



## **Health Canada Approves First New Advanced Kidney Cancer Treatment In More Than A Decade**

*Nexavar<sup>®</sup> offers hope to thousands of Canadians with kidney cancer*

**Toronto, ON – July 31, 2006** – For the first time in more than a decade, Canadians now have a treatment option for renal cell carcinoma (RCC), or kidney cancer. Health Canada has approved Nexavar<sup>®</sup> (sorafenib tablets) for the treatment of locally advanced / metastatic renal cell (clear cell) carcinoma in patients who failed prior cytokine therapy or are considered unsuitable for such therapy. This type of cancer is plagued with low survival rates (five-year survival is less than five per cent) once it spreads to other organs in the body. In clinical trials, NEXAVAR has shown to double progression-free survival in patients with this cancer. Progression-free survival defines the amount of time patients live without significant progression of their cancer.

“Until now, patients with advanced kidney cancer had limited treatment options,” says Dr. Jennifer Knox, medical oncologist, Toronto. “NEXAVAR is an effective option that has been shown to delay the progression of cancer in the majority of patients while maintaining a manageable side effect profile.”

NEXAVAR has been studied in the most common form of kidney cancer which will effect an estimated 5,000 Canadians in 2006 and 1,550 will die from the disease.<sup>1</sup> It is the sixth most common cancer in men and ranks eleventh in women.<sup>2</sup>

“I was devastated when I found out I had kidney cancer and that it had spread to my lungs,” says Tony Clark, married with three children and four grandchildren from Toronto. “I was given a year to live and did not accept that my physician could do nothing for me. Luckily, I found a clinical trial with a new drug called NEXAVAR. A year later, I feel better than ever; I’m going back to work and playing golf again.”

### **About Kidney Cancer**

Renal cell carcinoma is the most common form of kidney cancer.<sup>3</sup> An estimated 15 to 25 per cent of people with RCC already have metastatic or advanced disease at the time of prognosis.<sup>4</sup> Once the disease has spread to other organs, the five-year survival rate is less than five per cent.<sup>5</sup>

“Kidney cancer is often undiagnosed or misdiagnosed until it has spread,” said Celeste Kelley, vice president, Public Affairs, Kidney Cancer Association. “Once the disease has spread, chemotherapy and radiation are generally inappropriate. With the approval of this new treatment, Canadians with kidney cancer have a new option in the fight against this deadly disease.”

For more information about kidney cancer, please visit the Kidney Cancer Association website at: [www.curekidneycancer.org](http://www.curekidneycancer.org).

### **About NEXAVAR**

NEXAVAR is the first oral therapy and first multikinase inhibitor approved for the treatment in locally advanced / metastatic renal cell (clear cell) carcinoma. NEXAVAR works by slowing tumour growth and by cutting off the blood supply to the tumour (angiogenesis). In preclinical models, NEXAVAR targeted members of two classes of kinases known to be involved in both tumour cell proliferation (tumour growth) and tumour angiogenesis (tumour blood supply) - two important cancer growth activities. NEXAVAR acts on proteins called kinases which include RAF kinase, VEGFR-2, VEGFR-3, PDGFR- $\beta$ , KIT, and FLT-3.

On July 28, 2006, the Therapeutic Products Directorate of Health Canada (TPD) granted a Notice of Compliance with Conditions (NOC/c) for NEXAVAR for treatment of patients with locally advanced / metastatic renal cell (clear cell) carcinoma who have failed prior cytokine therapy or considered unsuitable for such therapy. This authorization reflects the promising nature of the clinical evidence which will require additional confirmatory data. Products approved under Health Canada's NOC/c policy have demonstrated promising benefit, are of high quality and possess an acceptable safety profile based on a benefit/risk assessment for the approved use.

Bayer Inc. has developed a program called the Assistance Bayer Canada (ABC) NEXAVAR Program to help patients understand insurance coverage and find other reimbursement sources. To gain access to these resources, a doctor's office or the patient/caregiver should call the ABC NEXAVAR Program at 1.800.NEXAVAR (1.800.639.2827) for assistance.

NEXAVAR is being studied in more than 20 tumour types, including hepatocellular carcinoma (liver cancer), metastatic melanoma (skin cancer), non-small-cell lung cancer, breast cancer, prostate cancer, and colon cancer. It is currently in Phase III clinical trials for the treatment of hepatocellular carcinoma (HCC), or liver cancer, and metastatic melanoma, or skin cancer. A Phase III clinical trial in non-small cell lung cancer (NSCLC) is planned in 2006.

NEXAVAR has been approved in the United States, the European Union, Switzerland, Chile and Mexico, Brazil, Korea and Argentina. In addition, filings have been completed in Australia, Japan and Turkey.

### **Bayer HealthCare**

Bayer HealthCare, a subsidiary of Bayer AG, is one of the world's leading, innovative companies in the healthcare and medical products industry and is based in Leverkusen, Germany. Bayer HealthCare generated sales amounting to some 9.4 billion euros and employed 33,800 people worldwide in 2005.

The company combines the global activities of the Animal Health, Consumer Care, Diabetes Care, Diagnostics and Pharmaceuticals divisions. The new Pharmaceuticals division was established on January 1, 2006, and comprises the former Biological Products and Pharmaceutical divisions. Pharmaceuticals now have three business units: Hematology/Cardiology, Oncology and Primary Care.

Bayer HealthCare's aim is to discover and manufacture products that will improve human and animal health worldwide. The products enhance well-being and quality of life by diagnosing, preventing and treating diseases.

*NEXAVAR<sup>®</sup> (sorafenib tablets) is a registered trademark of Bayer AG.*

## References

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<sup>1</sup> Canadian Cancer Society: Canadian Cancer Statistics 2006.

[www.cancer.ca/vgn/images/portal/cit\\_86751114/31/21/935505792cw\\_2006stats\\_en.pdf](http://www.cancer.ca/vgn/images/portal/cit_86751114/31/21/935505792cw_2006stats_en.pdf). p.18.

<sup>2</sup> Cancer Care Ontario. [www.cancercare.on.ca/index\\_statisticsKidney.htm](http://www.cancercare.on.ca/index_statisticsKidney.htm).

<sup>3</sup> BC Cancer Agency: Kidney. [www.bccancer.bc.ca/PPI/TypesofCancer/kidney/default.htm](http://www.bccancer.bc.ca/PPI/TypesofCancer/kidney/default.htm). Accessed May 17, 2006.

<sup>4</sup> Kidney Cancer Association: Diagnosis. [www.curekidneycancer.org/index.cfm?pageID=37](http://www.curekidneycancer.org/index.cfm?pageID=37). Accessed May 17, 2006.

<sup>5</sup> Medline Plus Medical Encyclopedia: Renal cell carcinoma. [www.nlm.nih.gov/medlineplus/ency/article/000516.htm](http://www.nlm.nih.gov/medlineplus/ency/article/000516.htm). Accessed May 17, 2006.