PUBLIC NOTICE

Public Notice

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

Gyroscope Therapeutics Limited (Gyroscope Therapeutics), of Rolling Stock Yard, 188 York Way, London N7 9AS, United Kingdom, in accordance with the above legislation has given notification to the Environmental Protection Agency (EPA) of a proposal to conduct two clinical trials in Ireland using a Genetically Modified Organism (GMO) for people with sight loss due to geographic atrophy (GA) secondary to age-related macular degeneration (AMD). If the proposal is approved by the EPA, the clinical trials would also be governed by the Health Products Regulatory Authority under the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations, 2004 S.I. No 190 of 2004 and amendments.

Description of the GMO proposed for use in the clinical trials

The GMO that is proposed to be used is Gyroscope Therapeutics' investigational gene therapy treatment called GT005. The Gyroscope Therapeutics approach to gene therapy is designed to deliver a functional gene into a cell to help the body make an important protein, in some cases to potentially compensate for a gene that is not working optimally.

GT005 is designed to deliver a gene that helps the eye make more of a naturally occurring human protein, called Complement Factor I (CFI), for patients with GA secondary to AMD. To deliver the CFI gene to cells in the eye, GT005 uses a modified version of a virus, called an adeno-associated virus (AAV). AAVs are frequently found in humans and have not been associated with any disease, allergic reaction or toxic effect. The use of a modified virus is currently the most common approach used in approved gene therapy treatments. 'GT005 does not replicate or spread to other organisms. Patients participating in the clinical trials will be administered the investigational GT005 gene therapy treatment through a one-time injection under the retina.

Purpose of the clinical trials

GA is a leading cause of permanent vision loss and blindness in people aged 55 and older, and there are currently no approved treatments.[i,ii] The purpose of the clinical trial is to test whether a single administration of GT005 is effective at slowing the progression of the disease and that it is safe to use in patients with GA secondary to AMD. Three different doses of GT005 will be tested as part of the clinical trials. Patients will receive only one dose each.

Proposed location of the clinical trials

During the course of the two clinical trials, the investigational GT005 gene therapy treatment will be given to patients with GA secondary to AMD at the UPMC Whitfield Hospital Institute of Eye Surgery, 2 Butlerstown, Waterford, X91 DH9W. Follow-up assessments of treated patients may also be conducted at The Institute of Eye Surgery, UPMC Kildare Hospital, Prosperous Road, Clane, W91 W535.

Date of the proposed clinical trials

The notification is to cover the treatment of clinical trial patients at the named hospital locations between January 2022 and July 2026. Patients will be followed up for a further 5 years after treatment. The doctors at the clinical trial locations will treat around 30 patients during this time.

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. Representations 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 licensing@epa.ie). Further information on the proposed deliberate release may be obtained from the Environmental Protection Agency.

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i U.S. Food and Drug Administration. Immunogenicity of Gene Therapy Products. https://www.fda.gov/vaccines-blood-biologics/biologics-research-projects/immunogenicity-gene-therapy-products. Page last reviewed October 27, 2020. Accessed October 7, 2021.

ii National Eye Institute. Age-Related Macular Degeneration. https://www.nei.nih.gov/learn-about-eye-health/eye-conditions-and-diseases/age-related-macular-degeneration. Page last reviewed June 22, 2021. Accessed September 28, 2021.

iii American Macular Degeneration Foundation. What is Macular Degeneration? https://www.macular.org/what-macular-degeneration. Accessed September 28, 2021.

Government wi

Taoiseach said he wanted to maintain 'seemless travel' on the island of Ireland

SARAH BURNS, HARRY McGEE and **FREYA McCLEMENTS**

Tánaiste Leo Varadkar has said the Government will express its objections and concerns to the British government about a proposal that would see non-Irish EU citizens living in the Republic having to apply online for pre-travel clearance from the UK to cross the Border.

Under the Nationality and Borders Bill, non-Irish EU/EEA citizens will be required to apply for a US-style visa waiver known as an Electronic Travel Authorisation (ETA) before entering the UK, including when crossing the land border into Northern Ireland.

The Bill is part of a wider post-Brexit overhaul of the UK's immigration laws, and includes provisions on asy seekers, nationality and ir gration control.

Groups working with grants in Border areas warned the plans of the UK ernment to require non- EU citizens to apply pre-travel clearance be crossing the Border will le racial profiling.

Speaking in the Dáil ye day, Mr Varadkar said Du was "certainly going to cor nicate to our UK counter our concerns and our o tions to this measure". "U tunately it does not come huge surprise," he added.

Mr Varadkar was respor to Sinn Féin TD Pearse Doh who said Ireland was facin prospect of "collateral dan from "a Tory governme

Over 50 organisations over failure to progres

FREYA McCLEMENTS
Northern Editor

Over 50 organisations representing civil society in the North have written to the First and Deputy First Ministers to express their "grave concerns" over the failure to progress a Bill of Rights in Northern Ireland.

In the letter they called on the Irish and British governments to intervene and for the British government to bring forward legislation at Westminster to "guarantee" its delivery.

The signatories also challenged the circumstances of the recent suspension of the Ad-Hoc committee on a Bill of Rights at Stormont, which they said was a "violation of the commitment made to this process in the New Decade, New Approach (NDNA) agreement.

The failure to agree progress on the Bill of Rights, they wrote, was "at odds with all evidence and public opinion", including a public survey by the committee of 2,400 individuals and organisations which found 80 per cent of respondents supported it.

As representatives of local civil society they could "no longer accept such a veto being exercised over legislation for badly-needed and long-awaited human rights protections for people in Northern Ireland,' said.

The letter, which has seen by The Irish Tim signed by human rights o sations including the H Rights Consortium and A ty International, trade u such as ICTU, NIPSA an son, students' union NU and other bodies incl Women's Aid Federati Disability Action, Friends Earth, the Children's La tre, Shankill Women's C Age NI and the Northe land Rural Women's Netv

It has also been sent Minister for Foreign Affa mon Coveney, the No Secretary, Brandon Lew to the leaders of the pa the Stormont Executive.

The creation of an Committee to consider t tion of a Bill of Rights faithful to the stated in of the 1998 [Belfast] ment" was a commitme NDNA deal which resto North's power-sharing tions in 2020.

The Bill is intended tain rights "supplemer those contained in the an Convention on Rights . . . and 'that re particular circumsta Northern Ireland'" as w