

For immediate release
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GSK and Prosensa announce start of Phase III study of investigational Duchenne Muscular Dystrophy medication

Leiden, The Netherlands and Brentford, UK, 19 January 2011 - GlaxoSmithKline (GSK) and Prosensa today announced that the first patient has commenced treatment in the Phase III clinical study investigating GSK2402968, in ambulant boys with Duchenne Muscular Dystrophy (DMD), who have a dystrophin gene mutation amenable to an exon 51 skip (up to 13% of boys with DMD). Commencement of this study confirms previously announced plans to progress this asset into Phase III.

This randomised, placebo controlled study will enrol 180 patients, from up to 18 countries, and is currently the most advanced ongoing study for this rare, severely debilitating, neuromuscular disease.

The study is designed to assess the efficacy and safety of GSK2402968 6mg/kg, once weekly, for 48 weeks in ambulant boys over 5 years of age with DMD, compared to placebo. The primary efficacy endpoint is a measure of muscle function using the six minute walking distance (6MWD) test.

“The commencement of this Phase III study is an important milestone,” said Dr Philippe Monteyne, Head of Development and Chief Medical Officer for GSK Rare Diseases. “Currently, there is no approved treatment to alter the course of DMD – a disease that puts boys in wheelchairs and often leads to death in early adulthood.”

“We are very pleased with this achievement. It is another step forward in our joint fight against Duchenne,” said Dr Giles Campion, Chief Medical Officer of Prosensa. “If the results of this study are positive, we hope it will lead to an approved treatment option for the thousands of young people worldwide living with this devastating disease.”

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Notes to editors:

About GSK2402968

GSK2402968, an antisense oligonucleotide which induces exon skipping of exon 51, is currently in late stage development for DMD. It has been designated orphan drug status in the EU and US, and is being developed as part of an alliance between GlaxoSmithKline and Prosensa.

For more information regarding the ongoing clinical studies involving GSK2402968 (including study protocols) visit www.clinicaltrials.gov

About DMD

Duchenne Muscular Dystrophy (DMD) is a severely debilitating childhood neuromuscular disease that affects 1 in 3,500 live male births. This rare disease is caused by mutations in the dystrophin gene, resulting in the absence or defect of the dystrophin protein.

Patients suffer from progressive loss of muscle strength due to the absence or defect of the dystrophin protein, often making them wheelchair bound before the age of 12. Respiratory and cardiac muscle can also be affected by the disease and most patients die in early adulthood due to respiratory and cardiac failure.

About exon skipping

The dystrophin gene is the largest gene in the body, consisting of 79 exons. Exons are small sequences of genetic code which lead to the manufacture of sections of protein. In DMD, when certain exons are mutated/deleted, the RNA cannot read past the fault. This prevents the rest of the exons being read, resulting in a non-functional dystrophin protein and the severe symptoms of DMD.

RNA-based therapeutics, specifically antisense oligonucleotides inducing exon skipping, are currently in development for DMD. This technology uses small pieces of DNA called antisense oligonucleotides to skip a defective exon and thereby correct the reading frame, enabling the production of a novel dystrophin protein. Up to 13% of boys with DMD have dystrophin gene mutation/deletions amenable to an exon 51 skip.

About GlaxoSmithKline

GlaxoSmithKline – one of the world’s leading research-based pharmaceutical and healthcare companies – is committed to improving the quality of human life by enabling people to do more, feel better and live longer. For further information please visit www.gsk.com

About Prosensa

Prosensa is an innovative Dutch biopharmaceutical company focused on the discovery, development and commercialization of RNA modulating therapeutics correcting gene expression in diseases with large unmet medical needs, in particular neuromuscular disorders. Prosensa’s focus is on developing a treatment for DMD. In 2009 Prosensa entered into a strategic alliance for part of its DMD exon skipping program with GlaxoSmithKline.

Prosensa is a privately held biopharmaceutical company, backed by a consortium of Abingworth, AGF Private Equity, GIMV, LSP and MedSciences Capital. For more information about Prosensa, please visit www.prosensa.com

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