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Investor News

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Results of pivotal Phase III study in differentiated thyroid cancer:

Positive Phase III Data on Sorafenib Show Significant Improvement in Progression-Free Survival Time in Patients with Radioactive Iodine Refractory Differentiated Thyroid Cancer

- Currently there are no approved therapies specifically for radioactive iodine refractory differentiated thyroid cancer
- Sorafenib (Nexavar®) significantly extended progression-free survival; median progression-free survival of 10.8 months, compared to 5.8 months with placebo
- Results from pivotal Phase III DECISION trial presented in plenary session at Annual Meeting of the American Society of Clinical Oncology

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Leverkusen, Germany, June 2, 2013 – Bayer HealthCare Pharmaceuticals and Onyx Pharmaceuticals, Inc. today announced positive data from the Phase III DECISION trial investigating the use of sorafenib (Nexavar®) tablets in patients with locally advanced or metastatic radioactive iodine (RAI)-refractory differentiated thyroid cancer. Sorafenib significantly extended progression-free survival (PFS) compared to placebo (HR=0.587 [95% CI, 0.454-0.758]; p<0.0001), which represents a 41 percent reduction in the risk of progression or death for patients who received sorafenib compared to placebo treated patients. The median PFS was 10.8 months in sorafenib-treated patients compared to 5.8 months in those taking placebo. PFS as defined by Response Evaluation Criteria in Solid Tumors (RECIST 1.0) was the primary endpoint of this study. These data will be presented in a plenary session on June 2, 2013, at the 49th Annual Meeting of the American Society of Clinical Oncology (ASCO) in Chicago, IL (USA) (Abstract #4).

“While most patients with differentiated thyroid cancer are cured, there is a major treatment gap for patients whose cancer no longer responds to standard therapies, suffer from progression and ultimately die of their disease," said Marcia Brose, M.D., Ph.D.,

principal investigator of the DECISION trial and Assistant Professor in the Abramson Cancer Center and the Perelman School of Medicine at the University of Pennsylvania. "The DECISION trial results demonstrate for the first time that sorafenib may extend the progression free period for thyroid cancer patients."

"Already the standard of care in HCC and an important treatment option in RCC, sorafenib's utility may also be extended to differentiated thyroid cancer given these positive trial results," said Kemal Malik, M.D., Member of the Bayer HealthCare Executive Committee and Head of Global Development. "This trial is representative of our continued commitment to fully understanding sorafenib's applicability across tumor types, especially in hard-to-treat cancers where there are limited treatment options."

There was no statistically significant difference in overall survival between treatment arms, which was expected due to the cross-over design of the study. After progression, patients receiving placebo had the option to begin open-label sorafenib at the discretion of the investigator; 71 percent of placebo patients ultimately began open-label sorafenib during the trial. Median overall survival has not yet been reached in either arm.

Safety and tolerability in the study were generally consistent with the known profile of sorafenib. The most common treatment-emergent adverse events in the sorafenib arm were hand-foot skin reaction, diarrhea, alopecia, rash/desquamation, fatigue, weight loss and hypertension.

Bayer plans to submit the Phase III DECISION data as the basis to apply for marketing authorization of sorafenib in the treatment of RAI-refractory differentiated thyroid cancer.

DECISION Trial Design

The DECISION (stu**D**y of soraf**E**nib in lo**C**ally advanced or metastat**I**c patient**S** with radioactive **I**odine refractory thyr**O**id ca**N**cer) trial was an international, multicenter, placebo-controlled study. A total of 417 patients with locally advanced or metastatic, RAI-refractory, differentiated thyroid cancer (papillary, follicular, Hürthle cell and poorly differentiated) who had received no prior chemotherapy, tyrosine kinase inhibitors, monoclonal antibodies that target VEGF or VEGF receptor, or other targeted agents for thyroid cancer were randomized to receive 400 mg of oral Nexavar twice daily (207 patients) or matching placebo (210 patients). Ninety-six percent of randomized patients had metastatic disease.

About Thyroid Cancer
Thyroid cancer has become the fastest-increasing cancer in the world in recent years and is the sixth most common cancer in women. There are more than 213,000 new cases of thyroid cancer annually and approximately 35,000 people die worldwide each year.

Papillary, follicular and Hürthle cell types of thyroid cancer are classified as “differentiated thyroid cancer” and account for approximately 94 percent of all thyroid cancers. While the majority of differentiated thyroid cancers are treatable, RAI-refractory locally advanced or metastatic disease is more difficult to treat and is associated with a lower patient survival rate.

About Nexavar® (sorafenib) Tablets
Nexavar®, an oral anti-cancer therapy for liver cancer and for the treatment of patients with advanced kidney cancer, is currently approved in more than 100 countries worldwide. In Europe, Nexavar is approved for the treatment of hepatocellular carcinoma and for the treatment of patients with advanced renal cell carcinoma (RCC) who have failed prior interferon-alpha or interleukin-2 based therapy or are considered unsuitable for such therapy.

In preclinical studies, Nexavar has been shown to inhibit multiple kinases thought to be involved in both cell proliferation (growth) and angiogenesis (blood supply) – two important processes that enable cancer growth. These kinases included Raf kinase, VEGFR-1, VEGFR-2, VEGFR-3, PDGFR-B, KIT, FLT-3 and RET.

Nexavar is also being evaluated by Bayer and Onyx, international study groups, government agencies and individual investigators in a range of other cancers.

About Oncology at Bayer
Bayer is committed to delivering *science for a better life* by advancing a portfolio of innovative treatments. The oncology franchise at Bayer now includes three oncology products and several other compounds in various stages of clinical development. Together, these products reflect the company’s approach to research, which prioritizes targets and pathways with the potential to impact the way that cancer is treated.

About Bayer HealthCare
The Bayer Group is a global enterprise with core competencies in the fields of health care, agriculture and high-tech materials. Bayer HealthCare, a subgroup of Bayer AG with

annual sales of EUR 18.6 billion (2012), is one of the world's leading, innovative companies in the healthcare and medical products industry and is based in Leverkusen, Germany. The company combines the global activities of the Animal Health, Consumer Care, Medical Care and Pharmaceuticals divisions. Bayer HealthCare's aim is to discover, develop, manufacture and market products that will improve human and animal health worldwide. Bayer HealthCare has a global workforce of 55,300 employees (Dec 31, 2012) and is represented in more than 100 countries. More information at www.healthcare.bayer.com.

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