. Amphotericin B nanoassembly: The antifungal agent was biomimetically transformed to nano-crystals (Ph D thesis Dr. Zia)
17. Poly glutamic acid nano-particles: Gama PGA based solid nano-particles were fabricated to various immunogenic antigens and antifungal agents (IJN 2014).
18. Essential oil bearing liposomes: Various essential oil bearing liposomes were developed to facilitate targeted delivery (JDT 2004).
19. Essential oil bearing microspheres: Perillyl alcohol, allyl sulphide derivatives of garlic were used for development of anticancer formulations (IJN 2013, Molecular Medicine 2007, Nanomedicine 2013)
20. siRNA bearing nano-particles: Fox-P3 and Plk-1 specific siRNA formulations were developed to treat various types of cancer in model animals (Plos One 2014).
21. Fatty acid based anticancer agents and their nano-particle based formulations: Propofol-fatty acid conjugates were encapsulated in nano-particles to treat breast and liver cancer (Nanomedicine 2013, EJMC 2012).

B. Biosensors:

1. **Gold immuno-nanoparticles:** Antibody conjugated gold nano-particles were fabricated to detect various types of cancer (IJN 2011).
2. **Bispecific antibodies:** Hybridization based bispecific antibodies were developed to detect food borne pathogens (Plos One 2014)

Details of the Technologies Developed

The nominee has been helping several Indian pharmaceutical industries such as Cadilla Pharmaceutical Ltd (Amphotericin B), Ahmedabad; Life Care, New Delhi (DAS, Perillyl alcohol, Eugenol etc.) and Gennova Biopharmaceuticals Limited, Pune (Doxorubicin) in development of nano-particle based drug formulations. He has used lipid as well as other polymers (e.g. fibrin, non-ionic surfactant, PLGA etc) based-nano-particles to overcome the problems that are encountered by the liposome based delivery systems in blood circulation. A number of patents in collaboration with these companies have been filed.

Various nanoparticle based novel formulations developed by nominee's group

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Significant Research contribution at the international level

Dr. Mohammad Owais is currently serving as a professor of biotechnology at Aligarh Muslim University, Aligarh. Besides active involvement in teaching

modern biochemistry/biotechnology courses to M.Sc./Ph.D. students, Dr. Owais has successfully established a small but active research group with focus on nano-particle-based novel delivery systems including dendrimers/virosomes for gene packaging and liposomes, niosomes, microspheres and solid core lipid nano-particles for vaccine delivery, gene delivery, targeted drug delivery *etc*; with a view to increase the efficacy and safety of encapsulated chemo-therapeutic agents/sub-unit vaccines for some important infectious diseases.

The research focus of Dr. Owais's group has been on:

- ❖ Nanoparticles based antigen/DNA vaccine against various infectious diseases with special converges on intracellular pathogens.
- ❖ Novel nano-carriers for targeted delivery of encapsulated therapeutic agents (siRNA/drug of interest) for improved treatment of cancer and some imperative infectious diseases.
- ❖ Nanoparticles with assorted applications in the field of diagnostics, taste/odor masking and treatment of hyper-bilirubinemia in model animals.