2. SYNOPSIS

<table>
<tr><td>Name of Sponsor/Company:
AVEO Pharmaceuticals, Inc.</td><td rowspan="3">Individual Study Table</td><td rowspan="3">(For National Authority Use Only)</td></tr>
<tr><td>Name of Finished Product:
Tivozanib hydrochloride capsules (AV-951)</td></tr>
<tr><td>Name of Active Ingredient:
Tivozanib hydrochloride (AV-951)</td></tr>
<tr><td colspan="3">Title of Study:
A Phase 3, Randomized, Controlled, Multi-Center, Open-Label Study to Compare Tivozanib (AV-951) to Sorafenib in Subjects With Advanced Renal Cell Carcinoma</td></tr>
<tr><td colspan="3">Investigators and/or Study Centers:
This study enrolled 517 patients at 76 sites in 15 countries (Bulgaria, Canada, Chile, Czech Republic, France, Hungary, India, Italy, Poland, Romania, Russia, Serbia, UK, Ukraine, and USA). [redacted] was the principal coordinating investigator for this study.</td></tr>
<tr><td colspan="3">Publications Based on the Study:
Motzer RJ, Bhargava P, Esteves B, et al. A Phase 3, randomized, controlled study to compare tivozanib with sorafenib in patients with advanced renal cell carcinoma. Poster presented at the American Society of Clinical Oncology (ASCO) Genitourinary Cancers Symposium, Feb 17-19, 2011, Orlando, FL.
Motzer RJ, Bhargava P, Esteves B, et al. A Phase 3, randomized, controlled study to compare tivozanib with sorafenib in patients (Pts) with advanced renal cell carcinoma (RCC). Abstract presented at ASCO Genitourinary Cancers Symposium 2011; J Clin Oncol 29: 2011 (suppl 7; abstr 310).
Motzer RJ, Nosov D, Eisen T, et al. Tivozanib versus sorafenib as initial targeted therapy for patients with advanced renal cell carcinoma: results from a Phase III randomized, open-label, multicenter trial. Abstract presented at ASCO Genitourinary Cancers Symposium, June 1-5, 2012, Chicago, Illinois.
Motzer RJ, Nosov D, Eisen T, et al. Tivozanib versus sorafenib as initial targeted therapy for patients with metastatic renal cell carcinoma: results from a Phase III trial. J Clin Oncol. 31:3791-9. 2013.</td></tr>
<tr><td colspan="2">Study Period:
11 February 2010 (First Patient Dosed) – 10 June 2013 (Last Patient Last Visit).
This final Clinical Study Report (CSR) references data from the interim CSR (snapshot date 15 December 2011) and includes the data through the end of Study AV-951-09-301 and data from patients who remained on treatment as-randomized in this study and went to the extension study AV-951-09-902 to fully report on their first-line treatment experience.
The final efficacy analyzes and other data are collected and evaluated with the data transfer date of 10 July 2013 for AV-951-09-301 and 03 June 2013 for AV-951-09-902.The final safety analyzes data are collected and evaluated through 20 Jan 2015.</td><td>Phase of Development:
Phase 3</td></tr>
<tr><td colspan="3">Objectives:
Primary:
• To compare the progression-free survival of patients with advanced renal cell carcinoma RCC randomized to treatment with tivozanib or sorafenib.</td></tr>
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Secondary:

- To compare the overall survival (OS) of patients randomized to treatment with tivozanib or sorafenib.
- To compare objective response rate (ORR) and duration of response (DR) of patients randomized to treatment with tivozanib or sorafenib.
- To compare the safety and tolerability of tivozanib and sorafenib.
- To compare kidney-specific symptoms and health outcome measurements in patients randomized to treatment with tivozanib or sorafenib.
- To evaluate the pharmacokinetics (PK) of tivozanib.

Tertiary:

- To study biomarkers in blood and archived tissue samples, and their correlations with clinical activity and/or treatment-related toxicity in patients randomized to treatment with tivozanib or sorafenib.

Methodology:

Open-label, randomized, controlled, multi-national, multicenter, parallel-arm study. Patients were randomized in a 1:1 ratio (tivozanib: sorafenib) stratified by the following factors: geographic region (North America/Western Europe, Central/Eastern Europe, or rest of the world); number of prior treatments (0 or 1); and number of metastatic sites/organs involved (1 or ≥ 2) as assessed by an independent radiologist. Patients began treatment with study drug within 10 days after randomization.

Number of Patients (Planned and Analyzed):

Approximately 500 patients were planned; 517 patients were randomized to study treatment (260 to tivozanib and 257 to sorafenib), and 516 patients were treated (259 patients with tivozanib and 257 patients with sorafenib).

Diagnosis and Main Criteria for Inclusion:

Males and females, ≥ 18 years of age, with prior nephrectomy (complete or partial) for excision of the primary tumor, histologically or cytologically confirmed RCC with a clear cell component, measurable disease, confirmed by blinded independent radiologist, per the Response Evaluation Criteria in Solid Tumors (RECIST) criteria version 1.0, treatment-naive or no more than one prior systemic treatment for metastatic RCC, no prior vascular endothelial growth factor (VEGF) targeted therapy, Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1, and life expectancy of ≥ 3 months were eligible patients for this study. Patients were required to have adequate hematological, renal, and hepatic function. Women of childbearing potential were required to have a negative pregnancy test prior to enrollment. Patients with significant cardiovascular disease, including uncontrolled hypertension or myocardial infarction, severe angina, or unstable angina within 6 months prior to first dose of study drug, were excluded. Patients with unhealed wounds or fractures, or skin ulcers, inadequate recovery from surgery or major surgical procedure within 4 weeks of study drug, significant thromboembolic or vascular disorders within 6 months of study drug were also excluded. Patients with primary central nervous system (CNS) malignancies or CNS metastases were excluded. Patients with previously treated brain metastasis were allowed if the brain metastasis had been stable without steroid treatment for at least 3 months following prior treatment (radiotherapy or surgery). Patients with active peptic ulcer disease, inflammatory bowel disease, ulcerative colitis, or other gastrointestinal condition with increased risk of perforation; history of abdominal fistula, gastrointestinal perforation, or intra-abdominal abscess within 4 weeks prior to administration of first dose of study drug were excluded. Patients with significant bleeding disorders within 6 month prior to administration of first dose of study drug were excluded.

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Test Product, Dose and Mode of Administration, Batch Number:

Tivozanib capsules, 1.5 mg once daily (qd), administered orally for 3 weeks followed by 1 week off study drug (1 cycle = 3 weeks on, 1 week off). One cycle was defined as 4 weeks of treatment. Cycles were repeated every 4 weeks.

Batch numbers: 1.0 mg capsule: 27114, 271113; 1.5 mg capsule: 27115, 271114

The batch numbers of the study drug administered to the patients on Study AV-951-09-902 are included in the respective CSR.

Duration of Treatment:

Patients with documented stable disease (SD) or an objective response could continue to receive therapy at the same dose and schedule for up to 2 years from the first dose as long as tolerability was acceptable. Patients who completed 2 years on study, without discontinuing for any reason and without progressive disease (PD), were given the option to continue treatment in an extension protocol, AV-951-09-902 (EudraCT number 2009-015987-32). In addition, patients who took sorafenib and experienced radiographic evidence of progression were also given the option to cross over to receive tivozanib in AV 951 09 902.

Reference Therapy, Dose and Mode of Administration, Batch Number:

Sorafenib tablets, 400 mg twice daily (bid) (2 × 200 mg tablets), administered orally for 4 weeks (1 cycle = 4 weeks on). One cycle was defined as 4 weeks of treatment. Cycles were repeated every 4 weeks.

Batch numbers: 27113, 271115, 271116, 271117, 271118, 271119, 271120, 271121, 271122, 271123, 271124, Batch 6 and Batch 7.

The batch numbers of the study drug administered to the patients on Study AV-951-09-902 are included in the respective CSR.

Criteria for Evaluation:

Disease Assessment / Response Assessment:

The following definitions, adapted from RECIST 1.0, were used to categorize response. All patients who developed early PD (regardless of the duration of the study treatment) prior to response evaluation were considered to have progressed on study. To be assigned a status of complete response (CR) or partial response (PR), changes in tumor measurements had to be confirmed by repeat evaluations performed no less than 4 weeks after the criteria for response were first met. In the case of SD, follow-up assessments must have met the SD criteria at least once after study entry, at a minimal interval of 4 weeks.

- CR: Disappearance of all target lesions (confirmed by repeat studies performed no less than 4 weeks after the criteria for response are first met).
- PR: At least a 30% decrease in the sum of the longest diameter (LD) of target lesions, taking as reference the baseline sum LD (confirmed by repeat studies performed no less than 4 weeks after the criteria for response are first met).
- PD: At least a 20% increase in the sum of LD of target lesions, taking as references the smallest sum LD recorded since the treatment started or the appearance of one or more new lesions.

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- SD: Neither sufficient shrinkage to qualify for PR nor sufficient increase to qualify for PD, taking as references the smallest sum LD since the treatment started. Follow-up measurements must have met SD criteria at least once after study entry, at a minimal interval of 4 weeks.

All patients were followed until death from any cause unless consent was withdrawn. After the 30-Day Follow-Up visit, patients were contacted once every 2 months to collect long-term survival data. For patients who enrolled in the extension protocol (Study AV-951-09-902) after completing this protocol, long-term survival data and PFS by investigator were collected under that protocol (Note, that this final CSR provides a mature OS data set which is included here for the patients in this study as well as Study AV-951-902 who remained on their initially randomized treatment throughout both studies). For patients with ongoing objective response or disease stabilization at the time of treatment discontinuation, who discontinued for reasons other than radiological evidence of progressive disease, tumor assessments continued to be collected every 2 months during the first year (beginning from the date of the last scan performed prior to treatment discontinuation), every 3 months during the second year, and every 6 months thereafter until disease progression was confirmed by independent radiology review or another therapy for cancer was started. For patients who enrolled in the extension protocol after completing this protocol, tumor assessments were performed under that protocol. The Functional Assessment of Cancer Therapy-General (FACT-G), Disease Related Symptom Scale of the Functional Assessment of Cancer Therapy - Advanced Kidney Cancer Symptom Index (FKSI-DRS), and European Quality of Life-5 Dimensions (EQ-5D) tools were used throughout the study to measure the patients' health-related quality of life. These scales were self-administered by patients at the start of the visit, before they saw the physician.

Safety:

Safety assessments included incidence, severity, and relationship of treatment emergent adverse events (AE)s; changes in vital sign measurements; changes in physical examination findings; ECOG performance status scores; changes in electrocardiogram (ECG) results; changes in laboratory values (hematology, serum chemistry, coagulation, urinalysis, and thyroid function tests); and concomitant medications and procedures.

Pharmacokinetics:

For the tivozanib treatment arm only, whole blood samples were collected for pharmacokinetic (PK) assessment in serum prior to dosing on Cycle 1 Day 1, Cycle 1 Day 15, Cycle 2 Day 1, and on Cycle 2 Day 22-28.

Pharmacodynamics:

Blood samples were collected to measure VEGF-a and soluble VEGF receptor-2 (VEGFR-2) levels. All patients had a total of 4 whole blood samples collected. It was planned that if remaining samples were available, further exploratory analyses could be evaluated on additional biomarkers, including but not limited to other VEGF ligands, hepatocyte growth factor, and placental growth factor. If available, archival tumor biopsies were collected to evaluate potential biomarkers, including but not limited to CAIX, CD68, Glut 1 expression, HIF 1α, and a biomarker signature based on transcriptional profiles. Expression of genes from the multigene signature was to be analyzed by polymerase chain reaction or other technologies. Immunohistochemical analysis included CD68 frequencies. These planned analyses were not conducted.

Statistical Methods:

Time-to-event endpoints were summarized using Kaplan-Meier (KM) and Cox regression methods. Statistical analyses were performed using SAS® version 9.2 or later. Unless otherwise noted, continuous data were summarized using the following descriptive statistics: number of observations (n), mean, standard deviation

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(STD), minimum, 25th percentile (Q1), median, 75th percentile (Q3), and maximum. Categorical data were summarized with frequencies (n) and percentages (%). In cases where missing data caused percentages not to add up to 100, a missing data row was provided. Percentages used column totals as the denominator unless otherwise indicated. Missing or invalid data were generally treated as missing, not imputed, unless otherwise stated. All study data were included in data listings. All summaries were presented by treatment group, unless otherwise stated. In general, all observations were included in the analysis. Descriptive statistics for continuous variables were examined to identify outlying observations. Outliers were queried and sensitivity analyses excluding the outlying variables could be conducted.

Study Populations: The intent-to-treat (ITT) population was defined as all randomized patients, and was used for the analysis of the primary and secondary efficacy endpoints. The per-protocol (PP) population was defined as all randomized patients who remained in the study for at least 8 weeks (2 cycles) (unless discontinued due to death or disease progression) and had no major protocol violations that would confound the effects of treatment. The PP population was used as a sensitivity analysis for the assessment of the primary efficacy endpoint. The Safety population was defined as all randomized patients who received at least one dose of either study drug, and was used for all safety analyses.

The reporting of the study populations for final efficacy and safety analyses includes the patients through the end of Study AV-951-09-301 and also the patients who continued on the same treatment as-randomized (first-line experience) into the extension Study AV-951-09-902 from Study AV-951-09-301. Fourteen patients continued on sorafenib from Study AV-951-09-301 into Study AV-951-09-902, but crossed over to tivozanib during Study AV-951-09-902. The data for these patients before the cross-over to tivozanib are included in this report.

Disposition: Patient recruitment over time was summarized by region, site, and treatment group. The ITT, PP, and Safety populations were summarized by treatment group. The frequencies and percentages of patients who discontinued therapy, along with reasons for discontinuation, were summarized for the ITT population. The numbers and percentages of patients in the ITT population who received study treatment in each cycle were summarized. Patients who discontinued were listed. A listing of all enrolled patients and the study populations to which they belonged was produced.

Demography and Baseline Characteristics: Demographic and baseline data, medical history, and disease history data were summarized by treatment group and listed by patient.

Efficacy:

Primary efficacy:

- Progression-free survival (PFS) - performed when approximately 310 PFS events had occurred. This analysis was based on independent radiological review (IRR) of tumor assessments and was considered positive if the 2-sided log-rank test for PFS was significant at the 5% level.

Secondary efficacy:

- Objective response rate (ORR) (independent review)
- Duration of response (DR) (independent review)
- Duration of stable disease (DS) (independent review)
- Overall survival (OS)
- Change from Baseline in target lesions
- Patient reported outcome (PRO) (quality of life assessments) - to be analyzed in a separate report

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Exploratory:

- Cox proportional hazard (PH) models adjusted for age group, sex, race, baseline ECOG score, time since diagnosis, geographic region, number of prior treatments, number of metastatic sites/organs, baseline systolic blood pressure (SBP), baseline diastolic blood pressure (DBP), and Memorial Sloan-Kettering Cancer Center (MSKCC) prognostic group were used to explore the influence of these factors on PFS.

Post Hoc:

- To further understand the effect of cross-over to next-line active treatment on OS in Study AV-951-09-301 a post hoc subgroup analysis based on the geographical region of the patients enrolled in the study was performed.

Safety:

- Treatment emergent adverse events (TEAEs) were coded by system organ class (SOC) and preferred term using the Medical Dictionary for Regulatory Activities (MedDRA™) version 15.0 Dictionary for Study AV-951-09-301 and MedDRA™ version 17.0 for Study AV-951-09-902 and summarized.
- Laboratory assessments and vital signs were summarized descriptively by treatment group and visit. Change from baseline was summarized for all post-baseline safety evaluations, including physical examination, ECG results, and performance status.
- Concomitant medications were coded using the World Health Organization Drug Dictionary (WHO-DD) and summarized by preferred term, treatment group, and whether medication was determined to be prior or concomitant.

Pharmacokinetics:

The serum concentrations of tivozanib were tabulated for individual patients and summarized by nominal time using descriptive statistics.

Pharmacodynamics:

Pharmacodynamics were planned to be analyzed in a separate report, but this was not performed.

Summary – Conclusions:

Demography/Patient Disposition Results:

Of the 517 randomized patients, 322 patients (151 in the tivozanib group and 171 in the sorafenib group) completed the study with progressive disease. The number of patients, who discontinued was 60 (23%) patients per arm. Seventy five patients neither completed nor discontinued Study AV-951-09-301 or AV-951-09-902. These patients were offered continued therapy through a number of mechanisms including compassionate use.

Efficacy Results:

- In the interim CSR, superiority was established for the primary endpoint of this pivotal Phase 3 study, with blinded independent radiological assessment of median PFS in the tivozanib arm of 11.9 months (95% confidence interval (CI) [9.3, 14.7]), compared with 9.1 months (95% CI [7.3, 9.5]) in the sorafenib arm. This is a statistically significant improvement in PFS, with a p-value of 0.042, and a hazard ratio of 0.797 (95% CI: 0.639, 0.993). The present study is one of the first superiority pivotal studies in advanced RCC to directly compare a targeted agent against a recently approved targeted drug.
- Efficacy conclusions remained consistent with those reported in the interim CSR.

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- To the end of Study AV-951-09-301, superiority was established for the primary endpoint of this pivotal Phase 3 study, with blinded independent radiological assessment of median PFS in the tivozanib arm of 11.5 months (95% CI [9.2, 14.7]), compared with 9.1 months (95% CI [7.3, 9.5]) in the sorafenib arm. This is a statistically significant improvement in PFS, with a p-value of 0.039, and a hazard ratio of 0.795 (95% CI: 0.638, 0.990). That is 20.5% longer progression-free survival duration of tivozanib patients compared to that of sorafenib patients.
- PFS as determined by investigator assessment through the Study AV-951-09-301 and AV-951-09-902 (first-line experience) remained significantly longer (p=0.006) for tivozanib patients (median 14.7 months) than for sorafenib patients (median 9.7 months) in the ITT population as well as in the PP population for tivozanib patients (median 15.8 months) than for sorafenib patients (median 9.7 months).
- The pre-specified subset of patients with no prior treatment for metastatic disease comprised approximately 70% of the population, and benefitted from tivozanib, with independent assessment of median PFS in the tivozanib arm of 12.7 months (95% CI [9.1, 15.0), compared with 9.0 months (95% CI [7.3, 9.7]) in the sorafenib arm. This is a statistically significant improvement in PFS for this subgroup, with a p-value of 0.034, and a hazard ratio of 0.788 (95% CI [0.631, 0.985]).
- The median OS including the deaths from both the studies (AV-951-09-301 and AV-951-09-902) was 28.2 months for the tivozanib treatment group and 30.8 months for sorafenib treatment group, with p-value of 0.276, and a hazard ratio of 1.147.
- The final data with the inclusion of the patients from the extension Study AV-951-09-902, who remained on their as-randomized treatment in Study AV-951-09-301, produces trends in efficacy that were consistent with the interim CSR.
- The post hoc subgroup analysis of geographical region revealed that for the North America (NA) and Western Europe region, the trend in OS was dependent on the territory and the use of second-line therapy in the tivozanib arm. For NA and Western Europe region the trend strongly favored tivozanib. For NA and all EU the trend favored tivozanib; but for the Ukraine and Russian the OS trend favored sorafenib. Regardless of territory the benefit for PFS remains for the tivozanib arm.

Safety Results:

- The safety conclusion also remained consistent with the interim CSR in terms of trends and followed the same pattern of higher or fewer numbers of events in either treatment group.
- Patients in the tivozanib group had a greater mean RDI (93.85%) as compared with sorafenib (80.80%) group.
- Patients in the tivozanib group experienced fewer dose interruptions (69, 26.6% patients) compared to sorafenib patients (179, 69.6% patients). Patients who received tivozanib had fewer dose reductions overall (41, 15.8% patients) as compared with sorafenib patients (113, 44.0% patients).
- A similar number of patients experienced AEs in the tivozanib group (238, 91.9%) and the sorafenib group (249, 96.9%). Similarly the number of patients who had study drug-related AEs in the tivozanib group (203, 78.4% patients) and the sorafenib group (231, 89.9% patients)

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was comparable.

- Fewer patients in the tivozanib group (166, 64.1%) had ≥ Grade 3 AEs compared to the sorafenib group (181, 70.4%).
- The number of patients who had fatal AEs was slightly higher in the tivozanib group (28, 10.8%) as compared with sorafenib (15, 5.8%). In the tivozanib group, the most common fatal AE was disease progression (9, 3.5% patients), whereas in sorafenib group the most common fatal AE was cerebrovascular accident (3, 1.2%). Eight deaths occurred after 30 days of last dose (7 deaths in tivozanib group and 1 death in the sorafenib group), of which 4 deaths in tivozanib group and 1 death from sorafenib group were due to disease progression.
- The most frequently occurring SAE in the tivozanib group was disease progression (9, 3.5%) and in the sorafenib group were myocardial infarction, pleural effusion and anemia (4, 1.6% each). The number of patients who had SAEs related to the study drug was similar in both the treatment groups (23 patients in tivozanib and 21 patients in sorafenib).
- The number of patients who had AEs leading to discontinuation was comparable in both the treatment groups (38; 14.7% and 34; 13.2% in the tivozanib and sorafenib groups, respectively).
- Ischemia cerebrovascular events were experienced by 9 (3.5%) patients in the tivozanib group and 5 (1.9%) patients in the sorafenib group. Grade 3 or higher ischemia cerebrovascular AEs were experienced by 8 (3.1%) patients in the tivozanib group and 3 (1.2%) patients in the sorafenib group.
- Clinical findings were generally similar between the two treatment groups. The greatest increase in mean BP tended to occur early in the study (by Cycle 1 Day 15). The increases were relatively small, and they resolved after being managed with appropriate antihypertensive therapy. There was very little mean change in heart rate, respiration rate, weight, or body mass index (BMI) over time. At the End-of-Treatment Visit, 28 (14.6%) patients in the tivozanib group and 34 (16.9%) patients in the sorafenib group had shifted from normal to abnormal ECG results.
- Physical Examination results shifted from normal to abnormal in fewer (0.0% to 17.8%) patients in the tivozanib group compared to sorafenib (0.0% to 29.6%). A higher number of patients from sorafenib group (35%) showed decreased ECOG performance status than tivozanib group (30%).

Pharmacokinetic Results:

The presence of significant trough serum concentration, together with data from previous tivozanib studies, suggests that tivozanib had approximated steady-state concentrations by 14 days after the first dose. Observations obtained during and after a 7-day rest showed a slow decrease in serum concentration, consistent with a terminal half-life that is substantially longer than the dosing interval. These results are consistent with previously observed PK data for tivozanib trough concentrations following daily dosing.

Pharmacodynamics Results:

These are provided in a separate report.

Conclusions:

Tivozanib improves progression-free survival in advanced RCC patients compared with sorafenib. The overall

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assessment of efficacy and safety in this Phase 3 trial of tivozanib versus sorafenib in advanced renal cell cancer indicates a favorable benefit/risk and tolerability profile for tivozanib. **Date of the Report:** 21 January 2016		