

## Lexicon's Carcinoid Syndrome Treatment Meets Primary Endpoint in Phase III Clinical Trial

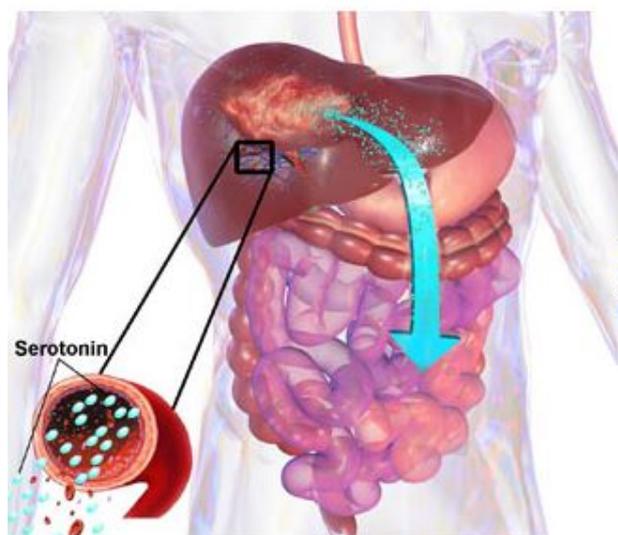
in

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**Lexicon Pharmaceuticals Inc.** has announced that the pivotal phase III clinical trial, **TELESTAR**, of its **oral drug candidate telotristat etiprate** met the primary endpoint in treating cancer patients with carcinoid syndrome that is not adequately controlled by the current standard of care.

When adding telotristat etiprate at 250 mg and 500 mg doses to a somatostatin analog injection **it significantly reduced the average number of daily bowel movements for patients with carcinoid syndrome compared to placebo over the 12-week study period.** One of the most debilitating symptoms of carcinoid syndrome is diarrhea, which significantly impacts patients' quality of life.

Lexicon received **Fast Track designation** and **Orphan Drug status** for telotristat etiprate from the FDA in 2008 and 2012, respectively. The company is working closely with the FDA to file their first new drug application (NDA). **If approved, telotristat etiprate would become the first oral treatment successfully developed for carcinoid syndrome and the first addition to the standard of care in more than 16 years.**



*Carcinoid syndrome is a combination of symptoms caused by the release of excessive serotonin and other substances into the blood stream from metastatic carcinoid tumors.*

**Carcinoid syndrome**, a chronic condition caused by neuroendocrine tumors, is **characterized by severe diarrhea and flushing**. One of the long-term consequences of carcinoid syndrome is **carcinoid heart disease**. For patients with carcinoid syndrome, the **concentration of blood serotonin** correlates with the severity of the symptoms of the syndrome — flushing, diarrhea, and wheezing – and with the potential damage to the heart. When carcinoid has metastasized to the

liver, the tumors there may produce a high concentration of serotonin which flows directly into the right side of the heart. **Telotristat etiprate is an orally-delivered serotonin synthesis inhibitor (SSI) drug that acts to reduce serotonin levels.**

[In a press release issued by the company, Lonnel Coats, Lexicon's President and Chief Executive Officer](#), commented on how pleased Lexicon is with these top-line results:

**"Carcinoid syndrome is severely debilitating, preventing many patients from leading active and predictable lives, and unfortunately, a majority of patients will not be adequately controlled over time with the current standard of care. We are committed to working closely with the FDA to file our first new drug application (NDA) and to bring this innovative new treatment to patients whose lives are already impacted by the challenges of cancer."**



[According to principal investigator Matthew H. Kulke, MD \(left\)](#), director, Program in Neuroendocrine and Carcinoid Tumors and Senior Physician at the Dana-Farber Cancer Institute in Massachusetts, "The TELESTAR results are promising, and the community of patients and caregivers who live and deal with carcinoid syndrome are excited about the prospect of a new treatment becoming available."

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