STriTuVaD press note

STriTuVaD consortium meeting lays down the foundations for a fruitful EU-India cooperation in the fight against Tuberculosis

New Delhi, 23 January 2019

The Horizon 2020[1] project STriTuVaD (In Silico Trial for Tuberculosis Vaccine), a consortium of European, American and Indian entities, held its Inauguration and Investigators meeting in New Delhi, India on 23 January in the presence of Indian and European authorities. The meeting was hosted by the All India Institute of Medical Sciences (AIIMS) who is the Indian lead scientific in this project. The project is funded by the European Commission through the H2020 programme and by DBT, the Department of Biotechnology of the Indian Ministry of Science & Technology.

The meeting was a good occasion to present the objectives of the project and how it came about. It showed how important international cooperation is to address health concerns in India which in turn could become a global challenge.

Dr Balram Bhargava, Director-General of the Indian Council of Medical Research (ICMR), gave an overview of research done at national level, to address the TB burden India is facing. He had high expectations in this international consortium for finding rapidly and at affordable conditions a vaccine. Professor Dipendra K. Mitra, outlined how the data for the clinical trials would be collected and Dr Guleria gave an overview on the capacity at AIIMs on TB vaccine trials. Professor Marco Viceconti (Bioengineering at the University of Bologna) stressed the importance of In Silico Trials, whose development is the main aim of the STriTuVaD project.

Both Dr Reinhard Glueck, representative of Zydus Cadila, Chairman of Etna Biotech coordinator of the STriTuVaD project, and Ms Tania Friederichs, Head of Research and Innovation Section at the EU delegation to India, underlined the importance of international cooperation. For Dr Glueck, who knows well the Indian scientific community, this project is responding to a real need and has the capacity to take up a challenge which many still think is not possible: finding a vaccine for TB. With this project, and thanks to new technologies, we can say that at least we try the impossible. Ms Friederichs welcomed very much that through joined efforts, Europe and India are engaged together in one project, including both Academia and Industry. This was a good illustration of Europe's commitment to addressing global challenges: as Professor Viceconti just illustrated, due to increased mobility of persons, a pandemic is never to be excluded. She thanked the Department of Biotechnology to have co-funded the Indian partner AIIMS. Ms Friederichs also recalled that the European Research and Innovation programme 'Horizon 2020', was open to the world. She expressed hope that after this first success project, more international cooperation on health, or any other area of mutual interest to India and Europe, will follow: "*Our doors are widely open to India"*.

After the opening addresses, the consortium members presented the work in the project, to begin with by Dr Epifanio Fichera from Etna Biotech who is the coordinator and who stressed importance to deliver the work according to agreed timelines to ensure a smooth implementation of the project. Prof. Francesco Pappalardo (Dept. of Drug Sciences at the

[1] The eighth Framework Programme for Research and Technological Development, named "Horizon 2020", is funding programmes created by the European Commission to support and foster research in the European Research Area (ERA).

University of Catania), Dr. Miguel Juarez (Lecturer of Maths & Statistics at the University of Sheffield, UK), Prof Anant Mohan (Dept. of Pulmonary Medicine, AIIMS), Dr Corey Casper (Chief Scientific Officer at IDRI), Olga Rué and Dr. Pere-Joan Cardona (respectively CEO and Scientific and Clinic advisor of Archivel Farma) elaborated on how they plan the work to come to a collective success.

At the end of two days of work, the consortium emerged with a solid plan for the execution of the clinical trial where two new therapeutic vaccines developed respectively by Archivel Farma and IDRI will be tested. The trial will also be used to quantify the predictive accuracy of the UISS computer model developed by Prof. Pappalardo, capable of predicting the individual response of patients with active TB when treated with new therapies. This information will be essential in the future regulatory qualification on these in silico trials methods, which we hope will speed up and reduce the costs for the development of more effective therapies for this deadly disease[2].

[2] In 2017 more than 10 million cases of active TB were reported worldwide, which resulted in 1.6 million deaths; of these around 220,000 were reported India. Source: "Global tuberculosis report". World Health Organization.

From Top left, to bottom right: Reinhard Glueck and Tania Friederichs; Salil Mitra; Tania Friederichs, Balram Bhargava, Reinhard Glueck, Randeep Guleria; Tania Friederichs; Randeep Guleria, Tania Friederichs, Balram Bhargava.

About STRITUVAD:

Acronym: STriTuVaD

Title: In Silico Trial for Tuberculosis Vaccine Development

Project ID: 777123

Funded by the European Commission under H2020-EU.3.1.5. - Methods and data

Duration: From 2018-02-01 to 2022-07-31

Total cost: EUR 5 050 656,25 (plus co-fund from DBT)

Consortium:

- ETNA BIOTECH SRL, Italy
- UNIVERSITÀ DEGLI STUDI DI CATANIA, Italy
- THE UNIVERSITY OF SHEFFIELD, United Kingdom
- ARCHIVEL FARMA, SL, Spain
- STICHTING TUBERCULOSIS VACCINE INITIATIVE, Netherlands
- INFECTIOUS DISEASE RESEARCH INSTITUTE, United States
- THE ALL-INDIA INSTITUTE OF MEDICAL SCIENCES, India
- ALMA MATER STUDIORUM – UNIVERSITY OF BOLOGNA, Italy

About the partner institutions

The University of Sheffield

With almost 29,000 of the brightest students from over 140 countries, learning alongside over 1,200 of the best academics from across the globe, the University of Sheffield is one of the world's leading universities.

A member of the UK's prestigious Russell Group of leading research-led institutions, Sheffield offers world-class teaching and research excellence across a wide range of disciplines.

Unified by the power of discovery and understanding, staff and students at the university are committed to finding new ways to transform the world we live in.

Sheffield is the only university to feature in The Sunday Times 100 Best Not-For-Profit Organisations to Work For 2017 and was voted number one university in the UK for Student Satisfaction by Times Higher Education in 2014. In the last decade it has won four Queen's Anniversary Prizes in recognition of the outstanding contribution to the United Kingdom's intellectual, economic, cultural and social life.

Sheffield has six Nobel Prize winners among former staff and students and its alumni go on to hold positions of great responsibility and influence all over the world, making significant contributions in their chosen fields.

Global research partners and clients include Boeing, Rolls-Royce, Unilever, AstraZeneca, Glaxo-SmithKline, Siemens and Airbus, as well as many UK and overseas government agencies and charitable foundations.

To read other news releases about the University of Sheffield, visit
http://www.shef.ac.uk/news

The Insigneo Institute for *in silico* Medicine

The Insigneo Institute for in silico Medicine is a collaborative initiative between the University of Sheffield and Sheffield Teaching Hospitals NHS Foundation Trust. It is a multidisciplinary collaboration between over 150 academics and clinicians to develop computer simulations of the human body and its disease processes that can be used directly in clinical practice to improve diagnosis and treatment.

In silico medicine (also known as "computational medicine") is the application of in silico research to problems involving health and medicine. It is the direct use of computer simulation in the diagnosis, treatment, or prevention of a disease. More specifically, in silico medicine is characterised by modelling, simulation, and visualisation of biological and medical processes in computers with the goal of simulating real biological processes in a virtual environment. This is almost certainly the most sophisticated application of computing technology in healthcare, and Sheffield has become the UK's principal centre for this work. Insigneo performs cutting-edge research in areas of fundamental and applied biomedical modelling,

imaging and informatics, as it pursues the research agenda of the Virtual Physiological Human initiative.

The Institute's work will bring about a transformational change in healthcare through multidisciplinary collaborations across many strategic areas, which will include personalised diagnosis and treatment and improvements in independent, active and healthy ageing. For more information please visit: www.insigneo.org or contact news@insigneo.org.

The University of Catania

The University of Catania was founded in 1434. Today it is one of the Italy's largest universities with 17 Departments and 2 Didactic Units, about 50000 students and about 1400 professors and researchers (www.unict.it/en).

The Department of Drug Sciences main activities are higher education and research in drug design, biochemistry and related topics (http://www.unict.it/en/drug-sciences).

Inside the Department, the Computational Systems Biomedicine Research Group (COMBINE) drives the research in applying computational methodologies to the field of biomedicine.

The goal of the group is to develop computational/mathematical models for better understanding of biomedical processes and design of new experiments. The expertise ranges from computational models based on cellular automata and agents to equation based models.

The modeling framework developed by the COMBINE group has been extensively used to model the immune response elicited by vaccines and immunotherapies against various diseases, including cancers.

TuBerculosis Vaccine Initiative

The TuBerculosis Vaccine Initiative (TBVI) is a non-profit foundation that facilitates the discovery and development of new, safe and effective TB vaccines that are accessible and affordable for all people. TBVI integrates, translates and prioritises R&D efforts to discover and develop new TB vaccines and biomarkers for global use. TBVI provides essential services that support the R&D efforts of its consortium partners – 50 partners from academia, research institutes and private industry in the TB vaccine field. These services include project identification, design and development; project management; resource mobilisation; knowledge development, exchange and networking; and technical advice and support for product and clinical development. www.tbvi.eu

Alma Mater Studiorum - University of Bologna

The University of Bologna, founded in 1088, is the oldest university in continuous operation, as well as one of the leading academic institutions in Italy and Europe. It is one of the most prestigious Italian universities, commonly ranking in the first places of national rankings. It was the first place of study to use the term universitas for the corporations of students and masters, which came to define the institution located in Bologna, Italy. The University's crest carries the motto Alma mater studiorum and the date A.D. 1088, and it has about 86,500 students in its 11 schools. It has campuses in Ravenna, Forlì, Cesena and Rimini and a branch center abroad in Buenos Aires, Argentina. It also has a school of excellence named Collegio Superiore di Bologna. In the STriTuVaD project it

participates with the **Department of Industrial Engineering**, which is active in research, and provides education in different fields of Engineering: Aerospace, **Biomechanics**, Power, Management, Mechanical, Nuclear, Technical Physics, and Metallurgy. The Biomechanics Group is led by Prof Luca Cristofolini and Prof Marco Viceconti, who is a world-class specialist in in silico trials. http://www.unibo.it.

Archivel Farma

Archivel Farma is a biotechnology R&D company that develops immunotherapeutic agents to respond to uncovered medical needs. It is currently developing the RUTI® vaccine for the treatment of tuberculosis which is in a phase II clinical trial. http://archivelfarma.com/.

All India Institute of Medical Sciences, New Delhi

Creating a country imbued with a scientific culture was Jawaharlal Nehru's dream, and immediately after independence he prepared a grand design to achieve it. Among the temples of modern India which he designed, was a centre of excellence in the medical sciences. Nehru's dream was that such a centre would set the pace for medical education and research in Southeast Asia , and in this he had the wholehearted support of his Health Minister, Rajkumari Amrit Kaur.

The health survey and development committee, chaired by Sir Joseph Bhore, an Indian Civil Servant, had in 1946 already recommended the establishment of a national medical centre which would concentrate on meeting the need for highly qualified manpower to look after the nation's expanding health care activities. The dreams of Nehru and Amrit Kaur and the recommendations of the Bhore Committee converged to create a proposal which found favor with the government of New Zealand. A generous grant from New Zealand under the Colombo Plan made it possible to lay the foundation stone of All India Institute of Medical Sciences (AIIMS) in 1952.The AIIMS was finally created in 1956, as an autonomous institution through an Act of Parliament, to serve as a nucleus for nurturing excellence in all aspect of health care.

All-India Institute of Medical Sciences was established as an institution of national importance by an Act of Parliament with the objects to develop patterns of teaching in Undergraduate and Post-graduate Medical Education in all its branches so as to demonstrate a high standard of Medical Education in India; to bring together in one place educational facilities of the highest order for the training of personnel in all important branches of health activity; and to attain self-sufficiency in Post-graduate Medical Education.

The Institute has comprehensive facilities for teaching, research and patient-care. As provided in the Act, AIIMS conducts teaching programs in medical and para-medical courses both at undergraduate and postgraduate levels and awards its own degrees. Teaching and research are conducted in 42 disciplines. In the field of medical research AIIMS is the lead, having more than 600 research publications by its faculty and researchers in a year. AIIMS also runs a College of Nursing and trains students for B.Sc.(Hons.) Nursing post-certificate) degrees.

Twenty-five clinical departments including four super specialty centers manage practically all types of disease conditions with support from pre- and Para-clinical departments. However, burn cases, dog-bite cases and patients suffering from infectious diseases are not entertained in the AIIMS Hospital. AIIMS also manages a 60-bedded hospital in the Comprehensive Rural Health Centre at Ballabgarh in Haryana and provides health cover to about 2.5 lakh population through the Centre for Community Medicine. https://www.aiims.edu/en.html

IDRI

The Infectious Disease Research Institute is a non-profit organization based in Seattle, in the United States, and which conducts global health research on infectious diseases. Founded in 1993 by Prof Steve Reed, IDRI technologies are used worldwide for the diagnosis of leishmaniasis, Chagas disease and leprosy. They are now exploring the therapeutic use of their ID93 vaccine for TB.