

MEDIA RELEASE • MEDIA RELEASE • MEDIA RELEASE •**New hope: Afinitor[®] approved in Canada as the first proven treatment for patients with advanced kidney cancer after initial failure of targeted therapy**

Dorval, QC, January 20, 2010 — Novartis Pharmaceuticals Canada Inc. (Novartis) announced today that Afinitor[®] (everolimus), a once-daily oral cancer treatment, has been approved by Health Canada for patients with metastatic renal cell carcinoma (mRCC), also known as advanced kidney cancer, after failure of initial treatment with VEGF-receptor targeted therapies Sutent[®] (sunitinib)* or Nexavar[®] (sorafenib)**. Afinitor[®] represents the first proven treatment option for patients whose cancer progressed despite prior targeted therapy with Sutent[®] or Nexavar[®].

“We have seen tremendous developments in the treatment of kidney cancer, as new targeted therapies are helping patients manage a difficult-to-treat disease that is often diagnosed at advanced stages. But for patients with advanced disease who have failed on initial therapies, access to new treatment options is urgently needed,” said Deborah Maskens, Vice-Chair, Kidney Cancer Canada. “Afinitor* is an important new option for sequential treatment, and brings new hope to Canadians living with kidney cancer.”

Prior to Afinitor*, no other therapy has been studied in a Phase III trial in this patient population where there is an important unmet medical need¹. Sutent and Nexavar are commonly used as initial treatments for metastatic RCC².

The approval is based on data that showed Afinitor*, when compared with placebo, more than doubled the time without tumour growth or death in patients with metastatic renal cell carcinoma (4.9 vs. 1.9 months) and reduced the risk of disease progression or death by 67% (hazard ratio=0.33 with 95% confidence interval 0.25 to 0.43; P<0.0001)³. Furthermore, additional data show that after 10 months of treatment with Afinitor*, approximately 25% of patients still had no tumour growth^{1***}.

“With nearly 40 per cent of renal cell carcinoma patients diagnosed at an advanced stage, new treatment options like Afinitor* are essential to help these patients battle their disease,” said Dr. Sebastien Hotte, Medical Oncologist, Juravinski Cancer Centre, and contributing investigator of the RECORD-1 trial, the basis for Health Canada’s approval of Afinitor*. “Prior to this approval, patients with metastatic renal cell carcinoma had limited options once they experienced tumour progression after VEGF-receptor targeted therapy. Based on clinical trial data, Afinitor* should be considered standard therapy when VEGF-receptor targeted therapy fails.”

Afinitor* inhibits mTOR, a protein in the cancer cell that controls tumour cell division and blood vessel growth. Preclinical and clinical data have established the important role of mTOR in the development and progression of several types of tumours¹.

About renal cell carcinoma

Renal cell carcinoma (RCC) is often referred to as kidney cancer. It is estimated that 4,600 new cases of kidney cancer developed in Canada in 2009 and 1,600 people died from the disease⁷. RCC is the most common type of kidney cancer, with occurrence rates rising steadily around the world due in part to smoking and obesity^{5,6}.

In RCC, cancer cells develop in the lining of the kidney's tubes and grow into a tumour⁸. If left untreated, the tumour can spread to neighboring lymph nodes and eventually other organs⁹.

RECORD-1 trial

The Health Canada New Drug Submission (NDS) for Afinitor* was based on data from RECORD-1 (Renal Cell cancer treatment with Oral RAD001 given Daily), the largest Phase III clinical trial to study the effects of an oral mTOR inhibitor in metastatic RCC patients whose cancer progressed despite prior treatment with sunitinib, sorafenib or both sequentially. In February, 2008, based on a recommendation from an independent data monitoring committee, Novartis stopped the trial after interim results showed that patients receiving Afinitor* experienced a significant delay in cancer progressing or death compared with patients receiving placebo¹.

This international, multi-centre, randomized, double-blind trial involved 416 patients with metastatic RCC whose cancer progressed despite prior treatment with sunitinib, sorafenib or both sequentially. In addition, prior therapy with bevacizumab, interferon alfa and interleukin-2 was allowed. Patients were randomized to receive Afinitor* (10 mg) daily or placebo, in conjunction with best supportive care. The primary endpoint of the study was progression-free survival, which was assessed via a blinded independent, central radiological review¹⁰.

About Afinitor*

Afinitor* is the first oral, daily therapy (10 mg tablets starting dose) to treat metastatic renal cell carcinoma after failure of initial treatment with either of the VEGF-receptor targeted therapies sunitinib or sorafenib. In cancer cells, Afinitor* continuously targets mTOR, a protein that acts as a central regulator of tumour cell division, blood vessel growth and cell metabolism. Afinitor* is also being studied in multiple cancer types, including neuroendocrine, breast, gastric and hepatocellular carcinoma (HCC), as well as tuberous sclerosis complex (TSC) and non-Hodgkin's lymphoma¹¹.

Important safety information

Afinitor* is contraindicated in patients with hypersensitivity to everolimus, to other rapamycin derivatives or to any of the excipients. Potentially serious adverse reactions include non-infectious pneumonitis and infections for which patients should be monitored carefully and treated as needed. In addition, non-infectious pneumonitis may require temporary dose reduction and/or interruption or discontinuation. Patients with systemic invasive fungal infections should not receive Afinitor*. Oral ulceration is a common side effect with Afinitor*. Renal function, blood glucose, lipids and hematological parameters should be evaluated prior to the start of therapy with Afinitor* and periodically thereafter. Strong or moderate CYP3A4 or P-glycoprotein inhibitors should be avoided. An increase in the dose of Afinitor* is recommended when co-administered with a strong CYP3A4 inducer. Live vaccinations and close contact with those who have received live vaccines should be avoided. Afinitor* should not be used in patients with severe hepatic impairment. Afinitor* may cause fetal harm in pregnant women.

The most common adverse reactions (incidence $\geq 30\%$) were stomatitis, infections, asthenia, fatigue, cough and diarrhea. The most common grade 3/4 adverse reactions (incidence $\geq 3\%$) were infections, dyspnea, fatigue, stomatitis, dehydration, pneumonitis, abdominal pain and asthenia. The most common laboratory abnormalities (incidence $\geq 50\%$) were anemia, hypercholesterolemia, hypertriglyceridemia, hyperglycemia,

lymphopenia and increased creatinine. The most common grade 3/4 laboratory abnormalities (incidence $\geq 3\%$) were lymphopenia, hyperglycemia, anemia, hypophosphatemia and hypercholesterolemia. Deaths due to acute respiratory failure (0.7%), infection (0.7%) and acute renal failure (0.4%) were observed for patients receiving Afinitor*.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as “risk,” “options,” “potential,” “continue to study,” “explore,” “estimated,” “can” or similar expressions, or by express or implied discussions regarding potential new indications or labeling for Afinitor*, potential approvals of Afinitor* in additional markets, or regarding potential future revenues from Afinitor*. You should not place undue reliance on these statements. Such forward-looking statements reflect the current views of the Company regarding future events, and involve known and unknown risks, uncertainties and other factors that may cause actual results with Afinitor* to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Afinitor* will be approved for sale in any additional markets. Neither can there be any guarantee that Afinitor* will be approved for any additional indications or labeling in any market. Nor can there be any guarantee that Afinitor* will achieve any particular levels of revenue in the future. In particular, management’s expectations regarding Afinitor* could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; unexpected clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data; the company’s ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; government, industry and general public pricing pressures; the impact that the foregoing factors could have on the values attributed to the Group's assets and liabilities as recorded in the Group's consolidated balance sheet, and other risks and factors referred to in Novartis AG’s current Form 20-F on file with the US Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those anticipated, believed, estimated or expected. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

About Novartis Pharmaceuticals Canada Inc.

Novartis Pharmaceuticals Canada Inc. (Novartis Canada), a leader in the healthcare field, is committed to the discovery, development and marketing of innovative products to improve the well-being of all Canadians. Novartis Canada conducts hundreds of clinical trials across the country seeking new treatments for cardiovascular disease, oncology, diabetes, cancer, ophthalmology and organ transplantation. In 2008, the Company invested close to \$96 million in research and development. Novartis Canada employs more than 750 people in Canada and its headquarters are located in Dorval, Québec. In addition to Novartis Canada, the Novartis Group in Canada consists of Novartis Animal Health Canada Inc., Novartis Consumer Health Canada Inc., CIBA Vision Canada Inc. and Sandoz Canada Inc. For further information about Novartis Canada, please consult www.novartis.ca.

References

1. Novartis data on file.
2. National Comprehensive Cancer Network. “NCCN Clinical Practice Guidelines in Oncology: Kidney Cancer.” Available at http://www.nccn.org/professionals/physician_gls/PDF/kidney.pdf. Accessed March 2009.
3. Prescribing Information for Afinitor*.
4. McLaughlin JK, et al. Epidemiologic aspects of renal cell carcinoma. *Semin Oncol*. 2006;33(5):527-533.
5. American Cancer Society. “What Is Kidney Cancer (Adult) - Renal Cell Carcinoma?” Available at http://www.cancer.org/docroot/CRI/content/CRI_2_4_1X_What_is_kidney_cancer_22.asp. Accessed March 2009.
6. Eisen, et. al. “Sorafenib for Older Patients with Renal Cell Carcinoma.” *J. Natl Cancer Inst*. 2008;100(20):1454-1463.
7. Canadian Cancer Society. “Canadian Cancer Statistics.” Available at http://www.cancer.ca/Canada-wide/About%20cancer/Cancer%20statistics/~/_media/CCS/Canada%20wide/Files%20List/English%20files%20headline

- [g/pdf%20not%20in%20publications%20section/Stats%202009E%20Cdn%20Cancer.ashx](http://pdf%20not%20in%20publications%20section/Stats%202009E%20Cdn%20Cancer.ashx). Accessed December 2009.
8. National Cancer Institute. "General Information About Renal Cell Cancer." Available at <http://www.cancer.gov/cancertopics/pdq/treatment/renalcell/patient>. Accessed March 2009.
 9. American Cancer Society. "How Is Kidney Cancer (Renal Cell Carcinoma) Staged?" Available at http://www.cancer.org/docroot/CRI/content/CRI_2_4_3X_How_is_kidney_cancer_staged_22.asp?nav=cri. Accessed March 2009.
 10. Escudier, B. et al. Phase-3 randomized trial of everolimus (RAD001) vs. placebo in metastatic renal cell carcinoma. Presented at the European Society for Medical Oncology (ESMO) 33rd Congress on September 16, 2008.
 11. A service of the U.S. National Institutes of Health. Available at <http://clinicaltrials.gov/>. Accessed March 2009.

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* Sutent[®] is a registered trademark of Pfizer Inc.

** Nexavar[®] is a registered trademark of Bayer HealthCare Pharmaceuticals, Inc. and Onyx Pharmaceuticals.

*** Data from RECORD-1 study findings presented at the 33rd European Society for Medical Oncology Congress.