Novartis Gains FDA Approval for AfinitorÃ,® as First New Treatment in Nearly Three Decades for Patients with Advanced Pancreatic NET

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EAST HANOVER, N.J., May 5, 2011 /PRNewswire/ -- Novartis Pharmaceuticals Corporation ("Novartis") announced today that the US Food and Drug Administration (FDA) approved Afinitor® (everolimus) tablets for the treatment of progressive neuroendocrine tumors of pancreatic origin (PNET) in patients with unresectable, locally advanced or metastatic disease(4). This marks the first approval of a treatment for this patient population in the US in nearly 30 years(5).

The approval was based on Phase III data from the RADIANT-3 (RAD001 In Advanced Neuroendocrine Tumors) trial, showing treatment with Afinitor more than doubled the time without tumor growth (median 4.6 to 11.0 months) and reduced the risk of cancer progression by 65% when compared with placebo in patients with advanced pancreatic NET (hazard ratio=0.35 [95% confidence interval (CI), 0.27 to 0.45]; p<0.001). A consistent improvement in progression-free survival was seen with Afinitor in all patient subgroups(1). The FDA determined that the safety and effectiveness of Afinitor in the treatment of patients with carcinoid tumors have not been established(4).

"The FDA approval of Afinitor represents an important step forward for patients with advanced pancreatic NET," said James Yao, MD, Associate Professor of Medicine, The University of Texas MD Anderson Cancer Center, Houston, Texas. "Patients will now have access to a treatment that has been shown to significantly delay tumor growth and reduce the risk of disease progression."

Approximately 60% of pancreatic NET patients are diagnosed with advanced disease(2). This means that the cancer has already spread to other parts of the body, and is considered aggressive and difficult to treat(3). The five-year survival rate for these patients is 27%(6).

"With this approval, physicians can now offer their patients with progressive pancreatic NET a new treatment helping to fulfill a critical unmet need," said Herve Hoppenot, President
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SOURCE [1]

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