

Everolimus (RAD001) Significantly Extends Progression-Free Survival in Advanced Kidney Cancer Patients After Failure of Other Targeted Therapy

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- - Outstanding interim results cause independent data monitoring committee to immediately share findings; patients on placebo to be offered everolimus
- - Everolimus (RAD001) tablet, taken once daily, demonstrated highly effective anti-tumor activity through continuous targeted inhibition of mTOR
- - Results of RECORD-1 trial address unmet medical need in renal cell cancer with worldwide regulatory filings planned for second half of 2008
- - Complete results to be submitted as late-breaking abstract for presentation at the American Society of Clinical Oncology meeting

EAST HANOVER, N.J., Feb. 28 /PRNewswire-FirstCall/ -- An independent data monitoring committee stopped a major Phase III clinical trial of the investigational drug everolimus (RAD001) today after interim results showed significantly better progression-free survival in patients with advanced kidney cancer who received everolimus compared to placebo.

The committee stopped the trial of more than 400 patients conducted in 12 countries because the study met its primary endpoint. The interim findings are being shared with investigators to allow them to offer everolimus to patients remaining on placebo. Everolimus may fulfill an unmet medical need for patients with advanced renal cell cancer (RCC) who currently have no approved treatment options.

Everolimus is a once-daily oral therapy that offers a new approach to cancer treatment by inhibiting the mTOR protein, a central regulator of tumor cell division and blood vessel growth in cancer cells. The trial included patients who had their cancer worsen despite receiving approved treatments for RCC, such as Nexavar® (sorafenib)(1) or Sutent® (sunitinib)(2) or both. In addition, prior therapy with Avastin® (bevacizumab)(3) and interferon was allowed.

"Everolimus has the potential to greatly help patients with kidney cancer, especially in advanced stage who up to now have had no treatment options, as patients in the clinical trial on everolimus experienced a significantly longer period of time during which their cancer did not progress," said Daniel Vasella, Chairman and CEO of Novartis. "Everolimus is a targeted therapy which is being studied in multiple tumor types, and could provide significant benefit to patients suffering from cancer."

"This progression-free survival benefit demonstrates the possibilities of continuous mTOR inhibition as a promising target in oncology," said David Epstein, President and CEO, Novartis Oncology. "These data are the first from a broad clinical research program that includes studies in patients with high unmet needs suffering from a variety of cancers. Everolimus is the first compound in our dynamic oncology late-stage pipeline with six compounds in registration trials to show exciting clinical data this year."

Complete results of the RECORD-1 (REnal Cell cancer treatment with Oral RAD001 given Daily) trial will be submitted as a late-breaking abstract for presentation at the American Society of Clinical Oncology annual meeting in May. Worldwide regulatory filings for this indication beginning with US and EU will occur in the second half of 2008.

RECORD-1 is the largest Phase III trial to investigate the potential of the oral mTOR inhibitor everolimus as a treatment option for patients with metastatic RCC who have failed prior targeted therapy. The randomized, double-blind multi-center Phase III study compared everolimus to placebo.

Patients in the study were randomized according to Memorial Sloan-Kettering Cancer Center (MSKCC) risk criteria and prior anti-cancer therapy. MSKCC risk criteria are standard clinical criteria to determine the prognosis of patients with RCC.

In addition to RCC, everolimus is presently being evaluated in neuroendocrine tumors, lymphoma, other cancers, and tuberous sclerosis as a single agent or in combination with existing cancer therapies.

Safety findings in the study were manageable and consistent with prior Phase II studies. Common adverse events in the study included mouth ulcers, high blood lipids, high blood sugar, skin rash, low red blood count, low phosphate levels, and inflammation of the lungs.

About Everolimus

Everolimus, an oral inhibitor of mTOR, is an investigational drug being studied in multiple tumor types. In cancer cells, everolimus inhibits mTOR, a protein that acts as a central regulator of tumor cell division, cell metabolism and blood vessel growth. Everolimus is a once-daily oral therapy that provides continuous inhibition of mTOR.

As an investigational compound, the safety and efficacy profile of everolimus has not yet been established in oncology. Access to everolimus is available only through carefully controlled and monitored clinical trials. These trials are designed to better understand the potential benefits and risks of the compound. Because of the uncertainty of clinical trials, there is no guarantee that everolimus will ever be commercially available for oncology indications anywhere in the world. Everolimus is approved under the trade-name Certican® for the prevention of organ rejection in heart and kidney transplant recipients. Certican was first approved in the EU in 2003 and is available in more than 60 countries.

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References

- 1 Nexavar is a registered trademark of Bayer.
- 2 Sutent is a registered trademark of Pfizer.
- 3 Avastin is a registered trademark of Genentech.

Novartis Media Relations

Media only:

Geoffrey Cook
Novartis Oncology
P: +1 862 778 2675
F: +1 973 652 7927

Investors only:

Jill Pozarek
Novartis Corporation
P: +1 212 830 2445

Dana Kahn Cooper
P: +1 732 817 1800
F: +1 732 817 1834

Veronique Boissonnas
Ruder Finn
P: +1 212 593 6396
F: +1 646 792 4415

SOURCE: Novartis Pharmaceuticals Corporation

CONTACT: Media: Geoffrey Cook of Novartis Oncology, +1-862-778-2675, Fax: +1-973-652-7927, or Dana Kahn Cooper of Novartis Corporation, +1-732-817-1800, Fax: +1-732-817-1834, or Veronique Boissonnas of Ruder Finn for Novartis Corporation, +1-212-593-6396, Fax: +1-646-792-4415; Investors: Jill Pozarek of Novartis Corporation, +1-212-830-2445

Web site: <http://www.pharma.us.novartis.com/>

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