Frequently Asked Questions for Patient Community:
NBI-921352 Phase 2 Clinical Trial for SCN8A-DEE
Sponsored by Neurocrine Biosciences, Inc.

Contents

Background for Families:

On behalf of Neurocrine Biosciences, thank you for your interest in the ongoing clinical trial of NBI-921352 in SCN8A Developmental and Epileptic Encephalopathy Syndrome (SCN8A-DEE). With enrollment now underway, we aim to provide as much information as we can about the study. However, please understand that many topics can only be addressed by discussion with a physician who can evaluate your child's condition and suitability for participation in the trial.

Our clinical trial consists of two treatment "arms," one in which participants will receive placebo (see question 2 in General Clinical Trial Questions section for description) and another in which participants will receive the study drug, NBI-921352. Participants will be randomly assigned between the placebo vs. study drug arms, and the trial will be double-blinded, meaning neither the participants nor the doctors and nurses administering the trial will know which participants receive placebo vs. NBI-921352. This structure is commonplace in clinical trials as a mechanism to test the safety & efficacy of a potential treatment compared to no treatment while seeking to avoid introducing any biases that could undermine the integrity of the results.

Participants assigned to the study drug arm will receive increasing doses of NBI-921352 based on weight for the first six weeks (titration period), followed by ten weeks of treatment at their final tolerated dose (maintenance period). Participants who enter into the separate active extension study will continue on treatment as a part of that extension study, whereas those who are not participating in the active extension study will receive decreasing doses for two weeks (taper period) prior to stopping treatment. Participants assigned to the placebo arm will receive placebo (inactive drug) for the full duration of the study, and will similarly have the option to enroll in the active extension study following completion of the maintenance period. The active extension study will allow participants on **both** placebo and study drug arms to receive NBI-921352 for an extended period.

If you have additional questions or concerns, please share them with your patient advocacy group to forward on to Neurocrine Biosciences.

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General Clinical Trial Questions

1. **What is a clinical trial?**
    a. A clinical trial is a medical research study involving human participants. It tests the use of a medical procedure, medical device, drug, or potential treatment, and is led by researchers and study doctors. Clinical trials provide valuable information and may help researchers to understand a condition better and learn how best to treat it or may lead to new or better treatments being made available.
    b. A study drug must generally pass multiple phases of clinical testing before it is approved by a country's regulatory authority and made available to the public. Descriptions of the different phases of clinical trials are provided below. This SCN8A-DEE clinical trial is a **Phase 2 trial**.
        i. **Phase 1**: The study drug is given to a small group of healthy volunteers. Researchers assess how much study drug is safe to take and how the human body responds when it receives the drug.
        ii. **Phase 2**: The study drug is given to a small group of people with the target disease or condition it is intended to treat. In this phase, researchers evaluate what dose is appropriate and begin to learn more about how safe the drug is and how well it works in people with the specific disease or condition.
        iii. **Phase 3**: Researchers test the safety and effectiveness of the study drug in a larger group of participants with the target disease or condition it is intended to treat over a longer time period. Sometimes, comparisons are made between the study drug and other medications that are already approved for the same purpose.
        iv. **Phase 4**: A Phase 4 trial is conducted after a study drug has been approved for public use. The approved drug may be compared with other drugs on the market or researchers may monitor the drug's long-term safety and effectiveness, and impact on patients' quality of life.

2. **What is a "placebo"?**
    a. If your child is enrolled in the trial, he/she will be randomly assigned by a computer to receive either NBI-921352 or placebo for the first 16 weeks (if participating in the extension study) or 18 weeks (if not participating in the extension study). The placebo looks like NBI-921352 but does not contain any active drug. Placebos are commonly used in clinical trials to help understand if the drug being researched is effective. In this trial, one of every two participants (50%) will take placebo. Neither you nor the study doctor or nurses will know if your child is receiving NBI-921352 or placebo. Only in the case of an emergency, is it possible for the study doctor to obtain this information.
        i. For information on the possibility of receiving study drug following participation in the placebo arm of the study, see question 12 in the section entitled *NBI-921352 Phase 2 Clinical Trial: Study Drug and Treatment Questions* below.

3. **What about side effects?**
    a. All medications, both those that are approved and those undergoing clinical trials, may potentially cause side effects – some of these are known, but there could be others that have not previously been observed. Trial procedures may also involve risks. You will be

informed about all the known potential side effects of the study drug and study procedures before you decide to take part in this clinical trial. If any further risks are discovered while the trial is ongoing, you will be informed immediately.

NBI-921352 Phase 2 Clinical Trial: Enrollment Questions

1. **When will the locations where the clinical trial will be offered, commonly called trial sites, be made public?**
    a. We will post new trial sites on clinicaltrials.gov as each site is ready to enroll patients into the trial. Neurocrine will also share any relevant trial updates with the SCN8A patient advocacy groups.

2. **How, where and when can I apply for my child to participate?**
    a. Enrollment has begun for our Phase 2 study to evaluate NBI-921352 in individuals with SCN8A. Additional sites will become available over the following months based on local trial site processes and timelines.
    b. We plan to launch a public clinical trial website with information about the study in the U.S. where you can submit your information and be directed to the study site nearest you. Site information can also be found on clinicaltrials.gov.
    c. Site preparation is highly regulated, reviewed and carefully documented in order to ensure patient safety, and each participating site has their own local requirements and processes that Neurocrine Biosciences has no control over. For this reason, it is not always possible to predict exactly when individual study sites will be up and running.

3. **Can you keep my information on file and notify me when enrollment opens up at a specific site?**
    a. We are unable to keep your information on file to notify you of the status of trial enrollment at certain sites. However, we will share the link to the clinical trial website with patient advocacy groups when available. This website and clinicaltrials.gov will be the best source of current trial site availability.

4. **What are the study eligibility criteria?**
    a. Participants must meet the inclusion criteria including, but not limited to:
        – Male or female 12 to 21 years of age.
        – SCN8A-DEE diagnosis supported by clinical and genetic findings.
        – Average of at least one countable motor seizure per week and not seizure-free for more than 20 consecutive days.
        – Treated with at least one but not more than four other antiseizure medications.
        – Use a nocturnal alerting system or practice consistent with standards of care at the time of screening and for the duration of the study.
        – Parent/caregiver who can accurately identify seizure types and can complete a seizure diary.
    b. Participants must not meet any of the exclusion criteria, including but not limited to:
        – Previously enrolled in this study and received blinded treatment.
        – Participated in an interventional clinical trial less than 30 days prior to screening.

- Symptoms more consistent with another epilepsy disorder.
- Receiving cannabinoids or medical marijuana, with the exception of Epidiolex/Epidyolex.
- Taking systemic steroids, with the exception of asthma treatments.
- Neurological disorders or trauma, medical condition, chronic disease, abnormal vital signs, clinical laboratory test values or cardiac abnormality that could preclude participation or pose a risk.

5. **Is there any leeway in including participants in the study who don't meet all inclusion criteria, such as seizure frequency?**
    a. At this time, NBI-921352 is only available to participants enrolled in the clinical study who meet all the study eligibility criteria.
    b. NBI-921352 is an investigational therapy. Its safety and efficacy are under evaluation and have not yet been established in patients.
    c. Eligibility criteria are an important part of clinical trial enrollment. They help to ensure participants are representative of the patient population the investigational therapy is being developed for, and exclude participants who have other conditions or are taking medications that could impact the efficacy of the investigational therapy or cause potential safety concerns, and minimize factors other than the investigational therapy that could impact the outcome measures being evaluated.

6. **Will my child need to stop taking any drugs in order to participate in the trial?**
    a. Your doctor should review and discuss your child's medications with you because each clinical trial is very specific regarding concurrent (at the same time) and past medications and trial eligibility. Please do not change or stop any medications unless directed by your doctor.

7. **The study description states that the use of CBD oil <u>may</u> cause an individual to be ineligible. What is the deciding factor for that?**
    a. Enrollment criteria states that patients will be ineligible to participate if they are receiving cannabinoids or medical marijuana, with the exception of Epidiolex/Epidyolex, unless approved by the Sponsor.
    b. These eligibility criteria are in place to help ensure the safety of study participants and to avoid any potential interactions with other medications.
    c. You can submit your information via the study website (which will soon launched in the U.S.) to be connected with the study site nearest you, and a study doctor will be able to provide additional details about whether your child qualifies.

8. **If my child is taking fenfluramine, does that disqualify them from enrolling in this study?**
    a. Eligibility criteria state that participants can be treated with at least one but not more than four other antiseizure medications. This can include fenfluramine.

9. **Should I change something now so that my child can be enrolled in the trial?**
    a. No, stable medication use is an important requirement for trial participation, so please do not make any changes to your child's current treatment plan unless instructed by your doctor.

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10. **Why don't participants have to stop taking other sodium channel blockers while participating in the study?**
    a. Eligibility criteria state that participants can be treated with at least one but not more than four other antiseizure medications. These can include sodium channel blockers.

11. **Will accommodations be made to facilitate participation for families that do not live near the trial sites (participating trial locations)?**
    a. Yes, we understand it may be difficult logistically and financially to participate in a clinical trial, and the study team will work with you and your family regarding travel, accommodations, and other logistical challenges to study participation.

12. **What support and reimbursement are available to study participants to help defray costs associated with participation?**
    a. There will be support available to enrolled participants to help ease any burdens associated with study participation, as allowed by local requirements. Study sites will make every effort to customize support based on the study-related travel and accommodation needs of each participant.
    b. Once enrolled, participants' families will work directly with their study site to determine support and/or reimbursement.

13. **Will there be possibilities for some participation directly from families' homes through home visits or telemedicine (i.e., using online platforms like telephone, Zoom, etc.)?**
    a. Yes, we have worked to allow telehealth or home visits when feasible and permissible by your trial site, but certain visits will require assessments that can only be conducted in a healthcare setting.

14. **Will there be trial sites outside of the United States? When?**
    a. We are conducting this study internationally and anticipate including more study locations in the U.S., as well as in Europe, Australia and other regions. As international (ex-U.S.) trial sites are confirmed, they will be listed on the clinicaltrials.gov website found here (ClinicalTrials.gov Identifier: NCT04873869).

15. **How do I get my doctor/healthcare practice/hospital to enroll to be a trial site (participating trial location)?**
    a. Trial sites are being selected based upon a rigorous review and qualification process, with input from the SCN8A patient advocacy groups.
    b. If you think your doctor would be interested in participating, please refer her/him to the study contact listed on the clinicaltrials.gov website found here (ClinicalTrials.gov Identifier: NCT04873869).

16. **My child's doctor said that he/she is a trial site. Why aren't they listed as a trial site yet?**
    a. There is a lot that happens behind the scenes in order to start a study at each site, and much of it is out of our control. Site preparation is highly regulated, reviewed and carefully documented in order to ensure patient safety. For this reason, it is not always possible to predict exactly when individual study sites will be up and running.

b. The site may be at some stage of preparation, though it will not be posted on the clinicaltrials.gov website found here (ClinicalTrials.gov Identifier: NCT04873869) or our own trial website (when the website launches) until the site is open for enrollment.

17. When should I talk with my doctor about the trial?

a. Feel free to inquire at any time.
b. If your doctor is interested in learning more about the trial, please refer her/him to trial listing on the clinicaltrials.gov website found here (ClinicalTrials.gov Identifier: NCT04873869).

18. Can we get on a waiting list for trial participation?

a. There is not a waiting list for this study, however, a study website will soon launch that will allow you to register your interest. We will share this study website with the SCN8A patient advocacy groups when available.

19. When will the younger kids (age 2-11) be able to enroll in the trial?

a. A specific date for enrollment of participants aged 2-11 is unknown at this time. We are working diligently to obtain the additional information required to support opening the trial to children in this age group, and then the U.S. Food and Drug Administration (FDA), as well as international regulatory agencies for any ex-U.S. trial sites, must review and approve expansion of the trial to younger children.

20. Can I enroll my child if his/her age is right on the cusp (i.e., about to turn 12 or 22 this year)?

a. Eligibility is determined by age upon the date of trial enrollment. If your child is between 12 and 21 on the date of enrollment, he/she will be of an eligible age to participate.

21. If my child is not enrolled in the double-blind, placebo-controlled trial, can he/she still participate in the active extension part of the trial?

a. No. Currently the planned active extension will only be available to patients that participate in the double-blind, placebo-controlled trial (see *Background for Families* section above for trial design description). The active extension is designed this way to allow us to collect the specific data needed by the regulatory agencies (e.g., FDA) to thoroughly assess both the short-term and long-term effects of the study drug.

22. Are there any reasons that parents of patients with SCN8A-DEE should consider one clinical trial over another?

a. We encourage you to discuss potential clinical trial participation with your doctor, as each clinical trial varies across multiple aspects (e.g., trial design, scientific rationale for the treatment, etc.). NBI-921352 is being studied as a study drug for SCN8A-DEE because it targets the sodium channel in the brain associated with the SCN8A gain of function mutation known to contribute to seizures.

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NBI-921352 Phase 2 Clinical Trial: Study Drug and Treatment Questions

1. **What is the mechanism of action? Is this drug targeted to the SCN8A genetic mutation?**
    a. NBI-921352 selectively inhibits the sodium channel in the brain associated with the SCN8A gain of function mutation (Nav 1.6) known to contribute to seizures. It is not a gene therapy and therefore does not directly target the SCN8A genetic mutation itself.

2. **What form will the medication be in?**
    a. This study uses a granule (small particles similar in size to table salt or pepper) form of NBI-921352, which can be mixed with soft foods or liquid prior to dosing.
    b. Using this form allows us to move forward with the trial as quickly as possible, but we are evaluating other forms for future development beyond this trial.

3. **The study says administered orally. What about feeding tubes?**
    a. Feeding tubes are permitted. NBI-921352 can be administered via a gastrostomy tube, often called a G-tube.

4. **Is the formulation ketogenic-friendly?**
    a. Yes, the formulation is ketogenic-friendly.
    b. Additional information may be provided upon request.

5. **How does NBI-921352 differ from other sodium channel blockers? Is there information on whether it may be effective in children for whom sodium channel blockers have <u>not</u> been effective in the past?**
    a. NBI-921352 is an investigational drug and has not previously been evaluated directly in patients with epilepsy, and therefore we do not have data to answer this question at this time.

6. **What existing medications has NBI-921352 been compared with?**
    a. NBI-921352 is an investigational drug and has not previously been evaluated directly in patients with epilepsy, and therefore we do not have data to answer this question at this time.

7. **Is NBI-921352 anticipated to work better for specific variants of SCN8A-DEE?**
    a. SCN8A-DEE is most commonly caused by a mutation of the *SCN8A* gene that leads to enhanced activity of Nav1.6, the most abundant sodium channel in the human brain. This type of mutation is called a gain-of-function, or GOF, mutation. The result is increased sodium currents, which can lead to epileptic seizures.
    b. For this reason, we are investigating the safety and efficacy of NBI-921352 for individuals with a pathological or presumed pathological GOF mutation in SCN8A.

8. **How is a specific variant for SCN8A determined (e.g., loss or gain of function)?**
    a. Molecular genetic testing allows doctors to detect biomarkers of disease in an individual's genes. Gene panels are a type of molecular genetic test that allows doctors to identify a specific variant.

b. You can talk to your child's doctor to learn more about how genetic testing can be used to determine their specific variant of SCN8A.

9. **In cases where children have been able to experience seizure freedom, would NBI-921352 be expected to still help with development?**
    a. We don't yet know whether NBI-921352 could help with development. This study is not designed to answer this specific question. To be eligible for this study, patients must have an average of at least one countable motor seizure per week and not seizure-free for more than 20 consecutive days. However, our research team may consider supporting additional studies to answer questions like this in the future. The study does include outcome measures to evaluate the efficacy of the investigational therapy.
    b. In a clinical study, the most important outcome measure used to evaluate the efficacy of an investigational therapy is referred to as the primary outcome measure. In this study, the primary outcome measure is percent change from baseline in 28-day seizure frequency for countable motor seizures during the treatment period.
    c. The study also includes several other measures potentially of interest, referred to as secondary outcome measures, including:
        – Percentage of participants with a 50% or greater treatment response for countable motor seizures during the treatment period.
        – Percentage change from baseline in 28-day seizures frequency for countable motor seizures during the maintenance period.
        – Percentage of participants with a treatment response during the treatment period as well as during the maintenance period of 25% or greater, 75% or greater, or 100%.
        – Clinical Global Impression of Change (CGIC) and Patient/Caregiver Global Impression of Change (GIC), which provide a rating on a scale that assess how much a participant's condition has improved or worsened.

10. **Is it clear whether NBI-921352 will help treat children with more severe symptoms?**
    a. NBI-921352 is an investigational drug and has not previously been evaluated directly in patients with epilepsy, and therefore we do not have data to answer this question at this time.
    b. We hope to learn more about whether NBI-921352 will help treat children with more severe symptoms as results of the study become available.

11. **Is there a critical age by which a child with SCN8A-DEE should start taking NBI-921352?**
    a. We don't yet know whether there is a critical age by which children with SCN8A-DEE should start taking NBI-921352. This study is not designed to answer this specific question. However, our research team may consider supporting additional studies to answer questions like this in the future.

12. **If my child participates in the trial and receives placebo as part of the study, can he/she eventually receive the study drug, NBI-921352?**
    a. Yes, participants who complete the double-blind, placebo-controlled trial through week 16 (completion of the maintenance period) will be eligible to enroll in a separate, active

extension trial beyond this period. **All participants** in the active extension trial will receive the study drug, including those who were on placebo in the initial trial.

13. **If my child participates in the trial and receives the study drug as part of the study, can he/she continue taking it after the trial is over?**
    a. Yes, participants who complete the double-blind, placebo-controlled trial will be eligible to enroll in an active extension trial. **All participants** in the active extension trial will receive the study drug.

NBI-921352 Phase 2 Clinical Trial: Study Design and Results Measurement Questions

1. **When will my trial site be open?**
    a. It is best to check with the trial website (which will soon launch) regularly for the trial site closest to you to see when they expect to be able to screen patients for this study. Not all sites will open at the same time.
    b. The first clinical site has begun enrolling, with additional sites to open over the following months.
    c. Trial sites each have local requirements for conducting clinical trials and will likely open at different times. These requirements may include review by their institutions (e.g., hospitals, universities), laboratory and pharmacy set up, and regulatory document review.

2. **How long is study participation and what should families expect in terms of requirements during participation?**
    a. For participants randomly selected for the treatment arm of the study, participation will include a titration period, a maintenance period and a taper period, for a total duration of 18 weeks. During the titration period, participants will receive increasing doses of the investigational therapy over a six-week period. During the maintenance period, participants will receive treatment at the final tolerated dose for 10 weeks. Finally, participants will receive decreasing doses during the two-week taper period. Participants will have the option to enroll in the active extension study following completion of the maintenance period.
    b. Participants randomly placed in the placebo arm of the study will receive placebo (inactive drug) for the full duration of the study, and will similarly have the option to enroll in the active extension study following completion of the maintenance period.
    c. Participation will include visits to your study physician throughout the duration of the study as well as requirements between visits, including adhering to study drug administration instructions and completing a seizure diary. Prior to enrolling in the study, a study physician can share additional details about what to expect during participation, such as number and length of office visits and assessments, exams and lab tests required.

3. **How do you determine what levels of efficacy are enough to advance the development further beyond this trial?**

a. We will evaluate outcomes including seizure frequency in study participants who received the study drug, NBI-921352, compared to those who received placebo and look for differences between the two groups.
b. Scientists have formed hypotheses, or scientific theories, about the study drug's effect based on what is known about NBI-921352 and will test these hypotheses in the clinical trial.

4. **Will parents of trial participants be trained to appropriately count and document seizures in the seizure journal?**
    a. Yes, parents and caregivers will receive training on seizure definitions and how to count seizures for this trial.

5. **What happens if a study participant experiences an adverse event – would this require them to withdraw from the study or are some adverse events anticipated? What is the procedure for withdrawing from the study in case of a severe adverse event?**
    a. The safety of every study participant will be monitored closely and regularly.
    b. If a participant experiences an adverse event, there are specific processes that the study site will follow. Not all adverse events require withdrawal from the study. However, if a participant experiences a serious adverse event that requires them to withdraw from the study, there is a specific procedure that the study site will follow, which includes required safety follow-ups.

6. **The trial completion date on clinicaltrials.gov is listed as December 2023, but when will you know the results of the trial?**
    a. December 2023 is when we estimate the last patient will complete their last trial visit. After all the data are collected, it will take several months to verify and interpret the data to know the final trial results.

Forward-Looking Questions

1. **Why did Neurocrine Biosciences acquire the rights to NBI-921352 from Xenon Pharmaceuticals, Inc. and start pursuing its development?**
    a. Our passion is to relieve suffering by working to develop treatment options for diseases in which a tremendous unmet need exists. We are committed to developing therapies for conditions that do not have any approved treatment options or for which there have been no recent advancements.
    b. We are committed to improving the lives of those impacted by SCN8A-DEE by deepening our understanding of the impact of this condition, improving awareness among the scientific and patient communities and developing treatment option(s) with the potential to improve lives.
    c. Neurocrine Biosciences acquired the exclusive rights to NBI-921352 from Xenon Pharmaceuticals.
    d. NBI-921352 is a part of the Neurocrine Biosciences epilepsy portfolio, which consists of compounds in development to target rare epilepsies and other neurological conditions with high unmet need that may benefit from precision treatment. To learn more about

our pipeline, including our epilepsy portfolio, visit: neurocrine.com/pipeline/pipeline-overview.

2. **Will you allow access to the study drug for individuals who do not qualify for the study?**
    a. We do not have an expanded access program at this time. NBI-921352 is an investigational therapy and its safety and efficacy have not yet been established in patients.
    b. We are currently in the process of evaluating whether expanded access to NBI-921352 is appropriate under the Right to Try law. For those of you who are not aware, the Right to Try law gives certain patients who do not qualify for a clinical study access to an investigational drug.

3. **When will we know whether the investigational drug is approved for SCN8A-DEE?**
    a. Once we know the results of this study, we will assess whether any further data or clinical trials are needed to understand whether the study drug NBI-921352 is safe and shows a beneficial effect in children with SCN8A-DEE.
    b. When we have collected enough data to support a thorough FDA review, we generally spend several months compiling, summarizing, and organizing all the information into the application for regulatory approval.
    c. Then, FDA review of drug approval applications generally takes approximately eight to 12 months. Other countries may have different timelines for review and approval.

4. **If my child participates in the clinical trial and the FDA approves NBI-921352, will my health insurance cover it?**
    a. There is no cost to you for the study drug while your child is participating in the clinical trial.
    b. Upon potential FDA approval, we cannot guarantee that NBI-921352 would be covered by all insurance plans, but our team would seek coverage by all U.S. insurance plans, supported by the best data package we can provide.
    c. For countries outside of the U.S., there are other local & national government bodies and/or private insurers that review new drugs and make pricing & reimbursement determinations.

5. **What incentives could Neurocrine Biosciences gain with the development of NBI-921352 given that it is being developed for a rare condition?**
    a. Neurocrine Biosciences has received Orphan Drug Designation (ODD) and Rare Pediatric Drug Designation (RPD) for NBI-921352 from the U.S. Food and Drug Administration (FDA).
    b. For an investigational therapy to receive ODD, it must meet certain criteria, including being developed for a rare condition – one that impacts fewer than 200,000 people in the U.S. ODD offers companies an incentive to develop treatments for rare diseases to help stimulate the development of new drugs for rare disease patient communities.
    c. Similarly, RPD offers companies an incentive to obtain FDA approval of treatments for rare pediatric diseases to help stimulate the development of new drugs for rare pediatric patient communities.

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6. **If my child is not involved in the clinical trial because they do not qualify, is there any other ways we can help?**
    a. Your participation in community engagement events hosted by Neurocrine Biosciences helps improve our team's understanding of the needs and experiences of those impacted by SCN8A-DEE.
    b. We will continue to inform patient advocacy groups of any opportunities in which you and your families can get involved to help advance our efforts.
    c. Please make your interest in helping known to your patient advocacy group. We do not know at this time when specific needs may arise, but they certainly do from time to time. If your patient advocacy group knows of your interest, they can connect to you as opportunities arise.
    d. Thank you for your interest in supporting the development of potential therapies for SCN8A.

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