

PLANNING

LEGAL NOTICES

Environmental Protection Agency
Acts, 1992 to 2007
Genetically Modified Organisms
(Deliberate Release) Regulations,
S.I. No 500 of 2003
PROPOSED DELIBERATE
RELEASE OF A GENETICALLY
MODIFIED ORGANISM

In accordance with the above
legislation, SparingVision,
headquartered at 5 avenue
Percier, 75008 Paris, France,
has submitted a notification to
the Environmental Protection
Agency (EPA) of a proposal to
conduct a clinical trial in Ireland
using a Genetically Modified
Organism (GMO).

Description and purpose of the
GMO and clinical trial SPVN20
or AAVi-GIRK1(F137S) is a
nonpathogenic recombinant
adeno-associated virus
(vector) containing an optimized
version of the human gene of G
protein-gated inwardly rectifying
potassium (GIRK) channel 1. The
vector has been engineered to
target cone photoreceptors
following an intravitreal injection.
The purpose of this clinical trial
is to study SPVN20 (or AAVi-
GIRK1(F137S)) for the treatment
of patients with no light
perception (NLP) due to end-
stage rod-cone dystrophy (RCD),
and who retain dormant foveal
cone photoreceptors (i.e., cells
that have lost their ability for
phototransduction). A target of
nine (9) subjects will be enrolled
in this study worldwide. SPVN20
will be administered to patients
in the eye via the intravitreal
route. In the SPVN20 treatment
approach, GIRK1(F137S)
transgene is expressed in
dormant foveal cone
photoreceptors, to restore their
ability for phototransduction.
Following SPVN20
administration to patients with
NLP due to end-stage
RCD, GIRK1(F137S) expression
in dormant cones could provide
an alternative
hyperpolarization mechanism in
response to light stimulus, in the
form of an alternative
phototransduction cascade,
allowing cone
reactivation. Proposed location
of the clinical trial
One (1) Irish site, the Royal
Victoria Eye and Ear Hospital
located at Adelaide Road, Dublin
2, Ireland, will participate in the
clinical trial.
Date of the proposed clinical
trial. The notification covers the
treatment of clinical trial patients
at the named location
between September 2025 and
September 2031. The clinical
trial aims to enroll a total of nine
(9), of which two (2) patients
enrolled in Ireland.
In accordance with article 16(1)
of the Genetically Modified
Organisms (Deliberate
Release) Regulations, S.I. No
500 of 2003, any person or body
may make representations in
writing, which will be no later
than 28 days from the date of
publication of this notice.
Representation will be to the
Environmental Protection
Agency, Office of Environmental
Sustainability, P.O. Box 3000,
Johnstown Castle Estate, Co
Wexford, Ireland and will be
subject to a fee of €10 (guidance
on fee payment may be obtained
by writing to gmo@epa.ie).
Further information on the
proposed deliberate release
may be obtained from the
Environmental Protection
Agency.