Addition of Tarceva® (erlotinib) to Nexavar® (sorafenib) did not Provide Additional Benefit to Patients with Unresectable Liver Cancer Versus Nexavar alone in Phase 3 Trial

Wayne, NJ, South San Francisco, CA and Tokyo, Japan – July 23, 2012 – Bayer HealthCare Pharmaceuticals, Onyx Pharmaceuticals, Inc. (Nasdaq: ONXX), and Astellas Pharma Inc. (TSE: 4503) today announced that a Phase 3 trial evaluating the efficacy and safety of the addition of Tarceva® (erlotinib) tablets to Nexavar® (sorafenib) tablets did not improve overall survival for patients with unresectable hepatocellular carcinoma (HCC) vs. Nexavar alone. The SEARCH (**S**orafenib and **E**rlotinib, a r**A**ndomized t**R**ial proto**C**ol for the treatment of patients with **H**epatocellular carcinoma) trial compared Nexavar in combination with Tarceva to Nexavar alone. The safety and tolerability of the treatment combination were generally as expected based upon experience and use of the two products alone and there were no new or unexpected toxicities or changes to the respective product safety profiles observed. Data from this study will be presented at an upcoming scientific meeting. Nexavar is jointly developed by Bayer and Onyx. Tarceva is jointly marketed by Astellas and Genentech, a member of the Roche Group.

"The data from SEARCH showed that the addition of Tarceva to Nexavar did not provide additional benefit to patients with unresectable HCC," said Dr. Dimitris Voliotis, Vice President, Global Clinical Development Oncology, Bayer HealthCare. "The results of this trial confirm the efficacy and safety profile of Nexavar in the treatment of unresectable liver cancer."

About the Phase 3 Study

The SEARCH trial was an international multicenter placebo-controlled Phase 3 study that randomized 720 patients with advanced liver cancer. The study examined whether the addition of Tarceva to Nexavar prolongs survival as compared to Nexavar alone in patients with unresectable HCC. The primary endpoint of the study was overall survival (OS) and the secondary endpoints were safety, time to radiographic progression (TTP), disease control rate (DCR) and patient-reported outcome. Patients were randomized to receive either 400 mg of Nexavar twice daily and 150 mg of Tarceva once daily or 400 mg of Nexavar twice daily with matching placebo.

About Hepatocellular Carcinoma

Hepatocellular carcinoma (HCC) is the most common form of liver cancer and is responsible for approximately 90 percent of the primary liver cancers in adults.[1,2] Liver cancer is the seventh most common cancer in the world and the third leading cause of cancer-related deaths globally.[3,4]

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

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[1] El-Serag HB. Hepatocellular Carcinoma. *N Engl J Med*. 2011;365:1118-27.

[2] Available at American Society of Clinical Oncology: http://www.asco.org/patient/Cancer+Types/Liver+Cancer

[3] GLOBOCAN 2008. Country Fast Stat. Available at: http://globocan.iarc.fr/factsheets/populations/factsheet.asp?uno=900.

[4] Forner A, Hessheimer AJ, Isabel Real M, Bruix J. Treatment of hepatocellular carcinoma. *Crit Rev Oncol Hematol*. 2006; 60: 89- 98.

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 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)
Nexavar in combination with carboplatin and paclitaxel is contraindicated in patients with squamous cell lung cancer.

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

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.

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

Uncommon but serious adverse reactions, including keratoacanthomas/squamous cell cancer of the skin and Stevens-Johnson Syndrome, have been reported in clinical trials.

An increased risk of bleeding may occur following Nexavar administration. If bleeding necessitates medical intervention, consider 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, as 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. Temporary interruption of Nexavar therapy is recommended in patients undergoing major surgical procedures.

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.

Elevations in serum lipase and reductions in serum phosphate of unknown etiology have been associated with Nexavar. Monitor patients taking concomitant warfarin regularly for changes in prothrombin time, INR, or clinical bleeding episodes. Avoid concomitant use of strong CYP3A4 inducers, when possible, because inducers can decrease the systemic exposure of sorafenib. Nexavar exposure decreases when co-administered 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%.

During post approval use of Nexavar, the following adverse drug reactions have been identified: angioedema and drug-induced hepatitis, including reports of hepatic failure and death.

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

About Tarceva

Maintenance Therapy and Second- or Third-Line Therapy in Advanced Non-Small Cell Lung Cancer (NSCLC):

- Tarceva is prescribed for patients with advanced-stage non-small cell lung cancer (NSCLC) whose cancer has not spread or grown after initial treatment with certain types of chemotherapy. (Maintenance treatment)
- Tarceva is prescribed for patients with advanced-stage non-small cell lung cancer (NSCLC) whose cancer has spread or grown after receiving at least 1 chemotherapy regimen. (2^{nd}/3^{rd}-line treatment)
- Tarceva is not meant to be used at the same time as certain types of chemotherapy for advanced NSCLC.

Advanced Pancreatic Cancer:

- Tarceva in combination with gemcitabine is prescribed for patients with advanced-stage pancreatic cancer whose cancer has spread, grown, or cannot be surgically removed and who have not received previous chemotherapy.

Important Safety Information for Tarceva

Serious side effects (including deaths) in patients taking Tarceva include Interstitial Lung Disease (ILD)-like events; liver and/or kidney problems; gastrointestinal (GI) perforations (the development of a hole in the stomach, small intestine, or large intestine); serious skin conditions; and bleeding events including gastrointestinal and non-gastrointestinal bleeding when taking warfarin or non-steroidal anti-inflammatory drugs (NSAIDs). Patients taking Tarceva plus gemcitabine were more likely to experience bleeding and clotting problems such as heart attack or stroke. Eye irritation and damage to the cornea have been reported in patients taking Tarceva. Women should avoid becoming pregnant and avoid breastfeeding while taking Tarceva. Patients should call their doctor right away if they have these signs or symptoms: new or worsening skin rash; serious or ongoing diarrhea, nausea, loss of appetite, or vomiting; new or worsening shortness of breath or cough; or eye irritation. Rash and diarrhea were the most common side effects associated with Tarceva in the non-small cell lung cancer clinical studies. Fatigue, rash, nausea, loss of appetite, and diarrhea were the most common side effects associated with Tarceva plus gemcitabine therapy in the advanced pancreatic cancer clinical study.

For full prescribing information, please call 1-877-TARCEVA or visit http://www.tarceva.com.

Tarceva is a trademark of OSI Pharmaceuticals, LLC, Farmingdale, NY 11735, USA, an affiliate of Astellas Pharma US, Inc.

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.

About Astellas
Astellas Pharma Inc., located in Tokyo, Japan, is a pharmaceutical company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. Astellas has approximately 17,000 employees worldwide. The organization is committed to becoming a global category leader in Urology, Immunology (including Transplantation) and Infectious Diseases, Oncology, Neuroscience and DM Complications and Kidney Diseases. For more information on Astellas Pharma Inc., please visit the company website at www.astellas.com/en.

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 Annual Report on Form 10-K for the year ended December 31, 2011, filed with the Securities and Exchange Commission under the heading "Risk Factors" and Onyx's Quarterly Reports on Form 10-Q 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® (sorafenib) tablets is a registered trademark of Bayer HealthCare Pharmaceuticals, Inc.

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