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Biocon and Quark Pharmaceuticals, a leader in the discovery and development of novel RNA interference (RNAi)-based therapeutics, announced the randomization of the first patient in India in the pivotal global Phase II/III study of QPI-1007, a novel siRNA (small interfering RNA) drug candidate for ocular neuroprotection.

Biocon and its partner, Quark Pharmaceuticals, have received approval from the Drug Controller General of India (DCGI) to proceed with the study, the first ever clinical trial of a siRNA therapy in India.

The QRK207 study will determine the effect of QPI-1007 on visual function in subjects with acute non-arteritic ischemic optic neuropathy (NAION), which is a rare ocular disorder with an unmet need globally. This is part of a global Phase II/III study run by Quark in collaboration with "Neuro-Ophthalmology Research Disease Investigator Consortium" (NORDIC) and is already enrolling in the US and a number of other countries.

Biocon Chairperson & Managing Director Kiran Mazumdar-Shaw said, "Biocon is committed to develop innovative therapies that address unmet medical needs and the initiation of the Phase II/III study investigating QPI-1007 in NAION in India is an important step towards this goal. India has a significant NAION patient population and we are pleased to be the first biopharma company in the country to provide an siRNA-based therapy that is likely to benefit thousands of patients who either have no access to treatment or cannot afford it."

"siRNA therapeutics is a new class of breakthrough medicines, with the potential to revolutionize drug development and offer therapeutic precision and widespread applicability and we are delighted to initiate QRK207 in India in this multi-national study to seek a treatment for NAION, a debilitating condition," stated Dr Daniel Zurr, chairman and CEO of Quark. "QPI-1007 represents a novel therapeutic strategy for treating NAION and future plans are to develop it for additional optic neuropathies, including glaucoma, which, similar to NAION, are characterized by the death of retinal ganglion cells."

"It takes strong partnerships to translate novel science into commercial therapies to help people and we are extremely pleased to have partnered with Biocon, an innovative company best positioned to lead the siRNA based drug class development in India," added Dr Zurr.

Biocon and Quark Pharma had entered into a licensing and collaboration agreement in 2013 to co-develop, manufacture and commercialize QPI-1007 in India and other key markets.