

SUTENT® (sunitinib malate) Capsules

Mace L. Rothenberg, MD

Senior VP, Clinical Development and Medical Affairs, Pfizer Inc

Oncologic Drugs Advisory Committee Meeting

12 April 2011
FDA White Oak Campus
Silver Spring, MD

Proposed Indication

- SUTENT® is indicated for the treatment of unresectable pancreatic neuroendocrine tumors (pNET)

Topics for Today's Discussion

Mace Rothenberg, MD

Head of Clinical Development & Medical Affairs
Pfizer Oncology
New York, NY

- Introduction and Background
- Evaluation of SUTENT® in Pancreatic NET

Matthew Kulke, MD

Director, Carcinoid & Neuroendocrine Tumor Program
Dana-Farber/Brigham and Women's Cancer Center
Boston, MA

- Clinical Aspects of Pancreatic NET
- Perspectives on Treatment Options

3

Additional Experts

Eric Raymond, MD, PhD

Chef de Service, Hôpital Beaujon, Clichy France

- Phase 3 Study Principal Investigator

Robert Maki, MD, PhD

Senior Faculty in Medicine, Mount Sinai Medical Center, New York, NY

- Phase 3 Independent DMC Chair

Gary Koch, PhD

Professor of Biostatistics, University of North Carolina, Chapel Hill, NC

- Statistical Consultant

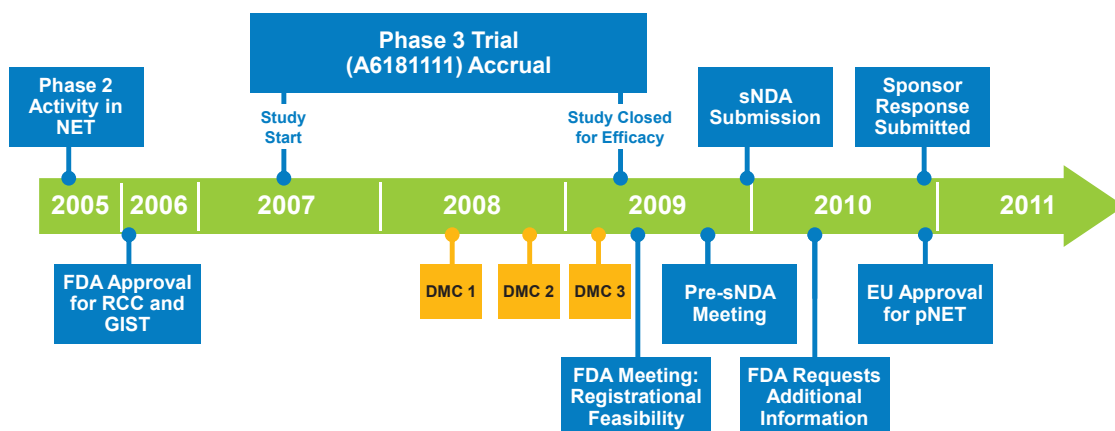
4

History

- SUTENT® (sunitinib malate) was approved in 2006 for the treatment of:
 - Advanced renal cell carcinoma (RCC)
 - Gastrointestinal stromal tumor (GIST) after disease progression on or intolerance to imatinib mesylate
- Over 100,000 patients have been treated globally

5

Development Timeline



6

Basis for sNDA

- Favorable Benefit/Risk profile
- ~6-month improvement in median PFS vs. placebo
- OS and ORR also favored sunitinib
- No new or unexpected adverse events

7

Pancreatic Neuroendocrine Tumors

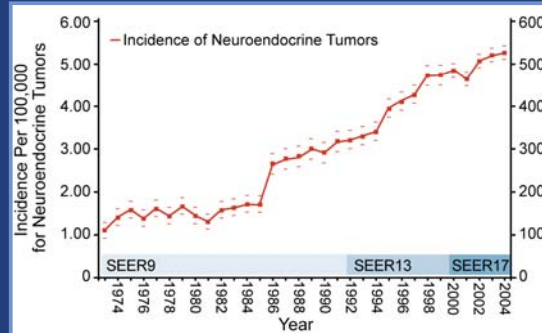
Matthew Kulke, MD

Director, Carcinoid and Neuroendocrine Tumor Program
Dana-Farber/Brigham and Women's Cancer Center
Boston, MA

Neuroendocrine Tumors: Incidence and Prevalence

- Early estimates of incidence 1–2 per 100,000 population¹
- Diagnosed incidence increasing, likely due to improved awareness, classification, and diagnostic modalities²
- Prevalence estimated to be >100,000 in United States

Incidence per 100,000 for Neuroendocrine Tumors



1. Modlin et al. *Cancer* 2003; 97: 934-59
 2. Yao JC et al. *J Clin Oncol*, 2008;26:3063-3072
 Cases selected from SEER database (1973 to 2004) using International Classification of Disease for Oncology histology codes 8150 to 8157, 8240 to 8246, and 8249

Neuroendocrine Tumors: Histologic Classification

Differentiation	Grade	Mitotic Count	KI-67 index	ENETS, WHO
Well Differentiated *	Low (G1)	< 2 per 10 HPF	≤ 2%	Neuroendocrine Tumor, Grade 1
	Intermediate (G2)	2–20 per 10 HPF	3–20%	Neuroendocrine Tumor, Grade 2
Poorly Differentiated	High (G3)	>20 per 10 HPF	>20%	Neuroendocrine Carcinoma, Grade 3, Small Cell
				Neuroendocrine Carcinoma Grade 3, Large Cell

* This includes moderately differentiated

HPF – high power field
 Kulke et al. *J Clin Oncol* 2011; 29: 934-43

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.