

New Study First to Confirm Sandostatin LAR(R) Depot Controls Tumor Growth in Patients with Rare Gastrointestinal Tumors

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- Data show significant 66% reduction in risk of disease progression versus placebo

- Sandostatin LAR more than doubled time without tumor growth for a median of 14 months compared to six months on placebo

- Results support Sandostatin LAR as first treatment after surgery in certain patients with newly diagnosed neuroendocrine tumors (NETs)

EAST HANOVER, N.J., Jan. 13 /PRNewswire/ -- Sandostatin LAR(R) Depot (octreotide acetate suspension for injection) demonstrated antitumor benefit in patients with metastatic neuroendocrine tumors (NETs) of the midgut, according to interim data presented today at the 2009 Gastrointestinal Cancer Symposium of the American Society of Clinical Oncology.

After six months of treatment, patients receiving Sandostatin LAR had a 66% reduction in risk of disease progression compared to patients taking placebo (P=0.000072). This reduction is based on findings that Sandostatin LAR halted tumor growth in 69% of patients, compared with 39% of patients receiving placebo. Patients who took Sandostatin LAR had no tumor progression for a median of 14.3 months, compared to six months for patients on placebo. This beneficial effect was seen in patients with either functioning (hormone secreting) or non-functioning (non-secreting) NETs.

The findings are from a Phase IIIb, multicenter, prospective, randomized, placebo-controlled, double-blind, study called PROMID (Placebo-controlled prospective Randomized study on the antiproliferative efficacy of Octreotide LAR in patients with metastatic neuroendocrine midgut tumors).

"Sandostatin LAR has a proven track record of treating the severe diarrhea and flushing associated with neuroendocrine tumors and now this study demonstrates that Sandostatin LAR also helps control tumor growth in patients with metastatic neuroendocrine tumors of the midgut," said PROMID Lead Investigator Professor Rudolf Arnold, Philipps-University Marburg, Germany. **"In addition, we saw the greatest benefit in those patients who were newly diagnosed and who had fewer liver metastases (<10% hepatic tumor load), underscoring the importance of early treatment."**

This is the first placebo-controlled study to confirm previous findings that suggested treatment with Sandostatin LAR could achieve stabilization of tumor growth in up to 50% of patients with NETs of various origin.(1)

"In recent years, a growing body of evidence has suggested that Sandostatin LAR provides antitumor effects, but these are the first data to confirm this effect from a well-designed, prospective, placebo-controlled study," said David Epstein, President & CEO of Novartis Oncology. "Studies are also underway to evaluate the benefit of combination therapy of Sandostatin LAR with our investigational mTOR inhibitor, RAD001, in patients with various types of NETs."

About NETs

The term "neuroendocrine tumor" or "NET," as defined by the World Health Organization, refers to a diverse mixture of tumors originating from the interface between the endocrine (hormonal) system and the nervous system, and includes carcinoid tumors and pancreatic NETs. Treatment options for patients with NETs are limited, with surgery being the only chance for cure. When the tumor is inoperable, the objectives of treatment are to control the potentially life-threatening symptoms (syndromes) caused by hormone secretion and to extend patient survival by reducing tumor volume or by stopping the tumor from growing. The PROMID study included only patients with well-differentiated metastatic midgut tumors.

About PROMID

PROMID is a Phase IIIb study conducted at 18 sites in Germany to evaluate the antitumor effect of Sandostatin LAR in patients with NETs. The study included 85 patients who were treated with either Sandostatin LAR or placebo until tumor progression. All patients in the study were treatment-naive, had locally inoperable or metastatic NETs with the primary tumor within the midgut, were without curative therapeutic options and had tumors that were functionally active (i.e., tumors that secrete various hormones and bioactive amines, causing symptoms such as diarrhea or flushing) or inactive.

The study was sponsored by Novartis. For information about Novartis Pharmaceuticals Corporation please visit <http://www.novartis.com>.

The safety findings observed in the PROMID study were consistent with those seen in previous studies of Sandostatin LAR in patients with NETs. The most frequently observed serious adverse events affected the gastrointestinal tract (octreotide LAR arm: n=6, placebo arm n=8), the hematopoietic system (octreotide LAR arm: n=5, placebo arm n=1) and the general health status (fatigue, fever; octreotide LAR arm: n=7, placebo arm n=2).

Serious adverse events occurred in 11 Sandostatin LAR treated patients and 10 placebo recipients. Discontinuation of treatment because of adverse effects occurred in two of 42 patients in the octreotide LAR and in zero of 43 patients in the placebo arm.

About Sandostatin LAR

Sandostatin LAR is a long-acting, injectable depot dosage form of octreotide acetate, a somatostatin analog which exerts similar pharmacologic effects on the human body as the natural hormone somatostatin. However, octreotide is even more potent than somatostatin at inhibiting growth hormone, glucagon and insulin. Based on these attributes, octreotide has been used to treat symptoms associated with metastatic carcinoid tumors (flushing and diarrhea) and vasoactive intestinal peptide (VIP) secreting adenomas (watery diarrhea). In addition, octreotide substantially reduces and in many cases can normalize growth hormone and/or IGF-1 levels in patients with acromegaly, a disease caused by a pituitary adenoma.

The active ingredient in Sandostatin LAR, octreotide acetate, was approved in the United States in October of 1988. In November of 1998, the FDA approved the long-acting formulation of octreotide acetate which Novartis markets as Sandostatin LAR. Through more than a decade and 600,000 patient years of experience, the active ingredient in Sandostatin LAR has achieved a long-standing track record of sustained efficacy and a well-established safety profile.

Sandostatin LAR important safety information

Adverse reactions identified in clinical studies include nausea, abdominal pain, gas, constipation, vomiting, pain on injection, high or low blood sugar levels and slow or irregular heart rate. Many patients developed gallstones, although few patients required treatment. For full prescribing information, please visit www.us.sandostatin.com.

References:

(1). Arnold et al Clin Gastro Hepatol 2005; Saltz et al. Cancer 1993; Arnold et al. Gut 1996; Di Bartolomeo et al Cancer 1996

Source: Novartis Pharmaceuticals Corporation

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