Greenovation receives BfArM approval to start phase I clinical trial for moss-aGal, the world’s first moss-produced drug candidate

FREIBURG, Germany, September 14, 2015

Greenovation Biotech GmbH announced today that it has received approval to begin a phase I clinical trial in Europe for its first drug candidate moss-aGal (agalsidase) from Germany’s regulatory authority, the Federal Institute for Drugs and Medical Devices (BfArM).

Moss-aGal, a recombinant form of human alpha galactosidase, has been developed by Greenovation as an enzyme replacement therapy (ERT) for patients with the genetic lysosomal storage disorder Fabry disease.

Greenovation has used its proprietary BryoTechnology, an innovative moss gene expression system, to express the moss-aGal protein in Physcomitrella patens. The technology attaches mannose molecules to the surface of the moss aGal protein. This improves the uptake of the proteins in the human body, mediated via mannose receptors on cell surfaces. This novel approach is very effective, according to preclinical studies published in the Journal of Inherited Metabolic Diseases.

“After very successful preclinical studies, we are excited to see our first drug candidate produced in moss entering into phase I clinical trials,” commented Dr. Thomas Frischmuth, CEO of Greenovation. “This milestone validates our BryoTechnology approach, confirming that it can serve as a production system for biopharmaceuticals. We have reached this goal through many years of hard work from all of our team.”

Fabry disease, a rare lysosomal storage disease, is caused by an inborn deficiency of the alpha-galactosidase (aGal) enzyme. A lysosomal enzyme, aGal breaks down a specific fatty acid, globotriaosylceramide (Gb3). In patients with Fabry disease, absence of aGal causes continuous accumulation of Gb3 in the cells. Symptoms include pain, and heart, skin and kidney complications, and can lead to organ failure. In enzyme replacement therapy, the missing enzyme is replaced with regular intravenous administrations of a biopharmaceutically produced substitute.

Greenovation’s pipeline includes three more next-generation drugs for rare diseases, such as Gauchers disease, atypical HUS (aHUS) and Pompe’s disease.

**About Greenovation Biotech GmbH**

Greenovation develops plant-made next-generation therapeutics using its proprietary BryoTechnology platform. The company aims to optimize the production of highly-efficient glycoproteins for the treatment of rare diseases.

Greenovation is a privately owned biopharmaceutical company based in Heilbronn, Germany. It was founded in 1999 by Prof. Dr. Ralf Reski and Prof. Dr. Gunter Neuhaus. Today, Greenovation Biotech GmbH is majority-owned by Zukunftsfonds Heilbronn and L-EigenkapitalAgentur (Karlsruhe).

**Contact and further information**

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