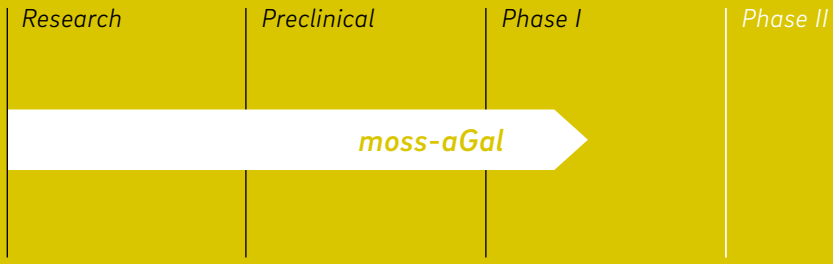
Phase I Clinical Trial

m
aGal

MOSS-AGAL

FOR FABRY DISEASE

Moss-aGal will be the first enzyme replacement treatment of Fabry disease based on moss that exhibits optimized N-glycosylation patterns of the protein alpha-galactosidase A. Studies in mice show that this translates into enhanced cellular uptake and favourable organ distribution.



GREENOVATION
Biopharmaceuticals

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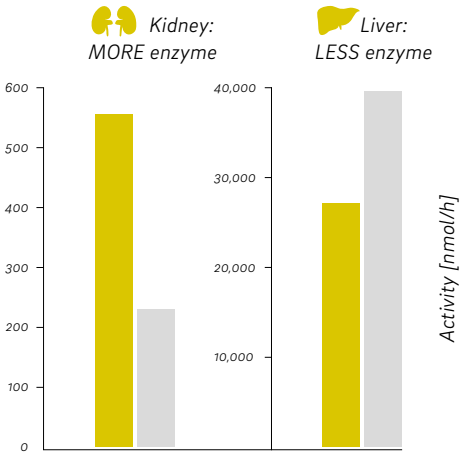
nature biotechnology

Moss-aGal in Nature Biotechnology:
FIRST MOSS-MADE DRUG. Published online, 06 November 2015

Moss-aGal: enhanced cellular uptake into the target organ kidney

Being an enzyme replacement therapy, moss-aGal replaces the missing or reduced activity of the lysosomal enzyme alpha-galactosidase A in patients with Fabry disease. The kidney and heart are the organs most affected by the disease. Compared with other replacement therapies, the mannose receptor-mediated uptake of moss-aGal leads to an increased uptake of the enzyme in the kidney in mice. This has the potential for substantial improvements to patients' quality of life.



Favourable organ-specific uptake of moss-aGal in Fabry mice

✚ *Start of phase I clinical trial for the world's first moss-produced drug candidate*

After successful preclinical studies, Greenovation's first drug candidate moss-aGal is in a phase I clinical trial. Greenovation has used its proprietary BryoTechnology® to express the moss-aGal protein in *Physcomitrella patens*. As a result, mannose molecules are atteched to the surface of the recombinant proteins, which improves cellular uptake. This milestone validates the use of BryoTechnology as a production system for biopharmaceuticals. For more information, please visit www.clinicaltrialsregister.eu, EudrCT-No.: 2014-004325-40.

STUDY SETUP

One dose group with 6 patients: 0.2mg/kg i. v.; single dose; clinical schedule of 28 days

Primary endpoints:

- Safety
- Pharmacokinetics

Secondary *(exploratory)* endpoints

- Efficacy (Gb3/lyso-Gb3 levels in plasma and urine)

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