Press Release

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Lupin signs an agreement with CSIR-NCL and DST for the development of a continuous manufacturing process for biosimilar monoclonal antibody therapeutic (mAb)

Pune, March 8, 2018: Pharma major Lupin today announced the signing of an agreement with CSIR-National Chemical Laboratory (CSIR-NCL, Pune) and Department of Science and Technology, (DST, Delhi) for conducting research on 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 of 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 institution like CSIR is an exemplary industry-academia collaboration that can further the development and commercialisation of biologics and biosimilars for a better and more affordable healthcare to customers across the globe.”

Prof. Ashwini Kumar Nangia, Director, CSIR-NCL, Dr. C. Rajadurai, DST representative and Dr. Rustom Mody, Senior Vice President and Head, R&D, Biotechnology, Lupin signed the agreement in presence of respective teams.

About Lupin Limited

Lupin 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.

Lupin is the 11th and 7th largest generics pharmaceutical company by market capitalization (December 31st, 2017, Bloomberg) and revenues (September 30th, 2017, Bloomberg LTM) respectively. The Company is the 4th largest pharmaceutical player in the US by prescriptions (IQVIA MAT December 2017); 2nd largest Indian pharmaceutical company by global revenues (September 30th, 2017, Bloomberg LTM); 6th largest generic pharmaceutical player in Japan and 5th largest company in Indian Pharmaceutical Market (IQVIA MAT December 2017).

For the financial year ended 31st March, 2017, Lupin's consolidated sales and Net profit stood at Rs. 171,198 million (USD 2.55 billion) and Rs. 25,575 million (USD 381 million) respectively. Please visit http://www.lupin.com for more information. You could also follow us on Twitter - www.twitter.com/lupinglobal

CIN: L24100MH1983PLC029442 Registered Office: Lupin Ltd, 3rd Floor, Kalpataru Inspire, Off Western Express Highway, Santacruz (East), Mumbai 400 055.

About National Chemical Laboratory

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) which is the largest network of publicly funded research institutes in India.

About Drugs & Pharmaceutical Research Programme

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.

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