Bayer and Onyx Pharmaceuticals Announce FDA Priority Review Designation of Nexavar® (sorafenib) Supplemental New Drug Application for the Treatment of Radioactive Iodine-Refractory Differentiated Thyroid Cancer

Whippany, NJ and South San Francisco, CA – August 27, 2013 – Bayer HealthCare and Onyx Pharmaceuticals (NASDAQ: ONXX) today announced that the U.S. Food and Drug Administration (FDA) has granted Priority Review designation to the supplemental New Drug Application (sNDA) for the oral multi-kinase inhibitor Nexavar® (sorafenib) tablets under evaluation for the treatment of locally advanced or metastatic radioactive iodine (RAI)-refractory differentiated thyroid cancer. The FDA grants priority review status to drug candidates that may offer a significant improvement in treatment over existing options. The Prescription Drug User Fee Act (PDUFA) date for completion of review by the FDA of the sNDA is December 25, 2013.

"We are very pleased that the FDA has chosen to grant Priority Review to sorafenib," said Pamela A. Cyrus, M.D., Vice President and Head of U.S. Medical Affairs, Bayer HealthCare Pharmaceuticals. "This is an important milestone for sorafenib and the designation highlights the urgent need for new treatments for patients with this type of thyroid cancer who have limited or no treatment options."

"Sorafenib could offer an FDA-approved treatment option for patients with this type of thyroid cancer," said Pablo J. Cagnoni, M.D., Executive Vice President, Global Research & Development and Technical Operations, Onyx Pharmaceuticals.

DECISION Trial Design

The submission is based on 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**Nc**er) trial, 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 sorafenib twice daily (207 patients) or matching placebo (210 patients). Ninety-six percent of randomized patients had metastatic disease.

The primary endpoint of the study was progression-free survival, as defined by Response Evaluation Criteria in Solid Tumors (RECIST). Secondary endpoints included overall survival, time to progression, response rate and duration of response. Safety and tolerability were also evaluated.

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.[1,2] There are more than 213,000 new cases of thyroid cancer annually and approximately 35,000 people die from thyroid cancer worldwide each year.[3]

Papillary, follicular, Hürthle cell and poorly differentiated types of thyroid cancer are classified as "differentiated thyroid cancer" and account for approximately 94 percent of all thyroid cancers.[4] 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.[4,5]

About Nexavar® (sorafenib) Tablets
Nexavar is approved in the U.S. for the treatment of patients with unresectable hepatocellular carcinoma and for the treatment of patients with advanced renal cell carcinoma. Nexavar is thought to inhibit both the tumor cell and tumor vasculature. In in vitro 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 include Raf kinase, VEGFR-1, VEGFR-2, VEGFR-3, PDGFR-B, KIT, FLT-3 and RET.

Nexavar is currently approved in more than 100 countries. Nexavar is also being evaluated by Bayer and Onyx, international study groups, government agencies and individual investigators in a range of cancers.

Important Safety Considerations For Nexavar® (sorafenib) Tablets
Nexavar in combination with carboplatin and paclitaxel is contraindicated in patients with squamous cell lung cancer.

Cardiac ischemia and/or myocardial infarction may occur. Temporary or permanent discontinuation of Nexavar should be considered in patients who develop cardiac ischemia and/or myocardial infarction.

An increased risk of bleeding may occur following Nexavar administration. If bleeding necessitates medical intervention, consider permanent discontinuation of Nexavar.

Hypertension may occur early in the course of treatment. Monitor blood pressure weekly during the first 6 weeks and periodically thereafter and treat, if required.

Hand-foot skin reaction and rash are common and management may include topical therapies for symptomatic relief. In cases of any severe or persistent adverse reactions, temporary treatment interruption, dose modification, or permanent discontinuation of Nexavar should be considered. Nexavar should be discontinued if Stevens-Johnson Syndrome or toxic epidermal necrolysis are suspected as these may be life threatening.

Gastrointestinal perforation was an uncommon adverse reaction and has been reported in less than 1% of patients taking Nexavar. Discontinue Nexavar in the event of a gastrointestinal perforation.

Patients taking concomitant warfarin should be monitored regularly for changes in prothrombin time (PT), International Normalized Ratio (INR) or clinical bleeding episodes.

Temporary interruption of Nexavar therapy is recommended in patients undergoing major surgical procedures.

Nexavar in combination with gemcitabine/cisplatin is not recommended in patients with squamous cell lung cancer. The safety and effectiveness of Nexavar has not been established in patients with non-small cell lung cancer.

Nexavar can prolong the QT/QTc interval and increase the risk for ventricular arrhythmias. Avoid use in patients with congenital long QT syndrome and monitor patients with congestive heart failure, bradyarrhythmias, drugs known to prolong the QT interval, and electrolyte abnormalities.

Drug-induced hepatitis with Nexavar may result in hepatic failure and death. Liver function tests should be monitored regularly and in cases of increased transaminases without alternative explanation Nexavar should be discontinued.

Nexavar may cause fetal harm when administered to a pregnant woman. Women of childbearing potential should be advised to avoid becoming pregnant while on Nexavar and female patients should also be advised against breastfeeding while receiving Nexavar.

Elevations in serum lipase and reductions in serum phosphate of unknown etiology have been associated with Nexavar.

Avoid concomitant use of strong CYP3A4 inducers, when possible, because inducers can decrease the systemic exposure of Nexavar. Nexavar exposure decreases when coadministered with oral neomycin. Effects of other antibiotics on Nexavar pharmacokinetics have not been studied.

Most common adverse reactions reported for Nexavar-treated patients vs. placebo-treated patients in unresectable HCC, respectively, were: diarrhea (55% vs. 25%), fatigue (46% vs. 45%), abdominal pain (31% vs. 26%), weight loss (30% vs. 10%), anorexia (29% vs. 18%), nausea (24% vs. 20%), and hand-foot skin reaction (21% vs. 3%). Grade 3/4 adverse reactions were 45% vs. 32%.

Most common adverse reactions reported for Nexavar-treated patients vs. placebo-treated patients in advanced RCC, respectively, were: diarrhea (43% vs. 13%), rash/desquamation (40% vs. 16%), fatigue (37% vs. 28%), hand-foot skin reaction (30% vs. 7%), alopecia (27% vs. 3%), and nausea (23% vs. 19%). Grade 3/4 adverse reactions were 38% vs. 28%.

For information about Nexavar including U.S. Nexavar prescribing information, visit www.nexavar-us.com or call 1.866.NEXAVAR (1.866.639.2827).

About Bayer HealthCare Pharmaceuticals Inc.
Bayer HealthCare Pharmaceuticals Inc. is the U.S.-based pharmaceuticals business of Bayer HealthCare LLC, a subsidiary of Bayer AG. Bayer HealthCare is one of the world's leading, innovative companies in the healthcare and medical products industry, and combines the activities of the Animal Health, Consumer Care, Medical Care, and Pharmaceuticals divisions. As a specialty pharmaceutical company, Bayer HealthCare provides products for General Medicine, Hematology, Neurology, Oncology and Women's Healthcare. The company's aim is to discover and manufacture products that will improve human health worldwide by diagnosing, preventing and treating diseases.

About Onyx Pharmaceuticals, Inc.
Based in South San Francisco, California, Onyx Pharmaceuticals, Inc. is a global biopharmaceutical company engaged in the development and commercialization of innovative therapies for improving the lives of people with cancer. The company is focused on developing novel medicines that target key molecular pathways. For more information about Onyx, visit the company's website at www.onyx.com. Onyx Pharmaceuticals is on Twitter. Sign up to follow our Twitter feed @OnyxPharm at http://twitter.com/OnyxPharm.

Forward Looking Statements
This news release may contain forward-looking statements based on current assumptions and forecasts made by Bayer Group or subgroup management. Various known and unknown risks, uncertainties and other factors could lead to material differences between the actual future results, financial situation, development or performance of the company and the estimates given here. These factors include those discussed in Bayer's public reports which are available on the

Bayer Web site at www.bayer.com. The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.

This news release contains "forward-looking statements" of Onyx within the meaning of the federal securities laws. These forward-looking statements include without limitation, statements regarding the progress and results of the clinical development, safety, regulatory processes, commercialization efforts or commercial potential of Nexavar. These statements are subject to risks and uncertainties that could cause actual results and events to differ materially from those anticipated, including risks related to the development and commercialization of pharmaceutical products. Any statements contained in this press release that are not statements of historical fact may be deemed to be forward-looking statements. Reference should be made to Onyx's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2013, filed with the Securities and Exchange Commission under the heading "Risk Factors" for a more detailed description of such factors. Readers are cautioned not to place undue reliance on these forward-looking statements that speak only as of the date of this release. Onyx undertakes no obligation to update publicly any forward-looking statements to reflect new information, events, or circumstances after the date of this release except as required by law.

Nexavar® is a registered trademark of Bayer HealthCare Pharmaceuticals, Inc.

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