



**AIFA APPROVES REIMBURSEMENT OF ZOLGENSMA,
GENE THERAPY FOR CHILDREN WITH SMA1**

AIFA's Board of Directors approved on 9 March 2021 the NHS reimbursement of the Zolgensma gene therapy for all children suffering from SMA1 weighing below 13.5 kg.

The final go-ahead was given at the end of a long process which began in May 2020 with the negotiating submission by Novartis.

In November 2020, after AIFA's Scientific-Technical Scientific Committee (CTS) had evaluated this therapy as innovative, it was decided to allow reimbursement for children up to six months of age, taking into account the valuable expected benefits. At the same time, rigorous negotiation was carried out by AIFA's Price and Reimbursement Committee (CPR) with an aim to fix a sustainable drug price for the NHS.

AIFA expresses its satisfaction with the opportunity of making available in our NHS a gene therapy offering a much better life prospect for children with SMA1.

The agreement with Novartis also included the company's commitment to make the drug available free of charge in clinical trials for children weighing between 13.5 and 21 kg, in order to acquire additional efficacy and safety data on such patients in a controlled setting.