SUPPLEMENTARY MATERIAL- REASONS FOR REFUSING PARENTERAL THERAPY: INTERVIEW GUIDE FOR PATIENT INTERVIEWS

A. Introduction

- During today’s call, we will be talking about your experience with pulmonary arterial hypertension, also known as PAH. We’ll be talking about your experiences living with PAH and the different therapies you’ve considered, with a focus on therapies that are delivered through a pump. There are a lot of questions I have to cover today, so I might be going over some of them fairly quickly in the next 45 minutes. Finally, during our conversation today, there are no right or wrong answers. I’m only interested in what your experiences are and what you think. With that in mind, sometimes it might seem like I’m asking you the same question more than once. If I do that, it is only to make sure I fully understand your experience and your point of view. Do you have any questions before we get started?

B. Patient Journey

1. When you were originally contacted, you indicated you were first diagnosed with PAH [INSERT RESPONSE FROM SCREENER] months/years ago. If you had to rate your health at that time, would you say your health was excellent, very good, good, fair, or poor?
   a. What are your reasons for saying your overall health was [INSERT RESPONSE]?

2. How did your healthcare provider describe the severity of your disease at the time you were diagnosed (for example, mild, moderate, or severe, as well as stable or progressing)?

   Now we’re going to talk about the different ways you could be treated and how you felt about them, if they were discussed with you. One type of treatment is called “parenteral” therapy, which you may also know as “pump therapy” because it uses a pump to continuously deliver medication. With parenteral therapy, the medication could be delivered to you intravenously, which means through a vein, or subcutaneously, which means just under the skin. If the medication is delivered intravenously, then a tube from the pump leads to a position in your chest and stays there. If it is delivered subcutaneously, a tiny tube goes from the pump to your abdominal or stomach area and is moved to different spots from time to time. The other two types of treatment are called “inhaled therapy” and “oral therapy.” With inhaled therapy, medication is inhaled through a nebulizer, which is a machine that converts medication into a mist that you breathe in. Oral therapy simply means you are prescribed pills to take.

3. At the time of your diagnosis, did your healthcare provider discuss starting a therapy or multiple therapies for your PAH?

4. At the time your healthcare provider first discussed starting a therapy or multiple therapies with you, what options did your healthcare provider discuss with you?
   a. Did you begin any therapies at that time?
      [IF YES] Which ones?
      i. Did your healthcare provider suggest that you consider pump therapy?
      [IF YES] How long after you began your [ORAL/INHALED] therapy?
Now, let's focus specifically on the discussions you had with your healthcare provider about pump therapy.

5. If you had to rate your health at the time your healthcare provider discussed pump therapy options with you, would you say your health was excellent, very good, good, fair, or poor?
   a. What are your reasons for saying your overall health was [INSERT RESPONSE]?

6. How did your healthcare provider describe the severity of your disease at the time you discussed pump therapy options (for example, Functional Class (FC) 1, FC 2, etc.)?
   [NOTE TO INTERVIEWER: IF THE PATIENT ISN'T SURE ABOUT THEIR FUNCTIONAL CLASS, ASK WHETHER THEIR DISEASE WAS DESCRIBED AS MILD, MODERATE, OR SEVERE, AND WHETHER IT WAS STABLE OR PROGRESSING]

7. What were your healthcare provider's reasons for why you should consider pump therapy?

8. In general, what was your reaction to the recommendation to consider pump therapy?
   a. What were you thinking?
   b. What concerns did you have?
   c. What factors did you consider when making a decision whether or not to start pump therapy?

C. Pump Discussion

Now I would like to ask you some additional questions about each of the specific pump therapies you’ve considered. When you were originally contacted to participate in this discussion, you noted your healthcare provider prescribed you or asked you to consider [INSERT RESPONSE FROM SCREENER ].

9. How did you think that pump therapy would benefit you for the treatment of your PAH, generally?

10. What concerns did you have about initiating pump therapy for the treatment of your PAH, generally?

11. What factors did you weigh when making a decision whether to start pump therapy?

12. I'd like to get a better understanding now of what you expected from pump therapy.
   a. How did you expect pump therapy to affect your PAH symptoms, if at all?
      i. In what ways?
   b. How did you expect it to affect the progression of your PAH, if at all?
      i. Did you expect your condition to get better, worse, or remain the same?
   c. Did you expect it to help you live longer or not?
   d. How did you expect it to affect how often you went to the hospital or visited your healthcare provider, if at all?
e. How did you expect it to affect your overall quality of life, if at all?
   i. In what ways, if any, did you expect it to have a positive effect on your quality of life?
   ii. In what ways, if any, did you expect it to have a negative effect on your quality of life?

13. What side effects, if any, did you expect to have from the pump therapy?
   a. How easy or difficult did you expect it would be for you to live with those side effects?

14. What concerns, if any, did you have about your ability to afford pump therapy?

15. What concerns, if any, did you have about your ability to administer your pump therapy?
   a. Mixing the drug?
   b. Working the pump?
   c. What else?

16. How did you ultimately decide if you were going to take the pump therapy or not?
   a. Did you speak with any other people before making a decision? If so, whom?
   b. Did you look up any information online before making a decision on your therapy?
      [IF YES]
      i. Which websites did you look at?
      ii. Which ones were most helpful for you?
      iii. What type of information were you specifically looking for online?
   c. Did you use any other resources that helped you make your decision?
   d. Other than what we already discussed, what, if anything, did your healthcare provider tell you about the potential positive or negative effects of these therapies on your PAH and how you would feel health-wise?
   e. Did your healthcare provider specifically discuss differences in the potential side effects of the various pump therapies?
      a. What were the differences?

17. Were there specific features of the pumps that impacted your decision to decline pump therapy? What were those features?

18. What else, if anything, affected your decision to decline pump therapy?

19. When you were originally contacted to participate in this discussion, you described your experience with pump therapy as [INSERT RESPONSE FROM SCREENER ].

[IF PATIENT IS IN GROUP B (REFUSED/INITIATED) ASK QUESTIONS 20 THROUGH 23]

20. What therapy or therapies did you end up taking?
   a. For what reasons did you end up with that therapy?

21. How long after you initially declined pump therapy did you decide to initiate pump therapy?
   a. What reasons did you have for beginning pump therapy?
22. How did your actual experience with pump therapy compare to the expectations we just talked about?
   a. Relative to your PAH symptoms
   b. Relative to the progression of your PAH
   c. Relative to your ability to extend your life expectancy
   d. Impact on the number of trips you made to the hospital or your healthcare provider because of your PAH
      i. Hospital
      ii. Healthcare provider
   e. Relative to your quality of life
   f. Relative to your ability to tolerate the side effects that you experience from your pump therapy
   g. The effect on your finances
      i. Your ability to afford pump therapy
      ii. What, if anything, did you have to cut back to afford the pump therapy?
   h. Your ability to administer your pump therapy
      i. Mixing the drug?
      ii. Working the pump?
      iii. What else?

23. How, if at all, did your therapy change over time?
   a. Did you add on or change other non-pump therapies over time? If so, which ones?
   b. [FOR THOSE WHO REPORTED THEY INITIATED PUMP THERAPY BUT ARE NO LONGER ON PUMP THERAPY] How long after you initiated pump therapy did you then stop pump therapy?
      i. What were your reasons for stopping pump therapy?
      ii. Once you stopped pump therapy, what other therapy or therapies did you begin?

D. Economic Impact

24. Since you declined pump therapy, were you admitted to the hospital or did you visit the emergency room because of your PAH?

   [IF YES]
   a. How many non-emergency room visits to the hospital?
      i. How long was each visit (in days)?
      ii. What led to each event?
   b. How many visits to the emergency room?
      i. What led to that event(s)?
c. Was the event related to concerns over your pump therapy?

25. Did you have any other types of unplanned visits to your healthcare professional related to your PAH?

26. For each visit, can you tell me whether you were using a pump at that time?

E. Devices

Earlier we talked about the pump features that impacted your decision to decline pump therapies.

[IF PATIENT IS IN GROUP A (REFUSED/NEVER INITIATED) ASK QUESTIONS 29 AND 30. IF PATIENT IS IN GROUP B (REFUSED/INITIATED) ASK QUESTIONS 27 THROUGH 30.]

27. Once you began pump therapy, how did your perceptions of pump features compare to your actual experience using the pump?

28. Are there any improvements that you’d like to see in pumps that would make you more likely to begin and continue using one or tolerate using one?

29. On a scale from 1 to 5, 1 being not at all to 5 being extremely impactful, how would you rate the impact of the following potential features of a pump on your interest in using one?

[RANDOMIZE ORDER WITH EACH PATIENT INTERVIEW]

   a. Smaller pump size
   b. Being able to make adjustments to your dosing using a remote that would not have to be with the pump at all times
   c. Water resistance up to a depth of 10 feet for up to 12 minutes
   d. The pump arrives to you prefilled, so no mixing or preparation is required
   e. A fully disposable pump you can throw away with the regular trash when it is done
   f. 72-hour battery life
   g. Fully implantable pump with a 7-year shelf life that is refilled every 3 months during an appointment with your healthcare provider

30. Of all the potential pump therapy features we’ve discussed, is there a particular pump feature or combination of features that would change your mind about declining pump therapy?

[IF TIME PERMITS]

31. There are several ways healthcare providers measure how well a patient is responding to therapy and what their risk is for their disease progressing. Has your healthcare provider ever mentioned any of the following non-invasive measurements of risk?

   a. How far a patient can walk in 6 minutes or the 6-minute walk distance (6MWD)
   b. Categorizing symptoms according to the World Health Organization’s Functional Classes (FC)
c. Measuring levels of the blood hormone called B-type natriuretic peptide or BNP, which is a way to assess strain on the heart or heart failure

32. Going back to when you were first diagnosed, did your healthcare provider set up follow-up appointments?
   
   [IF YES]
   
   a. How often?
   b. Has the frequency changed over time?
   c. Did your healthcare provider refer you to a different hospital or healthcare provider to manage your PAH?

F. Close

33. Great; do you have anything else you would like me to know before we finish up?

Thank you. I appreciate the time and effort you took to speak with me today.