Understanding the Patient Experience of Hunger and Improved Quality of Life With Setmelanotide Treatment in POMC and LEPR Deficiencies

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Appendix A. Original Interview Guide

Patient-Perceived Benefits of Setmelanotide: Interviews With Clinical Trial Participants: Interview Guide

I. Introduction

[Interviewer introduces herself and notetaker and briefly reiterates the purpose and format of the interview.]

- First, thank you again for participating in an interview with us.
- During the interview today, we will ask you about your hunger before starting the clinical trial and any changes you have experienced since you started taking the study medication (setmelanotide).
- The information gathered during these interviews will supplement the clinical trial results and contribute to knowledge about your condition.
- As a reminder, your participation is completely voluntary, and you may end the discussion at any time. Of course, you should also feel free to ask us any questions you have or request a break in the interview at any time.
- We expect today's interview to last about 50 minutes. We have a series of topics we wish to cover with you but also intend for these interviews to be conversational. As such, we encourage you to describe experiences related to your hunger and the study medication as they come to mind.
- With your permission, we will audio record today's interview to make sure we do not miss any important information. The recordings will also allow us to create typed transcripts of the interviews. After the completion of the study, the audio recordings will be destroyed. All information you provide to us will be kept confidential. While the transcripts will be provided to the study sponsor, all names and any other identifying information will first be removed from the documents.
- Please keep in mind that there are no wrong answers to our questions. Hunger is a completely internal state, and it is important that we better understand your experience with hunger. We appreciate the opportunity to learn from your experiences and are truly grateful for your time.
- Before we begin, do you have any questions?
- OK, I'm going to go ahead and turn on my recorder.

START RECORDING

I am now audio recording. Do I have your permission to continue with the audio-recorded interview?

- ☐ Yes → CONTINUE
- ☐ No → STOP INTERVIEW

II. Current Experiences Versus Before the Clinical Trial: Hunger

First, let's start with you telling us a little bit about how you experience hunger these days.

- How do you experience hunger now?
- What does hunger feel like to you now?
- How do you know when you are hungry now?

Now, we'd like to hear about your experiences before you started the clinical trial.

Please think back to the time just before you started taking the study medication and tell us about your hunger.

- How much of the time did you feel hungry?
- What did it feel like when you were hungry?
  - How did you feel physically? How did you feel psychologically?
- To what extent did your hunger change over time?
  - What made you feel more or less hungry?
- What kind of foods did you want to eat when you were hungry before starting the study medication?
- How did you act or behave differently if you were more or less hungry? *(Probe on food-seeking behavior if not reported spontaneously)*
- How much of the time, if ever, did you not feel hungry at all?
  - What did that feel like? How did this differ from when you felt hungry?
  - Under what circumstances would you not feel hungry?
  - How long would that last?
  - How did your hunger change, if at all, after you ate?
- How did your hunger affect your life?
  - Did it affect you at work/school? How?
  - Did it affect your relationships with your family or friends? How?

- What bothered you most about your hunger before starting the clinical trial?

III. Experiences During the Clinical Trial: Changes in Hunger

Next, we'd like to hear about your experiences during the clinical trial and how you feel today.

- How has your hunger changed, if at all, since you started taking the study medication?
  - Do you feel more or less hungry than you used to? Please tell me more about that.
  - Do you feel hungry more or less often? Please tell me more about that.
  - How much of the time, if ever, do you not feel hungry at all?
  - Do you get hungry for the same foods as before? Different foods? Has your sense of taste changed? How?
- How meaningful or important to you are these changes in your hunger? Why?
- How have the changes in your hunger affected you and your behavior?
  - Do you feel different physically? How?
  - Do you feel different mentally or emotionally? How?
  - Have the changes in your hunger affected you at work/school? How?
  - Have the changes in your hunger affected your relationships with family or friends? How?
  - Has your way of thinking about food changed? How?
  - Do you spend more or less time thinking about food? Please tell me more about that. *Probe on whether the patient has more time to think about other things besides hunger.*
  - Do you spend more or less time working to obtain food? Please tell me more about that.
  - What are the most important changes in your life that you associate with the changes in your hunger?
  - *Probe on food-seeking behavior if not reported spontaneously.*
- I know it's been a while, but how quickly did you start to notice the changes in your hunger?
  - What did you notice first? How did you know there was a change?
  - What did you notice after that? Did the changes become more noticeable, or did your hunger sort of stay the same after that?

- Now when you eat, how does it affect your hunger?

IV. Interpretation of Hunger Items

Let's take a look at 3 questions about hunger that you answered throughout the clinical trial [Verify that the patient has a copy of the items that was distributed prior to the interview]. I'm sure you are very familiar with these questions by now.

Let's walk through each of these questions. Please tell me in your own words what each one means to you.

- How did you feel about answering these questions during the trial?
  - Were they ever difficult for you to answer? [If yes] What would make them difficult to answer?
- Is there anything different about the way you think about or interpret these questions now compared with when you first started the trial? In other words, did you start thinking about the questions differently? [If yes] Please tell me more about that.
- I know some time has passed since you entered the clinical trial but we're really interested in knowing how you would have rated your hunger then given the way you think about hunger now.
  - Thinking back to the beginning of the trial, how would you rate your average hunger at that time? What about when you were the most hungry?

There was a period in the study when the study medication was replaced with a placebo. After that, you were given the medication again.

- Could you tell when you were given the placebo rather than the study medication? How?
- Did you notice any difference in your hunger during that period? ***Note****: Do not ask the remaining questions if the patient indicates that they don't remember or could not tell if they received placebo.*
- Did you find that you were responding to the hunger items differently during that period?
- When you went back on the medication, did you think about or respond to the hunger items differently than you did before you were given the placebo? How and why?

V. Treatment Satisfaction

- Overall, how satisfied are you with the effect of the study medication on your hunger? [Not at all satisfied, a little satisfied, very satisfied] What makes you say you're [participants' answer]?
  - [If not very satisfied] In what other way would you like a medication to change your hunger? Why is this important to you?
- Thinking about your experiences overall, what kind of impact has taking the study medication made on your life? How important is this impact to you? Why?
- How would you feel about it if you were told you had to stop taking the study medication? Why?

VI. Closing

Is there anything else about your experiences or any feedback related to the studies you've been participating in that you would like to share with us?

The sponsor of the study asked us to thank you, on their behalf, for participating in the clinical trial and for sharing your valuable thoughts and experiences with us! Thank you so much!

Appendix B. Modified (Final) Interview Guide

Patient-Perceived Benefits of Setmelanotide: Interviews With Clinical Trial Participants: Interview Guide

I. Introduction

[Interviewer introduces herself and notetaker and briefly reiterates the purpose and format of the interview.]

- First, thank you again for participating in an interview with us.
- During the interview today, we will ask you about your hunger before starting the (first) clinical trial and any changes you have experienced since you started taking the study medication (setmelanotide).
- The information gathered during these interviews will supplement the clinical trial results and contribute to knowledge about your condition.
- As a reminder, your participation is completely voluntary, and you may end the discussion at any time. Of course, you should also feel free to ask us any questions you have or request a break in the interview at any time.
- We expect today's interview to last about 50 minutes. We have a series of topics we wish to cover with you but also intend for these interviews to be conversational. As such, we encourage you to describe experiences related to your hunger and the study medication as they come to mind.
- With your permission, we will audio record today's interview to make sure we do not miss any important information. The recordings will also allow us to create typed transcripts of the interviews. After the completion of the study, the audio recordings will be destroyed. All information you provide to us will be kept confidential. While the transcripts will be provided to the study sponsor, all names and any other identifying information will first be removed from the documents.
- Please keep in mind that there are no wrong answers to our questions. Hunger is a completely internal state, and it is important that we better understand your experience with hunger. We appreciate the opportunity to learn from your experiences and are truly grateful for your time.
- Before we begin, do you have any questions?
- OK, I'm going to go ahead and turn on my recorder.

START RECORDING

I am now audio recording. Do I have your permission to continue with the audio-recorded interview?

☐ Yes → CONTINUE

☐ No → STOP INTERVIEW

II. Experiences Before the Clinical Trial: Hunger

Now, we'd like to hear about your experiences before you started the (first) clinical trial.

Please think back to the time just before you started taking the study medication and tell us about your hunger.

- How much of the time did you feel hungry?
- What did it feel like when you were hungry?
  - How did you feel physically? How did you feel psychologically?
- To what extent did your hunger change over time?
  - What made you feel more or less hungry?
- On a scale of 0-to-10, how would you rate your average hunger before you started taking the study medication? What about when you were the most hungry?
- What kind of foods did you want to eat when you were hungry before starting the study medication?
- How did you act or behave differently if you were more or less hungry? *(Probe on food-seeking behavior if not reported spontaneously)*
- How much of the time, if ever, did you not feel hungry at all?
  - What did that feel like? How did this differ from when you felt hungry?
  - Under what circumstances would you not feel hungry?
  - How long would that last?
  - How did your hunger change, if at all, after you ate?
- How did your hunger affect your life?
  - Did it affect you at work/school? How?
  - Did it affect your relationships with your family or friends? How?
  - Did it affect your sleep? How?

  - Did it affect your mood or emotions? How?
- What bothered you most about your hunger before starting the clinical trial?

III. Experiences on Treatment: Changes in Hunger

Next, we'd like to hear about your experiences during the clinical trial and how you feel today.

- How do you experience hunger now?
  - What does hunger feel like to you now?
  - How do you know when you are hungry now?
- How has your hunger changed, if at all, since you started taking the study medication?
  - Do you feel more or less hungry than you used to? Please tell me more about that.
  - Do you feel hungry more or less often? Please tell me more about that.
  - How much of the time, if ever, do you not feel hungry at all?
  - Do you get hungry for the same foods as before? Different foods? Has your sense of taste changed? How?
- On a scale of 0-to-10, how would you rate your average hunger now? What about when you are the most hungry?
- How meaningful or important to you are these changes in your hunger? Why?
- How have the changes in your hunger affected you and your behavior?
  - Do you feel different physically? How?
  - Do you feel different mentally or emotionally? How?
  - Have the changes in your hunger affected you at work/school? How?
  - Have the changes in your hunger affected your relationships with family or friends? How?
  - Have the changes in your hunger affected your sleep? How?
  - Has your way of thinking about food changed? How?
  - Do you spend more or less time thinking about food? Please tell me more about that. *Probe on whether the patient has more time to think about other things besides hunger.*
  - Do you spend more or less time working to obtain food? Please tell me more about that.

  - What are the most important changes in your life that you associate with the changes in your hunger?
  - *Probe on food-seeking behavior if not reported spontaneously.*
- I know it's been a while, but how quickly did you start to notice the changes in your hunger?
  - What did you notice first? How did you know there was a change?
  - What did you notice after that? Did the changes become more noticeable, or did your hunger sort of stay the same after that?
- Now when you eat, how does it affect your hunger?

IV. Treatment Satisfaction

- Overall, how satisfied are you with the effect of the study medication on your hunger? [Not at all satisfied, a little satisfied, very satisfied] What makes you say you're [participants' answer]?
  - [If not very satisfied] In what other way would you like a medication to change your hunger? Why is this important to you?
- Thinking about your experiences overall, what kind of impact has taking the study medication made on your life? How important is this impact to you? Why?
- How would you feel about it if you were told you had to stop taking the study medication? Why?

V. Closing

Is there anything else about your experiences or any feedback related to the studies you've been participating in that you would like to share with us?

The sponsor of the study asked us to thank you, on their behalf, for participating in the clinical trial and for sharing your valuable thoughts and experiences with us! Thank you so much!