

July 7, 2017



Submission Addendum  
National Comprehensive Cancer Network® (NCCN®)

**RE: Additional Clinical Evidence for Afinitor® (everolimus) in Patients With Advanced Neuroendocrine Tumor and Carcinoid Syndrome**

Name: Neilda Baron, MD  
Company/Organization: Novartis Pharmaceuticals Corporation  
Address: One Health Plaza, Building 345  
East Hanover, NJ 07936  
Phone: 1-862-778-5494  
E-mail: neilda.baron@novartis.com  
Date of Request: July 7, 2017  
NCCN Guidelines Panel: Neuroendocrine Tumors (NET)

To Whom It May Concern:

As an addendum to the submissions dated September 8, 2010 and July 31, 2012, we have enclosed the publication with final overall survival data from the RADIANT-2 study regarding everolimus plus octreotide long-acting release (LAR) for the treatment of patients with advanced neuroendocrine tumor and carcinoid syndrome.<sup>1</sup>

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**FDA status**

Everolimus is indicated for the treatment of adult patients with progressive NET of pancreatic origin with unresectable, locally advanced or metastatic disease. Everolimus is indicated for the treatment of adult patients with progressive, well-differentiated, nonfunctional NET of gastrointestinal or lung origin with unresectable, locally advanced or metastatic disease. Everolimus is not indicated for the treatment of patients with functional carcinoid tumors.

**Literature support**

1. Pavel ME, Baudin E, Öberg KE, et al. Efficacy of everolimus plus octreotide LAR in patients with advanced neuroendocrine tumor and carcinoid syndrome: final overall survival from the randomized, placebo-controlled phase 3 RADIANT-2 study. *Ann Oncol*. 2017 Apr 24; Epub. doi: 10.1093/annonc/mdx193.

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Sincerely,

Neilda Baron, MD  
Executive Director and Head, Medical Information Oncology  
Novartis Pharmaceuticals Corporation

Enclosures: Copy of Prescribing Information and referenced primary literature; author disclosures included within references