

## **Register of Genetically Modified Organisms (GMOs) Users in Ireland**

<b>The name and address of the notifier</b>	Gyroscope Therapeutics Ltd Rolling Stock Yard 188 York Way London N7 9AS United Kingdom
<b>The location (including, where necessary, the name of townland or townlands) of a deliberate release proposed under, or granted consent in accordance with, Part II of the GMO (Deliberate Release) Regulations 2003, S.I. No. 500 of 2003 - Part B release.</b>	UPMC Whitfield Hospital Institute of Eye Surgery 2 Butlerstown Waterford X91 DH9W
<b>Notification Ref. No.</b>	B/IE/21/01
<b>GMO Register No.</b>	G0784-01
<b>The date or dates of a deliberate release</b>	5 <sup>th</sup> July 2022 until 31 <sup>st</sup> July 2026. (Patients will be followed up for a further 5 years after treatment).
<b>The description and intended uses of each GMO involved</b>	GT005 is a gene therapy treatment comprising a recombinant, non-replicating, adeno-associated viral vector derived from wild-type adeno-associated virus serotype 2 (AAV2) carrying an expression cassette containing DNA encoding for human <i>Complement Factor I (CFI)</i> , the therapeutic transgene.
<b>The purpose of the deliberate release</b>	GT005 will be administered to patients with geographic atrophy (GA) secondary to age-related macular degeneration (AMD). The purpose of the clinical trials 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.
<b>The date of receipt of a notification or amended notification</b>	1 December 2021

<b>The date of publication of a notice under article 15(1)</b>	10 December 2021
<b>The number of representations, if any, received under article 16(1)</b>	0
<b>The date of any request by the Agency for further information</b>	21/01/2022 & 14/02/2022 13/04/2022 & 22/04/2022 04/05/2022
<b>The date of receipt by the Agency of any further information</b>	21/03/2022, 29/04/2022 & 31/05/2022
<b>The date of receipt, or the date on which the Agency otherwise became aware, of any information or any other matter referred to in article 22(1)</b>	
<b>The date of any exercise by the Agency of its powers under article 22(1)</b>	
<b>The date and nature of any decision by the Commission of the European Communities under Article 18 (1) or 23(2) of the Directive</b>	
<b>The date of withdrawal of a notification or an amended notification</b>	
<b>The date and nature of the decision by the Agency on a notification or an amended notification</b>	14 <sup>th</sup> June 2022