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Glenmark Pharmaceuticals S.A., a wholly owned Swiss subsidiary of Glenmark Pharmaceuticals Ltd., announced today that GBR 900, a novel monoclonal antibody is entering human trials. GBR 900 targets TrkA, a receptor for nerve growth factor (NGF) involved in chronic pain signaling.

In 2010, Glenmark gained an exclusive worldwide license from Lay Line Genomics S.p.A. (Italy) for anti-TrkA antibodies and their entire intellectual property portfolio in the TrkA field. GBR 900 is the optimized anti-TrkA antibody emerging from this exclusive worldwide license. Glenmark has now completed the Phase I enabling preclinical development programme for GBR 900 and has filed a Phase I clinical trial application with the MHRA, UK. GBR 900 is the first anti-TrkA monoclonal antibody to enter clinical development.

TrkA is the pain-signalling receptor for NGF. Monoclonal antibodies directed against NGF represent one of the rare clinical breakthroughs in chronic pain treatment and have shown excellent clinical activity in inflammatory and neuropathic pain. Unfortunately, development of the class has been curtailed due to suspected toxicity.

In the GLP toxicity studies no dose limiting toxicities were detected with GBR 900, even at high doses tested. This potentially differentiates GBR 900 from anti-NGF antibodies which are dose limited in clinical studies by preclinical toxicity findings at low doses.

Preclinical head to head comparisons with anti-NGF antibodies in animal models of inflammatory pain demonstrated that GBR 900's efficacy profile compares favorably with anti-NGF antibodies.

Commenting on the progress with GBR 900, Dr. Michael Buschle, president of Biologics and chief scientific officer, Glenmark Pharmaceuticals Ltd. said: "Since we licensed the TrkA IP from Lay Line Genomics we have been able to differentiate GBR 900 from anti-NGF antibodies. We are very excited about the Phase I clinical study starting and expect that this study will extend the preclinical differentiation into a drug which will be clinically differentiated from anti-NGF antibodies."

"We are extremely pleased that Glenmark has made significant progress with the anti-TrkA project and are excited about the

potential start of the first clinical trial of GBR 900," said Ennio Esposito, sole director at Lay Line Genomics S.p.A., Italy.