INFORMATION ON NIRSEVIMAB PROPHYLAXIS AGAINST INFECTION BY RESPIRATORY SYNCYTIAL VIRUS (RSV)

Respiratory Syncytial Virus (RSV) is one of the main pathogens affecting the respiratory tract in infants. More than half of all children contract RSV by the age of one, almost all of them become infected at least once by the age of two. These infections range from simple colds to more severe cases of bronchiolitis and pneumonia with fever, cough and difficulty breathing, requiring hospitalisation and, in 20% of cases, admission to intensive care units.

The risk of severe RSV infection depends on several factors, including in particular:

- seasonality - in Italy usually the six months between October/November and March/April,
- under one year of age, particularly in the first three months.

To date, there are no specific therapies for the treatment of severe RSV infections and therefore treatment of such forms of lower respiratory tract disease is most often limited to symptomatic therapies and supportive measures (hydration and oxygen).

MONOCLONAL ANTIBODY PROPHYLAXIS

The European Medicines Agency—in October 2022—and the Italian Medicines Agency—in January 2023—approved a new drug, **Nirsevimab**, a monoclonal antibody that, when administered in a single dose at the beginning of the epidemic season, provides protection against severe RSV infection for at least five months. This drug has been shown to be **safe and effective** in preventing over 80% of lower respiratory tract infections and reducing hospitalisations in immunised children by 87.6% in paediatric wards and 90.1% in intensive care units, respectively.

In light of the safety and efficacy data, the Italian Society of Hygiene, Preventive Medicine and Public Health (SItI), the Italian Society of Paediatrics (SIP), the Italian Federation of Paediatricians (FIMP), the Italian Federation of General Practitioners (FIMMG) and the Italian Society of Neonatology (SIN) unanimously support the strategy of universal prevention of RSV by immunisation with Nirsevimab, as reported in the document 'Position of the Board of the Vaccine Calendar for Life and the Italian Society of Neonatology on the possible use of long half-life monoclonal antibodies for the universal prevention of Respiratory Syncytial Virus (RSV) in newborns' (published in February 2023 and also found at https://sip.it/2023/02/17/vrs-calendario-per-la-vita-e-sin/).

Several European nations, including France and Spain, have already introduced universal prophylaxis of newborns and infants in the first year of life with Nirsevimab in their national prevention plans, and Valle d'Aosta was the first region in Italy to offer this prophylaxis to all newborns from the 2023-2024 epidemic season.

Nirsevimab is administered by the doctor or nurse as a single injection into the thigh muscle.

Uncommon side effects (may affect up to 1 in 100 children) can include:

- rash;
- injection site reaction (i.e. redness, swelling and pain at the injection site);
- fever.

Exceptionally—as with any drug—immediate severe allergic reactions such as anaphylactic reactions may occur; for such cases, the administering facility is equipped with the appropriate therapeutic aids to deal with the emergency (adrenaline, antihistamines, cortisone, oxygen, etc.).

INFORMED CONSENT FORM FOR THE ADMINISTRATION OF NIRSEVIMAB MONOCLONAL ANTIBODY FOR THE PROPHYLAXIS OF RESPIRATORY SYNCYTIAL VIRUS INFECTION

I, the undersigned _____ born in _____ on _____
Resident in _____ address _____

DECLARE THAT I AM: (please tick only the items that apply)

❑ **The parent** of the child and that I have **parental responsibility**:
- ❑ **jointly with the other parent**: first and last name _____
  born in _____ on _____
  Resident in _____ address _____
  who is ○ **present**
  ○ **absent**, but is INFORMED and AUTHORISES me to act for the child
- ❑ **separately from the other parent**

❑ **Legal guardian**

of the child (first name and surname) _____
born in _____ on _____
Resident in _____ address _____

I/WE HEREBY DECLARE

that I/we have been informed on the disease(s) to be prevented, the characteristics of the drug Nirsevimab used and on the benefits and potential risks of the above-mentioned prophylaxis, also with the help of reading the information sheet made available;

that I/we have been informed on the reasons for the proposed prophylaxis and the consequences for my child's health in the event of refusal;

that I/we have had the opportunity to ask questions regarding the information I/we have received and that I/we have understood the answers to requests for clarification regarding the disease(s) to be prevented, characteristics of the drug used, benefits and potential risks and complications of immunisation;

that I/we have correctly provided information on the current state of my/our health, the health of my/our child or the person I/we legally represent;

that I/we have been informed that, on the basis of the medical history of my/our son/daughter/person that I/we represent, there are no known contraindications to the proposed drug to date;

that I/we have been informed of the need to keep my/our child/the person I/we legally represent in the outpatient clinic for at least 15 minutes after the prophylaxis and to report any adverse reactions;

therefore

☐ **I/we agree** to the administration of the above-mentioned prophylaxis
☐ **I/we do not agree** to the administration of the above-mentioned prophylaxis

Legible signature of parent(s)/legal representative _____

_____

Name and Signature of the health professional _____

Date _____