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For more information:  
Mark Leonard  
[mleonard@tersera.com](mailto:mleonard@tersera.com)  
847-651-9682

**TERSERA® PRESENTS PATIENT-REPORTED CLINICAL AND PRODUCTIVITY OUTCOMES ASSOCIATED WITH XERMELO® (TELOTRISTAT ETHYL): LONG-TERM REGISTRY TRIAL OF PATIENTS WITH CARCINOID SYNDROME DIARRHEA**

- **Findings from the Real-World Evidence Study Evaluating Patient-Reported Outcomes with Xermelo (RELAX) study were presented during the North American Neuroendocrine Tumor Society's (NANETS) Multidisciplinary NET Medical Symposium.<sup>1</sup>**
- **The RELAX patient registry is designed to assess patient satisfaction and patient-reported clinical and productivity outcomes following continuous treatment with Xermelo (telotristat ethyl) in patients with Carcinoid Syndrome Diarrhea (CSD).**
- **Patients receiving Xermelo reported improved clinical outcomes, satisfaction with control of carcinoid syndrome (CS) symptoms, weight gain or maintenance, and reduced work productivity and activity impairment (WPAI) after 6 months of treatment.<sup>1</sup>**

DEERFIELD, IL — November 9, 2021 — TerSera Therapeutics LLC announced today the presentation of patient-reported clinical and productivity outcomes data from their registry trial (RELAX) in patients with carcinoid syndrome diarrhea (CSD) receiving treatment with Xermelo (telotristat ethyl). The data were presented in virtual poster sessions during the North American Neuroendocrine Tumor Society's (NANETS) Multidisciplinary NET Medical Symposium on November 3-6, 2021.<sup>1</sup>

Carcinoid syndrome (CS) 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>

RELAX is an ongoing, noninterventional prospective registry of U.S. patients with CS. Study participants completed online surveys before starting Xermelo and every 6 months for up to 3 years. At each time interval, patients reported on changes in their clinical symptoms, use of rescue medication, weight, and work productivity and activity impairment (WPAI). Patient satisfaction with Xermelo treatment was also assessed at each 6-month interval.



107 patients completed surveys at baseline and at month 6 of treatment with Xermelo. Patients' satisfaction with control of their CSD improved from 47% at baseline to 78% at 6 months. Most patients reported improvement in number of daily bowel movements (84%) and CS symptoms (80%) after 6 months of Xermelo treatment. Reduced or stable rescue medication use was reported after 6, 12, and 18 months of treatment (75%, 76%, 83% of patients respectively). Additionally, a majority of patients taking Xermelo reported stable or increased weight after 6, 12, and 18 months of treatment (76%, 80%, 74% respectively). Patients also reported a reduction in work productivity loss (mean reduction = 13.2 points, SD = 18.31) and overall activity impairment (mean reduction = 9.4 points, SD = 26.76) after 6 months of treatment with Xermelo.<sup>1</sup>

"Results of this long-term follow-up from the RELAX patient registry continues to show very encouraging sustained benefit with Xermelo in helping neuroendocrine tumor patients control the symptoms of carcinoid syndrome, maintain weight, and reduce impairments to work productivity and activity," said Daneng Li, M.D., Assistant Professor, Department of Medical Oncology & Therapeutics Research and Co-Director of the Neuroendocrine Tumor Program, City of Hope, a cancer research and treatment organization near Los Angeles.

#### **About the RELAX Study:**

The Real-World Evidence Study Evaluating Patient-Reported Outcomes with Xermelo (RELAX) study, is an observational, noninterventional, single-arm study of adult patients with carcinoid syndrome (CS) who are initiating continuous treatment with Xermelo (telotristat ethyl).<sup>1</sup> The primary objective of the study is to estimate the proportion of patients with CS who are satisfied with their overall symptom control 6 months after initiating treatment with Xermelo. Key secondary endpoints include: the proportion of patients reporting satisfaction with their CS-related diarrhea and flushing control, impact of Xermelo on work productivity and activity impairment and impact of Xermelo on weight gain or maintenance.

#### **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 CSD 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 gamma-glutamyl-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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