



## National Chemical Laboratory

(Council of Scientific & Industrial Research)

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### Publication and Science Communication Unit

Press release

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#### **CSIR-NCL and DST sign an agreement with Lupin for the development of a continuous manufacturing process for biosimilar monoclonal antibody therapeutic**

CSIR-National Chemical Laboratory (CSIR-NCL, Pune) and Department of Science and Technology (DST, New Delhi) signed a research collaboration agreement with Lupin Ltd. for a continuous purification process development of a biosimilar monoclonal antibody therapeutic.

Monoclonal antibodies represent the most important biopharmaceutical product class, serving the high-demand treatment area of immuno-oncology diseases. With an increasing demand for biosimilar therapeutics and an ever-increasing pressure for manufacturing cost reduction with quality maintenance, the biopharmaceutical industry is showing keen interest in the development of continuous manufacturing processes. All unit operations in existing manufacturing processes are currently performed in a batch mode with an overall process recovery limiting to 40-50%. Existing purification platforms for biosimilar mAb therapeutics involve an integration of two to three offline controlled chromatography processes which severely limits the throughput and yield of the target therapeutic product. Additionally, in comparison to the innovators drug manufacturing processes, biosimilar manufacturers also have the compulsion to match the purity profile to innovator drug molecule thereby limiting the performance of the conventional batch manufacturing processes.

Through this research collaboration, CSIR-NCL and Lupin Ltd. would collaboratively work towards the development of a novel continuous purification process for manufacturing a biosimilar monoclonal antibody therapeutic (mAb). The process development team of CSIR-NCL lead by Dr. Rahul Bhambure will work in collaboration with the team of Lupin for developing the target process, said Prof. Ashwini Kumar Nangia, Director, CSIR-NCL. Biopharmaceuticals, biologics and monoclonal antibodies are next wave of discovery and innovation in new pharmaceuticals. This early research collaboration between industry and CSIR institute is expected to yield rich dividends for the country.

Speaking about the partnership, Dr Rustom Mody, Senior Vice President and Head – R&D, Biotechnology, Lupin said, “Biotech is one of Lupin’s key growth drivers and we are committed to advancing our biotech R&D capabilities through strategic partnerships. Our collaboration with a premier CSIR institution is an exemplary industry-academia collaboration that can help further the development and commercialization of biologics and biosimilars for a better and more affordable healthcare to customers across the globe”.

Prof. Ashwini Kumar Nangia, DST representative Dr. C. Rajadurai and Dr. Rustom Mody signed the agreement in presence of respective teams on Feb 6, 2018.



Prof. Ashwini Kumar Nangia (Middle) exchanges agreement document with Dr. Rustom Mody (Left) in presence of Dr. C. Rajadurai (Right)

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**Notes to Editor:**

**CSIR-National Chemical Laboratory** (CSIR-NCL, <http://www.ncl-india.org>), Pune, India is a research, development and consulting organization with a focus on chemistry and chemical engineering. It has a successful record of research partnership with the industry. NCL is a flagship laboratory of the Council of Scientific & Industrial Research (CSIR, [www.csir.res.in](http://www.csir.res.in)) which is the largest network of publicly funded research institutes in India.

**Lupin** ([www.lupin.com](http://www.lupin.com)) is an innovation led transnational pharmaceutical company developing and delivering a wide range of branded & generic formulations, biotechnology products and APIs globally. The Company is a significant player in the Cardiovascular, Diabetology, Asthma, Paediatric, CNS, GI, Anti-Infective and NSAID space and holds global leadership position in the Anti-TB segment.

**Drugs & Pharmaceutical Research Programme** (DPRP <http://dst.gov.in/drugs-pharmaceutical-research>) is a programme on drug development mounted by Department of Science and Technology (DST), Government of India during 1994-95 to promote collaborative R&D in drugs and pharmaceuticals sector with specific objectives to synergise the strengths of publicly funded R&D institutions and Indian Pharmaceutical Industry.