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## **TERSERA® ANNOUNCES PUBLICATION OF REAL-WORLD STUDY ON XERMELO® (TELOTRISTAT ETHYL) IN PATIENTS WITH CARCINOID SYNDROME DIARRHEA**

- **Study showed significant improvement in carcinoid syndrome symptoms in patients receiving Xermelo: Findings from the TELEPRO-II real-world study now published online<sup>1</sup>**
- **TELEPRO-II was the largest, prospective observational study with Xermelo. The study evaluated Xermelo's effectiveness over the first 3 months of treatment for symptoms of carcinoid syndrome diarrhea (CSD).<sup>1</sup>**
- **Patients reported significant improvements in all symptoms of CSD after 3 months of Xermelo therapy. Mean daily bowel movements (BMs) were reduced by 64% (P<0.0001). Stool consistency and stool urgency were reduced by 55% and 73%, respectively (P<0.0001).<sup>1</sup>**

DEERFIELD, IL — October 27, 2021 — TerSera Therapeutics LLC announced today the online publication of the TELEPRO-II study in the *Journal of Cancer Management and Research*.<sup>1</sup> The findings are from the largest, real-world study with Xermelo® (telotristat ethyl) and included 684 patients with carcinoid syndrome (CS).

Carcinoid syndrome is a rare condition that occurs in patients living with metastatic neuroendocrine tumors (mNETs) and is characterized by frequent and debilitating diarrhea that often prevents patients from leading active, predictable lives, as well as by facial flushing, abdominal pain, fatigue and, over time, heart valve damage.<sup>2-4</sup>

“Results of this prospective, real-world study show that Xermelo provides significant and clinically meaningful improvements in treating symptoms of patients suffering from Carcinoid Syndrome.” says Dr. Matthew Kulke, Chief of Hematology/Oncology, and co-director of the Boston University/Boston Medical Cancer Center.

TELEPRO-II, a follow-up study to TELEPRO-I, was a prospective, observational study. Patients reported their experience with Xermelo within the first three months of therapy.

Patients in TELEPRO-II (n=684) reported a substantial burden of CS-related symptoms at baseline.<sup>1</sup> Patients reported a mean of 6.3 bowel movements (BMs) per day, mean stool



consistency of 6.5/10 (1 being “very hard” and 10 being “watery”) and mean stool urgency score of 8.3/10 (0 being “no symptoms” and 10 being “worst imaginable symptoms”). Other CS-related symptoms included a mean nausea severity score of 8.4/10, mean abdominal pain score of 6.8/10 (0 being “no symptoms” and 10 being “worst imaginable symptoms”) and a mean of 3.1 episodes of flushing per day. Significant improvements in all CS symptoms were observed after 3 months of Xermelo therapy. Mean daily BMs were reduced from 6.3 BMs/day at baseline to 2.3 BMs/day at the end of 3 months of therapy. This reflects a statistically significant reduction of 64% ( $P < 0.0001$ ). Patients also reported significant 3-month reductions in stool consistency and stool urgency with a reduction in the severity of their symptoms by 55% and 73%, respectively ( $P < 0.0001$ ).

"The TELEPRO-II findings demonstrate how impactful Xermelo can be for patients experiencing carcinoid syndrome diarrhea," said Maryann Wahman, Executive Director, Neuroendocrine Cancer Awareness Network. "Xermelo is an effective treatment for patients with carcinoid syndrome, who need another option."

#### **About the TELEPRO-II Study:**

In 2018, TELEPRO-II was initiated as a prospective, observational real-world study assessing the effectiveness of Xermelo (telotristat ethyl) in treating symptoms of carcinoid syndrome (CS) in a US clinical practice setting.<sup>1</sup> TELEPRO-II collected information from patients initiating Xermelo who opted in to participate in a nurse support program. Patient responses were collected during monthly telephone interviews before initiating treatment (baseline) and at 1, 2, and 3 months after initiating drug. The mean change from baseline to months 1, 2 and 3 were reported for the primary outcome measures of: daily BM frequency, stool consistency, stool urgency, nausea, abdominal pain, and daily number of flushing episodes. Changes in CS symptoms were evaluated overall and in subgroups of patients who did or did not experience a  $\geq 30\%$  reduction in BM movement frequency.

#### **About Carcinoid Syndrome and Carcinoid Syndrome Diarrhea**

Carcinoid syndrome (CS) is a rare disease which affects approximately 1 out of every 5 patients with neuroendocrine tumors (NETs).<sup>5</sup> In CS, patients have NETs that overproduce certain hormones such as serotonin, bradykinin, and histamine.<sup>2</sup> One key hormone that is overproduced in CS is serotonin. Elevated serotonin levels in patients with CS can cause carcinoid syndrome diarrhea (CSD) which is characterized by increased motility in the gastrointestinal (GI) tract and reduced absorption of water and nutrients.<sup>3</sup> Patients with CSD can experience multiple, urgent, loose and watery stools several times a day. CSD can have a prominent effect on patients' quality of life. Patients with CSD may avoid social activities have increased fatigue, anxiety, and weight loss.<sup>3,4</sup>



## **About Xermelo**

Xermelo is the first and only approved oral therapy for CSD.<sup>6</sup> Xermelo targets tryptophan hydroxylase, an enzyme that mediates the excess serotonin production within metastatic neuroendocrine tumor (mNET) cells. Xermelo is approved in the United States, the European Union, and certain additional countries for the treatment of carcinoid syndrome diarrhea in combination with somatostatin analog (SSA) therapy in adults inadequately controlled by SSA therapy. Xermelo targets the overproduction of serotonin inside mNET cells, providing an additional treatment option for patients suffering from CSD.

Patients and healthcare professionals with questions about Xermelo should contact 1-844-334-4035 or visit [www.Xermelo.com](http://www.Xermelo.com).

## **Important Safety Information about Xermelo:**

### **Indication**

Xermelo is a tryptophan hydroxylase inhibitor indicated for the treatment of carcinoid syndrome diarrhea in combination with somatostatin analog (SSA) therapy in adults inadequately controlled by SSA therapy

**Warnings and Precautions:** Xermelo may cause constipation, which can be serious. Monitor for signs and symptoms of constipation and/or severe, persistent, or worsening abdominal pain in patients taking Xermelo. Discontinue Xermelo if severe constipation or severe, persistent, or worsening abdominal pain develops.

**Adverse Reactions:** In a clinical trial of patients with carcinoid syndrome diarrhea and 4-12 bowel movements per day, the most common adverse reactions (>5%) include nausea, headache, increased gammaglutamyl-transferase, depression, flatulence, decreased appetite, peripheral edema, and pyrexia. In a second clinical trial of patients with carcinoid syndrome diarrhea and less than 4 bowel movements per day, additional adverse reactions of abdominal pain and constipation were reported in >5% of patients.

**Drug Interactions:** If necessary, consider increasing the dose of concomitant CYP3A4 and CYP2B6 substrates, as Xermelo may decrease their systemic exposure. If combination treatment with Xermelo and short-acting octreotide is needed, administer short-acting octreotide at least 30 minutes after administering Xermelo.

**Use in Special Populations:** Xermelo is not recommended in patients with moderate and severe hepatic impairment.

**For more information, please see the full [Prescribing Information](#) for Xermelo.**

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call 1-800-FDA-1088. You can also contact TerSera Therapeutics at 1-844-334-4035 or [medicalinformation@tersera.com](mailto:medicalinformation@tersera.com).



## About TerSera Therapeutics

TerSera Therapeutics acquires, develops, and markets specialty pharmaceutical products with a focus on oncology and non-opioid pain. Its mission is to provide products which truly make a difference for patients. For more information about TerSera Therapeutics, please visit [www.tersera.com](http://www.tersera.com).

## References:

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