Clinical Study Synopsis

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The study listed may include approved and non-approved formulations or treatment regimens. Data may differ from published or presented data and are a reflection of the limited information provided here. The results from a single trial need to be considered in the context of the totality of the available clinical research results for a drug. The results from a single study may not reflect the overall results for a drug.

Bayer HealthCare

Clinical Trial Results Synopsis

Study Design Description		
Study Sponsor:	Bayer Pharmaceuticals Inc.	
Study Number:	12007	NCT00791778 EudraCT Number: 2008-004429-41
Study Phase:	IIb	
Official Study Title:	A double-blind, randomized phase II study evaluating the efficacy and safety of sorafenib compared to placebo in ovarian epithelial cancer or primary peritoneal cancer patients who have achieved a complete clinical response after standard platinum/taxane containing chemotherapy	
Therapeutic Area:	Oncology	
Test Product		
Name of Test Product:	Sorafenib (Nexavar, BAY 43-9006)	
Name of Active Ingredient:	Sorafenib	
Dose and Mode of Administration:	400 mg bid (approximately every 12 hours) per oral, continuously.	
Reference Therapy/Placebo		
Reference Therapy:	Placebo	
Dose and Mode of Administration:	2 tablets bid	
Duration of Treatment:	Treatment with sorafenib/placebo was to begin within 42 days of documented complete response. Study treatment continued until relapse of disease, unacceptable toxicity or the endpoint of the study was reached. For patients who continued to benefit after the endpoint of the study was reached, sorafenib was made available (by extension program or other mechanism) until disease progression or unacceptable toxicity.	
Studied period:	**Date of first subjects' first visit:**	04 NOV 2008
	Date of last subjects' last visit:	12 DEC 2012
Substantial Study Protocol Amendments:	The original study protocol was dated 30 JUL 2008. Four protocol amendments (including 1 local) were produced. Protocol Amendment 1, dated 22 AUG 2008 (valid in Japan only) was prepared to adjust the protocol in order to comply with the Japanese Good Clinical Practice (GCP) regulations and local requirements. Protocol Amendment 2, dated 26 FEB 2009 was applicable to all countries and included changes in the inclusion/exclusion criteria, screening procedures, laboratory evaluations during the study, timing of eligibility scan and start of treatment, Day 1 Cycle 1 procedures, time schedule of CA 125 (cancer-associated tumor marker) analysis, randomization / stratification and dose modifications. Protocol Amendment 3, dated 08 MAR 2010 was applicable to all	

	countries. The purpose of this amendment was to implement the recording of the results of Computed tomography (CT) scans / Magnetic resonance imaging scans (MRIs) performed in patients who had discontinued from the treatment phase of the study for reasons other than disease progression / relapse. In addition, consent to follow-up in order to enter the follow-up period was to be proposed to patients who had withdrawn consent from study drug treatment. Protocol Amendment 4, dated 29 NOV 2011 was applicable to all countries. The purpose of this amendment was to clarify the end of follow-up for patients ongoing at the final analysis, once/after the final analysis results were known and clarify the continuation of sorafenib treatment and the required collection of data (adverse events of CTCAE [Common Terminology Criteria for Adverse Events] Grade 3 or 4, ongoing adverse events at the EOT [end of treatment], treatment-related events of all CTCAE grades and serious adverse events) for those patients ongoing on treatment after the final analysis, once/after the final analysis results were known.
Study Centre(s):	The study was conducted at 60 centers in 14 countries: Korea (South) (9 centers), Poland (7), Belgium (6), Japan (6), Spain (5), France (5), Italy (5), Canada (4), United States (4), Finland (2), China (Hongkong) (2), Netherlands (2), Singapore (2), and Germany (1)
Methodology:	Patients with clinical complete response after standard platinum/taxane containing therapy were randomized to receive either sorafenib or placebo as "maintenance therapy". Patients were stratified according to the degree of surgical cytoreduction (optimal/suboptimal) and the presence/absence of previous intraperitoneal (IP) chemotherapy. During the treatment period, patients were assessed for safety every 28 days and for efficacy every 56 days. Progression-Free Survival (PFS) was defined as the time from randomization to the first documented disease progression by radiological or pathologic assessment or death due to any cause, whichever occurred first. For patients who had not progressed or died at the time of analysis, PFS was censored at the date of their last evaluable tumor scan. When the final analysis was complete, patients who were still alive and off treatment were no longer to be followed up (clarified by Protocol amendment 4).
Indication/ Main Inclusion Criteria:	Patients aged ≥ 18 years with International Federation of Gynecology and Obstetrics (FIGO) stage III or IV ovarian cancer or primary peritoneal cancer who had had extensive debulkment surgery and who had achieved a clinical complete response (disappearance of all clinical and radiological evidence of tumor) after one regimen of standard platinum/taxane-containing chemotherapy. In addition, the following criteria were to be fulfilled: • Normal serum CA-125 level within 14 days prior to first dose of the study drug • Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 • Life expectancy of at least 12 weeks • Adequate bone marrow, liver and renal function
Study Objectives:	**Primary:**

	The primary objective of the study was to compare the sorafenib and placebo treatment groups in terms of progression-free survival (PFS). **Secondary:** The secondary objectives were to compare the treatment groups in terms of: • Time to first pathologic CA-125 serum levels (required to be confirmed with a second measurement within 14 days) and • Overall survival (OS) Other efficacy evaluations included: • Ovarian cancer symptom response and • General health status. Evaluation of safety included assessment of adverse events (AEs) and abnormalities in laboratory parameters.
Evaluation Criteria:	**Efficacy (Primary):** The primary efficacy endpoint was PFS. PFS was defined as the time from randomization to the first documented disease progression by radiological or pathologic assessment or death due to any cause whichever occurred first. **Efficacy (Secondary):** Secondary efficacy variable were: • CA 125: Time to first pathologic CA-125 serum levels • OS: The OS time was measured from the date of randomization until the date of death due to any cause. **Efficacy (Other):** Other efficacy variables included ovarian cancer symptom response based on Functional Assessment of Cancer Therapy (FACT)/National Comprehensive Cancer Network (NCCN) Ovarian Symptom Index (FOSI) and general health status based on EQ-5D **Safety:** Adverse events were assessed using the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) Version 3.0. Other safety assessments included: vital signs, physical examination, Eastern Cooperative Oncology Group (ECOG) performance status, electrocardiogram (ECG) and laboratory tests

Statistical Methods:	**Efficacy (Primary):** The analysis of PFS was to be performed when approximately 105 PFS events had occurred. The two treatment groups (sorafenib and placebo) were compared based on the full analysis set (FAS) which comprised all patients who were randomized to a treatment group following the intent-to-treat principle. A stratified one-sided log rank test with a one-sided alpha of 10% was used stratified by degree of surgical cytoreduction (optimal/suboptimal) and previous IP chemotherapy (presence/absence). The product-limit estimates of the PFS distribution functions (Kaplan-Meier) were presented for each treatment group in a plot and in descriptive parameters. The hazard ratio (HR) sorafenib over placebo and its 95% CI was generated from the Cox model. Three sensitivity analyses (one using a modified PFS definition, one using the scheduled rather than the actual date of tumor evaluation for calculation and one using an non-stratified log rank test) were performed. **Efficacy (Secondary):** Time to first pathologic CA 125-serum level (TTCA125) was defined as the time from randomization to the first documented increase of CA 125 above the upper limit of normal. Analysis was based on the per protocol analysis set (PPS) which comprised all patients randomized to a treatment group with normal CA-125 serum level at baseline and at least one post-baseline CA-125 assessment. OS, which was defined as the time from randomization to death due to any cause, was analyzed based on the FAS. The secondary efficacy variables were analyzed similarly to the primary analysis. The primary and secondary efficacy variables were analyzed with data cutoff 15 JUL 2011. **Safety:** Safety analyses were performed on the safety analysis set (SAF) which comprised all patients randomized to a treatment group who had taken at least one dose of study medication. Summary statistics were used in the analysis of safety parameters. At the time of the primary cut-off 15 JUL 2011, there were 18 patients still on treatment in the sorafenib group and 30 in the placebo group. Restricted safety information was collected from these patients until last patient's last visit (LPLV) according to Protocol Amendment 4, dated 29 NOV 2011. Data presented in this synopsis were based on cumulative data covering the period from 04 NOV 2008 (first patient's first visit [FPFV]) to 12 DEC 2012 (LPLV). **Other - if applicable:** **Subgroup analyses** Subgroup analyses of PFS, time to first pathological CA 125 level and OS by treatment group were performed for age (<65, ≥65, ≥75 years), baseline ECOG performance status, degree of surgical cytoreduction, previous IP chemotherapy, increase of CA 125 before progression. Descriptive statistics and hazard ratio estimates with 95% CI were provided. **Other efficacy variables** Descriptive statistics of the PRO instruments FOSI and EQ-5D (index and visual analogue scale [VAS]) based on the FAS population with evaluable PRO assessments at baseline and at least one assessment post baseline (PROAS) were presented. For the FOSI questionnaire,

	the total score was described at each time point together with the difference from baseline (N, mean, SD, median, range). Plots were presented. For the EQ-5D questionnaire, the EQ-5D index and the VAS were described at each time point together with the difference from baseline (N, mean, SD, median, range). Plots were presented.
Number of Subjects:	A total of 246 patients were randomized (123 in the sorafenib group and 123 in the placebo group). All of the patients received study medication. Both the Safety analysis set (FAS) and the Full analysis set (SAF) comprised 123 patients in each treatment group. The Per-protocol analysis set for CA 125 analysis (PPS) comprised 119 patients in the sorafenib group and 121 patients in the placebo group. At the time of the primary cut-off 15 JUL 2011, there were 18 patients still on treatment in the sorafenib group and 30 in the placebo group. Restricted safety information was collected from these patients until LPLV according to Protocol Amendment 4, dated 29 NOV 2011.

Study Results

Results Summary — Subject Disposition and Baseline

A total of 246 patients were randomized (123 in the sorafenib group and 123 in the placebo group). All of the patients received study medication. Both the FAS and the SAF comprised 123 patients in each treatment group. The PPS comprised 119 patients in the sorafenib group and 121 patients in the placebo group.

The primary reason for treatment discontinuation in the sorafenib group was AE (39.8%), in the placebo group the primary reason for treatment discontinuation was progression (61.0%).Majority of patients who discontinued study treatment entered the survival follow-up (81.3% in the sorafenib group and 74.0% in the placebo group). The primary reason for discontinuation of follow-up was study termination by the sponsor, 64.2% in the sorafenib group and 63.4% in the placebo group.

With respect to demography and baseline disease characteristics the treatment groups were comparable. All patients were females, the mean age was 55.7 ± 10.4 years and 53.3% of the patients were White. The vast majority of patients (93.1%) had ovarian cancer; only 6.9% had primary peritoneal cancer. In the mean, 6.7 ± 1.4 months had passed since the initial diagnosis. A small proportion of 3.7% of patients had received IP chemotherapy. In 85.4% of patients surgical cytoreduction had been optimal and in 8.1% suboptimal (in 6.5% the information was missing); 81.7% had shown between 0 and 5 lesions post debulking. As required per protocol all patients presented with complete response after standard platinum/taxane containing therapy which most frequently consisted of carboplatin and paclitaxel.

Results Summary — Efficacy

Table A: Progression-free survival (PFS) (full analysis set)

	Placebo (N = 123)	Sorafenib (N = 123)
Total censored	55 (44.72%)	84 (68.29%)
Total failed	68 (55.28%)	39 (31.71%)
Median PFS (days)	478	386
95% CI for median	(337, 567)	(230, 691)
P-value (stratified one-sided log rank test with alpha=10%)	0.655	
Hazard ratio [a] (sorafenib/placebo)	1.09	
95% CI for hazard ratio	(0.72, 1.63)	

Note: Analyses were stratified by degree of surgical cytoreduction and previous IP chemotherapy.
[a]: Hazard ratio and its 95% CI are based on a stratified proportional hazard model.
Abbreviations: CI – confidence interval; IP – intra-peritoneal; PFS – progression-free survival

The primary efficacy results are summarized in Table A above. The primary efficacy variable was PFS. Up to and including the data cut-off date, a total of 107 PFS events (68 in the placebo group and 39 in the sorafenib group) were observed. Median PFS was 478 days in the placebo group and 386 days in the sorafenib group. The p-value of the stratified one-sided log rank test was 0.655; thus, with a pre-specified alpha of 0.10, this study failed to show superiority of sorafenib compared to placebo with respect to the primary endpoint of PFS. According to the hazard ratio of 1.09 (95% CI 0.72 to1.63) there was no distinct difference in PFS between the treatment groups.

Remarkable was that a considerable number of patients in the sorafenib group were censored early. Of the 84 patients in the sorafenib group who were censored, 20 patients were censored at Day 1 because no post-baseline tumor assessment was available. In contrast, 55 patients in the placebo group were censored and of these only 2 were censored at Day 1. This imbalance in the number of early censored patients could have affected the reliability of the results.

The primary efficacy results were supported by the results of 3 sensitivity analyses (applying a modified definition of PFS[1] [HR sorafenib/placebo: 1.19; 95% CI: 0.82 to 1.71], using the scheduled rather than the actual visit dates [HR: 1.18; 95% CI: 0.78 to 1.79] and performing the analysis in a non-stratified manner [HR: 1.09; 95% CI: 0.73 to1.62]).

None of the subgroup analyses of PFS (by age group, ECOG status, degree of surgical cytoreduction, previous IP, increase in CA 125 before progression) showed distinct differences between the treatment groups.

In the analysis of secondary variables, the median time to the first pathologic CA-125 serum level was 617 days in the placebo group and 337 days in the sorafenib group. Again, no benefit of sorafenib treatment was shown (p=0.951, one-sided log rank test). The hazard ratio (sorafenib/placebo) of 1.43 (95% CI: 0.93 to 2.20) represented a 43% increase in hazard under sorafenib and thus pointed towards more favorable results under placebo. A similar observation was made in the subgroup of patients with an increase in CA 125 before progression (N=65; hazard ratio sorafenib/placebo: 1.80 [95% CI: 1.09 to 2.97]). Progression-free rates based on a pathologic CA-125 serum level were descriptively higher under placebo at Month 6 (difference sorafenib-placebo: -9.0% [95% CI: -22.2% to 1.5%]), Month 12 (-11.7% [95% CI: -27.2 to 2.0%]), Month 18 (-12.6% [95% CI: -28.1 to 2.2%]) and Month 24 (difference sorafenib-placebo: -13.0% [95% CI: -28.1 to 2.4%]).

Due to the relatively low number of death events (12 patients in the placebo group and 16 patients in the sorafenib group died), the median overall survival time could not be estimated, making it difficult to draw any firm conclusions. The p-value of the stratified one-sided log rank test (alpha=10%) was 0.844 and the hazard ratio (sorafenib/placebo) was 1.49 (95% CI: 0.69 to 3.23).

[1] In this analysis clinical progressions, progressions after more than one missed evaluation and progressions in follow-up were considered as PFS events.

Among the 246 patients randomized in the study, 219 patients (89.0%) completed the FOSI at baseline and had at least one assessment post-baseline, and were included in the PROAS. For the EQ-5D, 220 (89.4%) and 216 (87.8%) patients were included in the PROAS for EQ-5D index and VAS, respectively. The mean FOSI total scores appeared to be similar at baseline and at the end of treatment for both treatment groups. A similar finding was observed for EQ-5D index. The mean EQ-5D VAS scores were similar at baseline for both groups, and appeared to be slightly lower at end of treatment for the sorafenib group. Finally, none of the score changes from baseline to end of treatment for the FOSI, EQ-5D index and VAS scores reached the minimal clinically meaningful difference for both treatment groups.

Results Summary — Safety

A considerable proportion of patients in the sorafenib group discontinued the study at a very early stage. A total of 36.6% of patients in the sorafenib group compared to 3.3% in the placebo group were treated for a maximum of 8 weeks and 23.6% versus 1.6%, respectively, only for a maximum of 4 weeks. Consequently, the median treatment duration in the sorafenib group was markedly shorter than in the placebo group (17.6 weeks vs. 51.9 weeks, respectively) and less treatment cycles were administered (8.0 ± 7.9 cycles vs. 14.1 ± 8.6 cycles, respectively). The predominant reason for early discontinuation (within the first 8 weeks) in the sorafenib group was AE (in 30 of 45 patients). The proportions of patients with dose reduction (67.5% in the sorafenib group [predominant reason: AE] vs. 30.1% in the placebo group [predominant reason: patient error]) and treatment interruption (83.7% vs. 35.0% [predominant reason in both groups: AE]) were also higher under sorafenib than under placebo. Only 30.9% of patients under sorafenib compared to 91.1% of patients under placebo received > 90 to 110% of the planned dose. Additional exposure data collected after primary data cut-off until LPLV were in agreement with the data collected for primary analysis, and did not change previous conclusions.

The overall incidence of treatment emergent AEs was high in both treatment groups (98.4% in the sorafenib group vs. 88.6% in the placebo group). AEs in the sorafenib group most commonly concerned dermatology/skin events (93.5%), gastrointestinal events (69.9%), pain (56.1%), constitutional symptoms (42.3%) and cardiac general events (36.6%), whilst in the placebo group pain (59.3%), gastrointestinal events (55.3%), dermatology/skin events (44.7%) and constitutional symptoms (36.6%) were most commonly reported. Clearly higher incidences of AEs under sorafenib as compared to placebo were observed in the categories dermatology/skin (93.5% vs. 44.7%, respectively), cardiac general (36.6% vs. 8.1%), gastrointestinal (69.9% vs. 55.3%), blood/bone marrow (20.3% vs. 8.9%) and hemorrhage/bleeding (13.8% vs. 3.3%). In the placebo group, the most common AEs (by CTCAE term) were fatigue (22.8%) and nausea (21.1%). In the sorafenib group, the most common AEs were hand-foot skin reaction (sorafenib: 66.7% vs. placebo: 14.6%) and rash/desquamation (50.4% vs. 13.8%). These were the AEs with the greatest differences in incidences between the sorafenib group and the placebo group. Markedly higher incidences for sorafenib vs. placebo were also observed for hypertension (36.6% vs. 5.7%), diarrhea (38.2% vs. 17.1%), mucositis functional/symptomatic, oral cavity (19.5% vs. 4.9%), anorexia (16.3% vs. 4.1%) and pruritus (19.5% vs. 8.1%). In the sorafenib group, the AEs hand-foot skin reaction, pruritus, rash/desquamation and hypertension tended to start during the first cycle of study treatment.

AEs with greater severity were more frequent under sorafenib than under placebo (Grade 3-5 events: 72.4% vs. 34.1%, respectively). The highest incidence of Grade 3-5 events and the greatest difference between the treatment groups was observed in the CTCAE category dermatology/skin (49.6% in the sorafenib group vs. 1.6% in the placebo group). Grade 3-5 AEs which were notably more common under sorafenib than under placebo were hand-foot group (98.4% vs. 55.3%). By CTCAE category, the most placebo group were dermatology/skin events (91.9% vs. 37.4%), cardiac common drug-related AEs with a skin reaction (39.0% vs. 0.8%), rash/desquamation (14.6% vs. 0%) and hypertension (8.1% vs. 0.8%). Grade 4 events were relatively rare (4.9% under sorafenib and 3.3% under placebo) and there were no treatment-emergent Grade 5 AEs. One Grade 5 AE (GI hemorrhage) occurred in a patient who was never randomized.

Drug-related AEs were notably more frequent in the sorafenib group than in the placebo

group (98.4% vs. 55.3%). By CTCAE category, the most common drug-related AEs with a markedly higher incidence in the sorafenib group than in the placebo group were dermatology/skin events (91.9% vs. 37.4%), cardiac general events (30.9% vs. 2.4%), gastrointestinal events (52.0% vs. 24.4%), constitutional symptoms (30.9% vs. 17.9%) and blood bone marrow events (16.3% vs. 5.7%) and by CTCAE term hand-foot skin reaction (65.9% vs. 13.8%), rash/desquamation (48.8% vs. 9.8%), hypertension (30.9% vs. 1.6%), diarrhea (27.6% vs. 8.1%), mucositis functional/symptomatic, oral cavity (14.6% vs. 1.6%) and pruritus (17.9% vs. 6.5%). Drug-related Grade 3 AEs were more frequent under sorafenib (65.0%) than under placebo (11.4%). Most common were hand-foot skin reaction (38.2% vs. 0.8%), rash desquamation (13.8% vs. 0%) and hypertension (8.1% vs. 0.8%). Drug-related Grade 4 AEs were reported in none of the patients in the placebo group and in 3 patients (2.4%) in the sorafenib group. These comprised hemoglobin, supraventricular arrhythmia, atrial fibrillation and metabolic/lab - other.

None of the patients in either group died as a consequence of an AE. Twelve patients in the placebo group and 16 patients in the sorafenib group died off-study (most frequent reason disease progression). Whilst the overall incidence of SAEs was similar in both treatment groups (17.9% in the placebo group and 20.3% in the sorafenib group), Grade 3 SAEs were slightly more frequent under sorafenib (14.6% vs. 9.8%) and drug-related SAEs were only reported in the sorafenib group (12.2%). Apart from the fact that dermatology/skin events were slightly more frequent in the sorafenib group (5.7% vs. 1.6%), there were no marked differences between the treatment groups with regard to the pattern of SAEs. Drug-related Grade 3 SAEs occurred mostly in individual patients; exceptions were dermatology/skin events and gastrointestinal events. Events with a Grade 4 rating were hemoglobin and 'supraventricular arrhythmia, atrial fibrillation'. The vast majority of drug-related SAEs had resolved by the end of the study. For 5 events the outcome was reported as "improved": urticaria, hand-foot skin reaction and hemoglobin (each of which occurred in 1 patient) and rash/desquamation (2 patients). Both the incidence of AEs necessitating dose modification (74.0% under sorafenib and 27.6% under placebo) and of those leading to permanent discontinuation of the study drug (39.0% vs. 6.5%, respectively) were markedly higher under sorafenib than under placebo. Dermatology/skin events (predominantly hand-foot skin reaction and rash/desquamation) were the events which most frequently induced dose modification or treatment discontinuation. Treatment discontinuation due to hand-foot skin reaction was reported in 15.4% of patients in the sorafenib group vs. 0% of patients in the placebo group, due to rash/desquamation in 7.3% vs. 0% and due to hypertension in 3.3% vs. 0%. Laboratory abnormalities were generally mainly Grade 1 or 2 events and most commonly concerned hematological parameters. With regard to blood pressure, higher rates of increased values in the sorafenib group were particularly observed for diastolic blood pressure (diastolic blood pressure $\geqslant$ 100 mmHg: 15.0% vs. 5.7%). The incidence of hypertension reported as AE was clearly higher under sorafenib (36.6% vs. 5.7%). The evaluation of ECG findings did not reveal conclusive differences between the treatment groups. Cardiac arrhythmia AEs were slightly more common under sorafenib (5.7% vs. 1.6%).

After the primary data cut-off date (15 JUL 2011), additional safety data were collected until 12 DEC 2012 (LPLV). The additional safety data were restricted including adverse events of CTCAE Grade 3 or 4, ongoing adverse events at the EOT, treatment-related events of all CTCAE grades and serious adverse events, which needs to be taken into account when interpreting the findings. These safety data were combined with the previously collected safety data to have cumulative safety data covering the period from 04 NOV 2008 (FPFV) to 12 DEC 2012 (LPLV). In this cumulative safety analysis, most common events were of the CTCAE categories dermatology/skin (69.5% in total), gastrointestinal (64.2%) and pain (57.7%). Dermatology/skin events were markedly more frequent in the sorafenib group than in the placebo group (93.5% vs. 45.5%, respectively).The same applied to events of the categories cardiac general (36.6% vs. 8.9%), gastrointestinal (70.7% vs. 57.7%), blood/bone marrow (22.8% vs. 9.8%) and hemorrhage/bleeding (14.6% vs. 3.3%). There was overall a similar trend in the incidences of AEs as reported in the primary safety analysis

(from FPFV to primary data cut-off). In conclusion, additional safety data collected did not change conclusions of the primary safety analysis.
Conclusion(s) The study failed to show superiority of sorafenib compared to placebo with respect to the primary endpoint of PFS in patients with ovarian epithelial or primary peritoneal cancer. The safety profile of sorafenib was overall as expected; compared to placebo, the rate of treatment discontinuations due to AE – most frequently attributable to dermatologic toxicities – was high. Additional safety data collected for the cumulative safety analysis (until LPLV) did not change previous safety conclusions.

Publication(s):	Herzog TJ, Scambia G, Kim BG, Lhommé C, Markowska J, Ray-Coquard I, et al. A randomized phase II trial of maintenance therapy with Sorafenib in front-line ovarian carcinoma. Gynecol Oncol. 2013 Jul;130(1):25-30.		
Date Created or Date Last Updated:	18 Nov 2013	**Date of Clinical Study Report:**	14 Nov 2013

Product Identification Information

Product Type	Drug
US Brand/Trade Name(s)	Nexavar
Brand/Trade Name(s) ex-US	Nexavar
Generic Name	Sorafenib
Main Product Company Code	BAY43-9006
Other Company Code(s)	BAY54-9085
Chemical Description	**(1)** 2-Pyridinecarboxamide, 4-[4-[[[[4-chloro-3trifluoromethyl)phenyl]amino]carbonyl]amino]phenoxy]-N-methyl-**(2)** 4-(4-{3.[4-chloro-3-(trifluoromethyl)phenyl]ureido}phenoxy)-N2-methylpyridine-2-carboxamide
Other Product Aliases	Sorafenib tosylate

Date of last Update/Change: 28 Apr 2012

Investigational Site List

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Sponsor in Germany (if applicable)	
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