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NOW ENROLLING:

A new clinical study in 22q11DS

PROTOCOL NB-001-01

Dear Patient,

A new clinical study in 22q11.2 Deletion Syndrome (22q11DS) has started.

The aim of this study is to assess the safety and efficacy of NB-001 (the medication) in children and adolescents with 22q11DS.

There are several sites in the US and Canada. Children with 22q11DS and symptoms of anxiety, inattention, and/or autism may be eligible. A brief outline of the study is provided in this leaflet.

ONLY ONE (1) VISIT TO THE INVESTIGATIVE SITE IS REQUIRED.
The rest of the study visits are by telemedicine and/or nurse visits to your home.

Contact the nearest study doctor (see below) or ask your child's doctor for information about this study.

www.nobiastx.com or
www.clinicaltrials.gov

ClinicalTrials.gov Identifier: NCT05290493

A LABEL WITH INVESTIGATOR/ SITE-SPECIFIC CONTACT INFORMATION CAN BE ADHERED HERE. AT PRINTING, THIS AREA WILL BE LEFT BLANK.

STUDY PROCEDURES

To be in the study, you will be asked questions and your child will have tests.

Except for the first visit which will be planned in-person at the Study Doctor's office, ALL other study visits will be done in your home by a study nurse.*

- Your child will take study medicine two times each day; once in the morning and again around dinner time.
- A nurse will periodically come to your house to see how your child is doing, listen to your child's heart, take his/her temperature, and collect blood samples.
- Your child will be asked to pee in a cup so we can test his/her urine.
- Your child's heart beat will be measured through a common procedure called an electrocardiogram (EKG) during which small sticky pads will be placed on your child's body and legs and wires attached for a short period of time; this is not painful.
- A research team member will periodically ask your child a set of questions, either in person or by video. A parent or guardian will be asked questions in a similar way.

**Additional in-person visit(s) may occur, only if necessary, based on clinical judgment.*

KEY ELIGIBILITY CRITERIA

To be part of the study, your child must match **ALL** the traits in this list:

1. Genetic test shows 22q11DS
2. Age 6 to 17 years old
3. Symptoms of anxiety, inattention, and/or autism
4. Willing to use birth control (if needed)
5. Understands and agrees to participate in the study

To be part of the study, your child must **NOT** match any of the traits in this list:

1. Psychotic symptoms (e.g., hearing voices)
2. Seizures within the past 3 months
3. Currently pregnant or breastfeeding, or plans to become pregnant soon
4. Suicidal ideas or behavior
5. Recent or frequent changes (within the last 3 months) in medications or therapies for 22q11DS
6. Any uncontrolled (i.e., not treated) medical condition or illness that may make it unsafe to participate

STUDY MEDICATION

If the Study Doctor agrees it is safe for your child to be in the study, your child will take two capsules of study medication, by mouth, two times per day with liquid (i.e., 2 capsules in the morning and 2 capsules in the evening). If your child is unable to swallow a capsule whole, the capsules may be opened, and the contents sprinkled on applesauce.

NB-001 is investigational, meaning it is not approved by the Food & Drug Administration (FDA) or Health Canada but may be tested in studies like this one.

NB-001 may be available to your child at the end of this study, as part of another study. You should discuss this possibility with the study doctor.

22q11DS Study
Protocol NB-001-01
www.nobiastx.com

STUDY SCHEMATIC

**Treatment and treatment order are secret until the study is over*