News Release

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Merck KGaA, Darmstadt, Germany, Initiates Phase III Study of MSB11022, a Proposed Biosimilar of Adalimumab, in Chronic Plaque Psoriasis

- **First patient treated in global phase III clinical study AURIEL-Psoriasis**
- **Study will evaluate efficacy, safety and immunogenicity of adalimumab biosimilar candidate MSB11022 compared with Humira®**

Darmstadt, Germany, March 2, 2016 – Merck KGaA, Darmstadt, Germany, a leading science and technology company, today announced the initiation of a global phase III clinical study of MSB11022, a proposed biosimilar of adalimumab, in chronic plaque psoriasis. This milestone is a strong reflection of Merck KGaA, Darmstadt, Germany's progress in biosimilars, with the goal of delivering high-quality biologics to patients all over the world.

"With the first patient now being treated in our adalimumab biosimilar candidate study, we are moving closer to expanding access to affordable, high quality biologics for people living with serious diseases," said Michael Soldan, Head of the Biosimilar Business of Merck KGaA, Darmstadt, Germany. "At the same time, this milestone supports our broader healthcare strategy to complement our innovative R&D pipeline with biosimilars that serve as important therapeutic options for patients in need."

The AURIEL-Psoriasis (PsO) study is a randomized, double-blind, active-controlled trial evaluating the efficacy, safety and immunogenicity of Merck KGaA, Darmstadt, Germany's adalimumab biosimilar candidate MSB11022 compared with the brand Humira® (adalimumab) in patients with moderate to severe chronic plaque psoriasis. Humira® is marketed globally by AbbVie, Inc.

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The study is expected to recruit approximately 400 patients across Europe, Asia and North and Central America.

Adalimumab is a recombinant human monoclonal antibody that binds specifically to tumour necrosis factor-alpha (TNF-α), blocking interaction with its cell surface receptors and thereby reducing the impact of inflammation. Humira® (adalimumab) is approved for use in a range of chronic inflammatory conditions such as plaque psoriasis, psoriatic arthritis, rheumatoid arthritis, ankylosing spondylitis, ulcerative colitis, Crohn's disease and juvenile idiopathic arthritis.

For more information on the AURIEL-PsO study, or to find a participating center and eligibility criteria, please visit www.clinicaltrials.gov.

About MSB11022, a proposed biosimilar of Humira® (adalimumab)
MSB11022 is being developed as a high quality biosimilar of adalimumab in the Swiss facilities of Merck, KGaA, Darmstadt, Germany using advanced analytical methods. Adalimumab is a biologic therapy used in the treatment of several chronic conditions including plaque psoriasis, Crohn's disease, ulcerative colitis, juvenile idiopathic arthritis, psoriatic arthritis, rheumatoid arthritis and ankylosing spondylitis.

About Merck KGaA, Darmstadt, Germany
Merck KGaA, Darmstadt, Germany, is a leading science and technology company in healthcare, life science and performance materials. Around 50,000 employees work to further develop technologies that improve and enhance life – from biopharmaceutical therapies to treat cancer or multiple sclerosis, cutting-edge systems for scientific research and production, to liquid crystals for smartphones and LCD televisions. In 2014, Merck KGaA, Darmstadt, Germany, generated sales of € 11.3 billion in 66 countries. Founded in 1668, Merck KGaA, Darmstadt, Germany, is the world's oldest pharmaceutical and chemical company. The founding family remains the majority owner of the publicly listed corporate group. Merck KGaA, Darmstadt, Germany, holds the global rights to the Merck KGaA, Darmstadt, Germany, name and brand. The only exceptions are the United States and Canada, where the company operates as EMD Serono, MilliporeSigma and EMD Performance Materials.