

## **Gastroparesis - FDA-requested Patient Listening Session**

December 2, 2019

### **Objectives of the session**

- To better understand the burden of the disease
- To better understand how patients are managing their symptoms with no/limited approved therapies available
- To understand what features of a potential treatment are most important to patients

*Discussions in FDA Listening Sessions are informal and not meant to replace, but rather complement, existing patient engagement opportunities in the Agency. All opinions, recommendations, and proposals are unofficial and nonbinding on FDA and all other participants. This report summarizes the input provided by patients and those representing patients with gastroparesis at the meeting. To the extent possible, the terms used in this summary to describe specific manifestations of gastroparesis, and the health effects and impacts, reflect those of the participants. This report is not meant to be representative of the views and experiences of the entire gastroparesis patient population or any specific group of individuals or entities. There may be experiences that are not mentioned in this report.*

### **Summary of the discussion by question**

- 1. Please share 1-3 of the most burdensome symptom(s) you experience as a result of your gastroparesis. How have they impacted your life?***
  - Nausea was the most common symptom, which was mentioned by all of the patients. One patient mentioned abdominal pain as the most bothersome symptom.
  - Three of the five patients described difficulty or the inability to sustain employment due to nausea. The other two patients described the inability to participate in social activities, such as school or camping due to nausea and pain.
  - Patients shared that they experience bloating, vomiting, fatigue, and severe stomach pain. They experience early satiety, or in other words, feel full after a few bites of food or sips of liquid.
  - Patients shared feelings of isolation due to the inability to participate in social interactions, which contributes to anxiety and/or depression.
- 2. Are symptoms such as nausea, bloating, and the feeling of fullness similarly measured on a severity scale the way that pain is? Do the symptoms feel interrelated?***
  - Patients generally reported that their symptoms vary between mild, moderate, and severe. One patient described the symptoms as either being present or not and indicated the severity does not vary much. Patients noted that the presence and severity of symptoms varies from day to day.
  - Most patients experienced worse symptoms in the morning, but one patient shared that they are worse at night.
  - Responses varied about whether symptoms are interrelated. Sometimes symptoms (e.g., pain, nausea, and bloating) feel interrelated, but other times they seem independent of each other. Many patients indicated that nausea typically seems to be separate from the other symptoms, however this can vary day to day. It was suggested that motility may be related to all symptoms.
- 3. When thinking about an “ideal” treatment for gastroparesis, are there specific symptoms that you would you most want relief from? Would you consider using a potential medical product that***

*decreased the severity of your symptom, rather than completely removing or resolving it? How long would you be willing to continue taking a new medical product before you started to feel relief from gastroparesis?*

- Patients generally desire relief from nausea.
- Patients also want relief from vomiting and pain. Some expressed that they think improving motility would also ease the other symptoms experienced.
- All patients would be willing to try a new potential treatment for multiple months (up to 6 months) to see whether the drug relieves their symptoms, if the drug had no or limited side effects.

**4. *With regard to managing gastroparesis, what specific symptom(s) do your treatment(s) address? How well does your current treatment regimen improve these symptoms? How has your treatment regimen changed over time?***

- Three of the five patients described using devices such as a pacer, stimulator, or G-tube to manage gastroparesis.
- Generally, all patients have or currently take medications, such as dronabinol, domperidone, ondansetron, and promethazine, to help manage symptoms of gastroparesis. Nearly half of the patients take or have taken dronabinol and domperidone.
- Patients shared that the devices and medications help to regulate nausea and vomiting. Several patients noted that the devices help relieve the vomiting but frequently need to be replaced, and medications relieve nausea only temporarily until the next dose is needed, several hours later.
- Four of the five patients indicated that some of the drugs taken for nausea cause fatigue.
- Patients indicated that their current medications sometimes make their symptoms manageable, but that some of the current medications generally seem to lose effect after weeks to months of use.
- Patients would prefer that new treatments have fewer side effects and that the effect on their symptoms lasts longer.
- Nearly all patients expressed that a modified diet (e.g., identifying and avoiding trigger foods, or limiting food consumption) aids in easing symptoms, such as nausea.

### **FDA centers represented**

Office of the Commissioner (OC)

Center for Drug Evaluation and Research (CDER)

Center for Devices and Radiological Health (CDRH)

### **Patients represented**

5 gastroparesis patients participated in the listening session:

- All of the 5 patients were female
- Patient ages ranged from 25 years old to 60 years old

- 4 patients had idiopathic gastroparesis; 1 patient had gastroparesis as the result of diabetes
- 1 patient was previously enrolled in a clinical trial
- Patient's severity of gastroparesis ranged from moderate to debilitating
- Some patients were diagnosed within the last year and others were diagnosed over 20 years ago

Prior to the Listening Session, patients shared:

- Burdensome symptoms: nausea, fatigue, and pain
- Management of gastroparesis and/or its symptoms: medications, medical devices, surgery, and dietary modifications

### **Financial Interest**

Participants did not identify financial interests relevant to this meeting and are not receiving compensation for this listening session.

### **Partner organization**

The National Organization for Rare Disorders (NORD) helped identify and prepare patient community participants. NORD was present during the listening session teleconference.

The Reagan-Udall Foundation for the FDA assisted with producing the summary of this meeting.