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CLASSIFIED EXTRA

PUBLIC NOTICES

Genetically Modified Organisms (Deliberate Release) Regulations, S.I. No 500 of 2003

PROPOSED DELIBERATE RELEASE OF A GENETICALLY MODIFIED ORGANISM

The Clinical Research Facility at St James's Hospital, James's Street, Dublin 8, and Children's Health Ireland at Temple Street Hospital, Temple Street, Dublin 1 in accordance with the above legislation has given notice to the Environmental Protection Agency (EPA) of the proposal to administer a Genetically Modified Organism (GMO) to patients with spinal muscular atrophy (SMA). If the proposal is approved by the EPA, the GMO will be supplied as an Exempt (unauthorised) medicine in accordance with Paragraph 2 of Schedule 1 of S.I. No. 540/2007 - Medicinal Products (Control of Placing on the Market) Regulations 2007 and S.I. No. 538/2007 - Medicinal Products (Control of Wholesale Distribution) Regulations 2007.

Description of the genetically modified organism

The genetically modified organism is called AVXS-101 or onasemnogene abeparvovec-xioi (marketed by Novartis in the US under the brand name Zolgensma). Paediatric patients will be administered with the AVXS-101 gene therapy treatment. AVXS-101 is a recombinant adeno-associated virus-based vector which has been designed to express the survival motor neuron-1 (SMN-1) in paediatric patients less than 2 years of age with SMA. AAV is frequently found in humans and can infect animals but is non-pathogenic, toxigenic, virulent, allergenic or a carrier of a pathogen. AVXS-101 is not capable of replicating.

Date and Location of Release

The proposed treatment of patients with AVXS-101 will take place at St James's Hospital (in the Wellcome-HRB Clinical Research Facility) between March - December 2020. Patients will be followed up at Children's Health Ireland at Temple Street Hospital, Temple Street, Dublin 1 as part of the AveXis global Managed Access Programme.

In accordance with article 16(1), any person or body may, within the 28- day period beginning on the day of publication of the notice and subject to the payment of the fee specified in Article 48 (€10), make representations in writing to the Agency regarding this notification. Representations will be to the Environmental Protection Agency, P.O. Box 3000, Johnston Castle Estate, Co. Wexford, Y35 W821. Further information on fee payment and the proposed deliberate release may be obtained from the EPA.

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Last Year: REBEL EARLY 5 11 4, Rachael Blackmore 12-1 (W J Burke), 11 ran.

Last Year: ASK HEATHER 7 11 11, Donagh Meyler 9-2 (D Queally), 18 ran.