TIVO-3 Overall Survival Update Conference Call

May 29, 2020

Passionately pursuing a better life for patients with cancer

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Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements AVEO makes due to a number of important factors, including substantial risks and uncertainties relating to: AVEO’s ability, and the ability of its licensees, to demonstrate to the satisfaction of applicable regulatory agencies such as the FDA and the EMA the safety, efficacy and clinically meaningful benefit of AVEO’s product candidates, including, in particular, tivozanib; AVEO’s and its collaborators’ ability to successfully enroll and complete clinical trials; AVEO’s ability to enter into and maintain its third party collaboration and license agreements, and its ability, and the ability of its strategic partners, to achieve development and commercialization objectives under these arrangements; the timing and costs of seeking and obtaining regulatory approval; AVEO’s ability to maintain compliance with regulatory requirements applicable to its product candidates; AVEO’s ability to obtain and maintain adequate protection for intellectual property rights relating to its product candidates; AVEO’s ability to successfully implement its strategic plans; AVEO’s ability to raise the substantial additional funds required to achieve its goals, including those goals pertaining to the development and commercialization of tivozanib; unplanned capital requirements; adverse general economic and industry conditions; and those risks discussed in the sections titled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources” included in AVEO’s quarterly and annual reports on file with the SEC and in other filings that AVEO may make with the SEC in the future. All forward-looking statements contained in this presentation speak only as of the date of this presentation, and AVEO undertakes no obligation, and specifically disclaims any obligation, to update any of these statements, except as required by law.

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Introductions

- **Sumanta Kumar (Monty) Pal, M.D.**
  Clinical Professor, Department of Medical Oncology & Therapeutics Research; Co-director, Kidney Cancer Program, City of Hope Cancer Center
- **Michael Bailey, CEO**
- **Michael Needle, MD, CMO**
- **Erick Lucera, CFO**
- **Mike Ferraresso, SVP, Business Analytics and Commercial Operations**

Agenda

- **TIVO-3 Data Review with Dr. Pal**
- **Regulatory Update and Considerations**
- **Commercial Opportunity**
- **Summary**
- **Q&A**

TIVO-3: Final OS analysis of a phase 3, randomized, controlled, multi-center, open-label study to compare tivozanib to sorafenib in subjects with metastatic renal cell carcinoma (RCC)

May 29, 2020

TIVO-3: Clinical Context

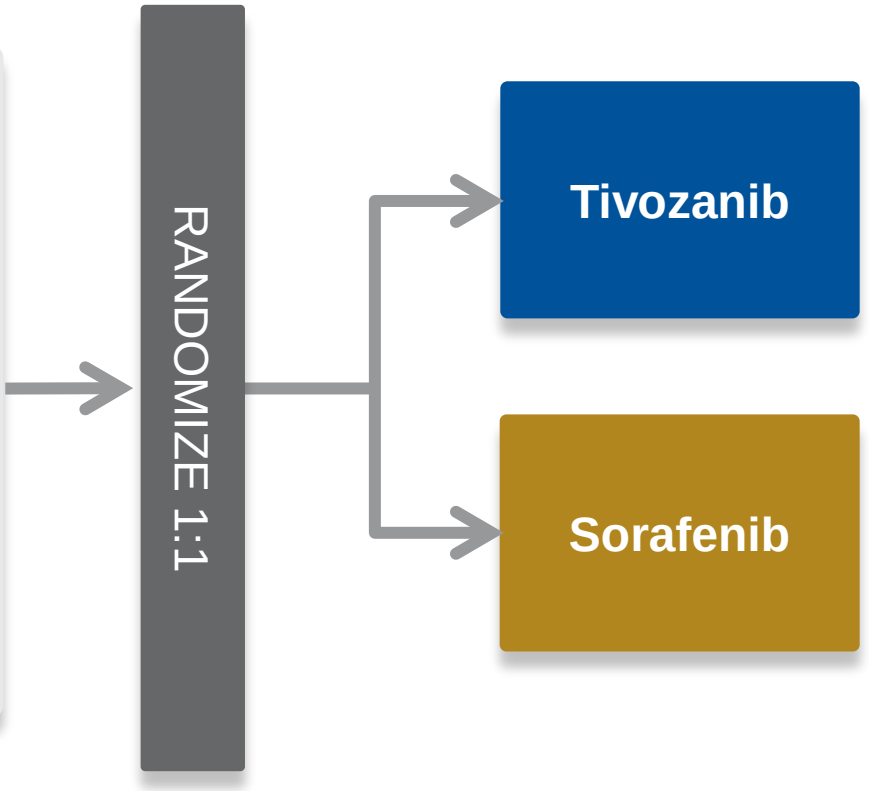
- **The treatment of patients with renal cell carcinoma (RCC) has advanced with the advent of anti-angiogenic drugs known as vascular endothelial growth factor receptor tyrosine kinase inhibitors (VEGFR TKI)**
- **Tivozanib is a highly potent and selective VEGFR TKI with a long half-life and an ability to down regulate T-regulatory cells**
  - Tivozanib was developed to optimize VEGFR blockade while minimizing off-target toxicities
- **Tivozanib is approved by the European Medicines Agency for the first-line treatment of adult patients with RCC**
- **The TIVO-3 study was designed to assess the safety and efficacy of tivozanib versus sorafenib for treatment of patients with highly refractory metastatic RCC**
  - In TIVO-3, a significant reduction in the risk of progression-free survival (PFS) was reported for tivozanib compared with sorafenib at a hazard ratio (HR) of 0.73 (95% confidence interval [CI]: 0.56, 0.94; *P*=0.016); median PFS was 5.6 months vs. 3.9 months
  - Tivozanib demonstrated superior and durable tumor shrinkage as indicated by superior overall response rate (ORR) 18% vs 8% and a longer duration of response (DoR) than sorafenib.
  - Tivozanib treatment demonstrated a favorable tolerability profile as demonstrated by significantly fewer dose reductions, interruptions, and discontinuations due to AEs

TIVO-3: Study Schema

Randomized Trial in Relapsed or Refractory Advanced Renal Cell Carcinoma

N = 350

- Recurrent/metastatic RCC
- ECOG PS 0 or 1
- Failed at least two prior regimens including VEGFR-TKI
- Stratified by IMDC and prior regimen (TKI-TKI; TKI-CPI; TKI-Other)



Endpoints

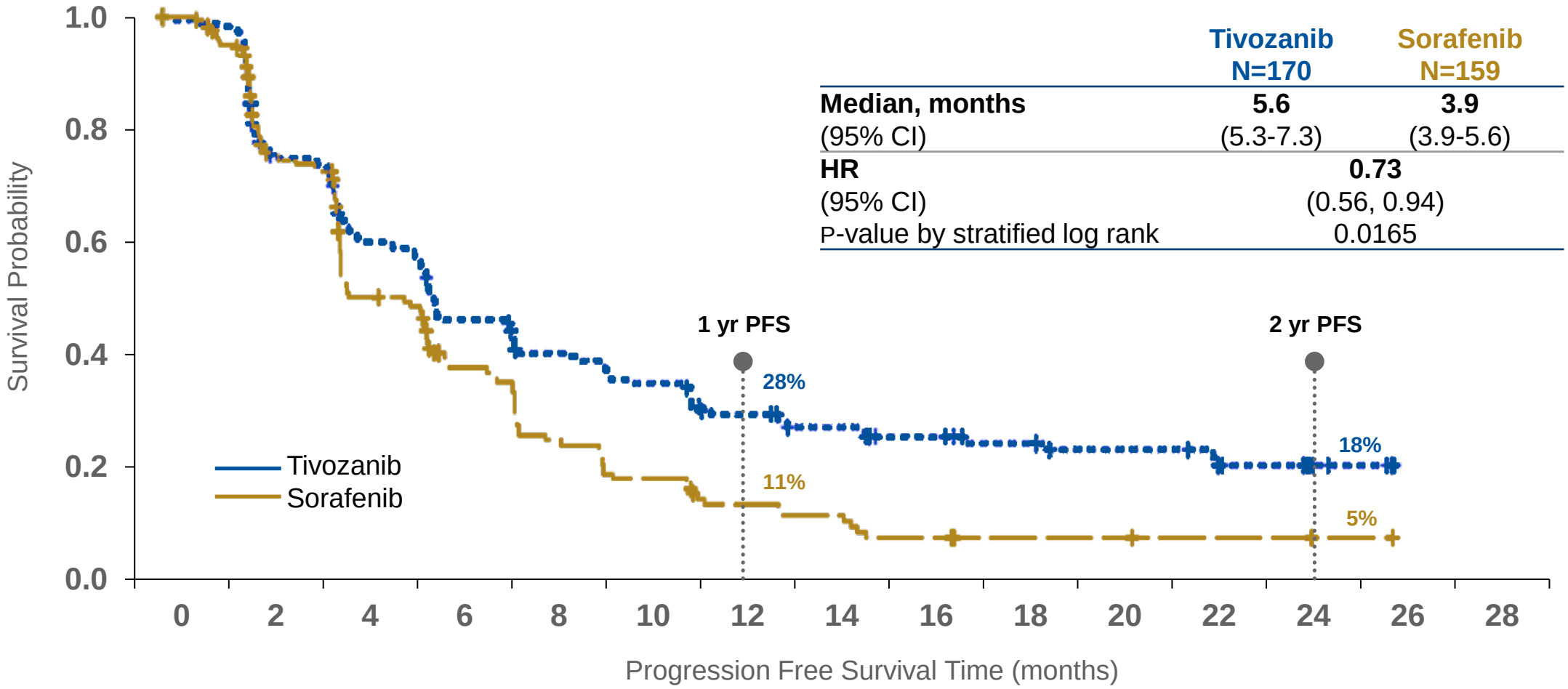
- Primary: PFS
- Secondary: OS, ORR, DoR, Safety and Tolerability for ITT

TKI – VEGFR TKI; CPI – checkpoint inhibitor

TIVO-3: Patient Demographics

Characteristic	Tivozanib (N=175)	Sorafenib (N=175)
Median age, years	62	64
Male	72%	73%
IMDC prognostic risk		
Favorable	19%	21%
Intermediate	62%	60%
Poor	18%	19%
ECOG performance status (0/1)	(49% / 50%)	(47% / 48%)
Region (NA/EU)	(18% / 82%)	(15% / 85%)
Prior Lines of Therapy (2/3)	(62% / 38%)	(59% / 41%)
Prior Treatment Regimen		
TKI-CPI	27%	25%
TKI-TKI	45%	46%
TKI-Other	28%	29%

TIVO-3: Met Primary Endpoint of PFS



	Tivozanib N=170	Sorafenib N=159
Median, months	**5.6**	**3.9**
(95% CI)	(5.3-7.3)	(3.9-5.6)
HR	**0.73**	
(95% CI)	(0.56, 0.94)	
P-value by stratified log rank	0.0165	

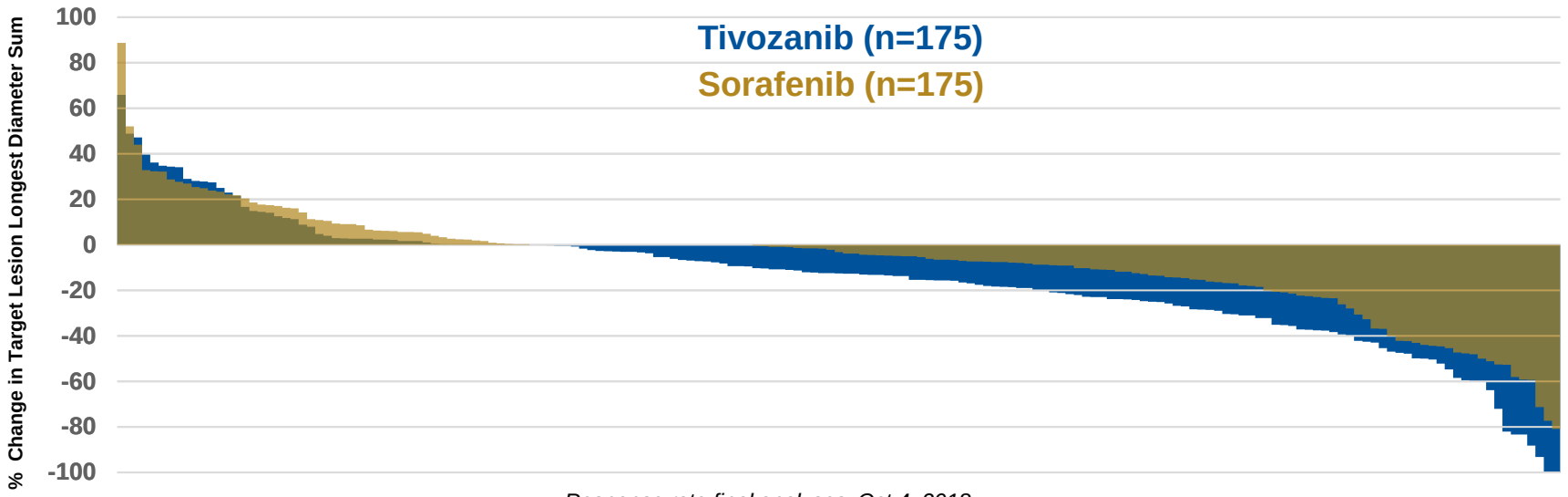
Subjects at risk

Tivozanib	**170**	**128**	**94**	**69**	**56**	**48**	**37**	**31**	**24**	**20**	**16**	**14**	**6**	**0**	**0**
Sorafenib	159	116	65	42	27	18	11	9	5	3	3	2	2	0	0

Primary PFS endpoint final analyses, Oct 4, 2018

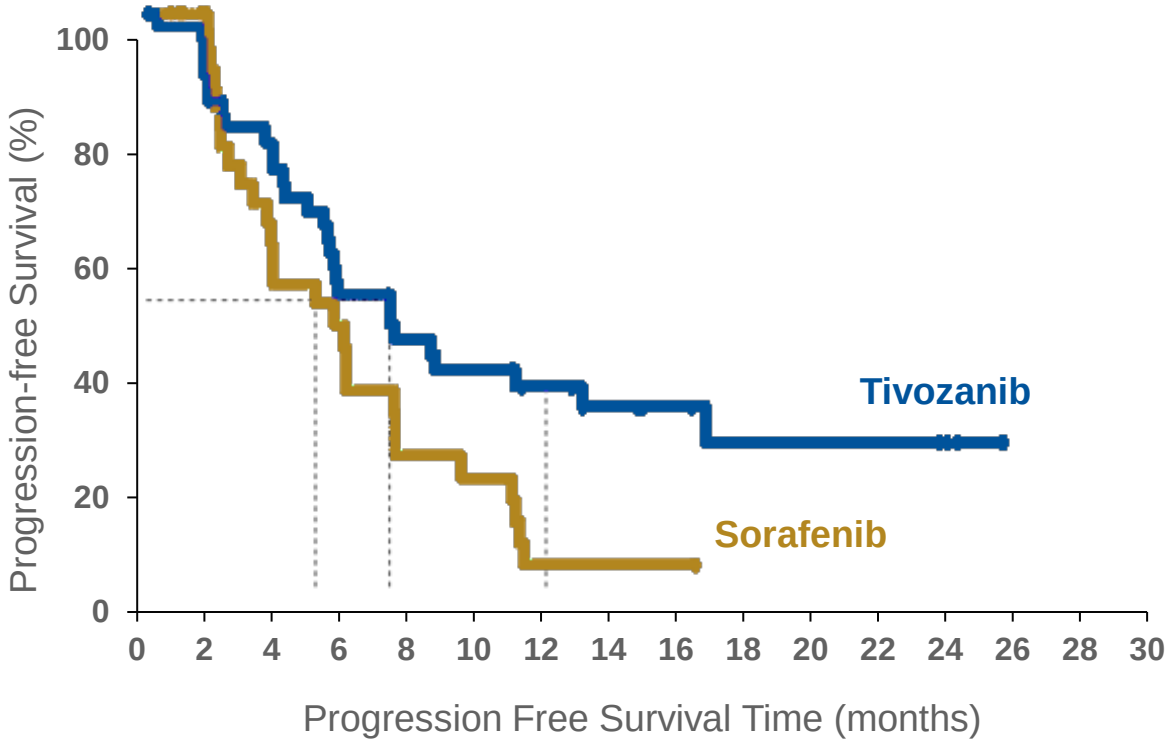
TIVO-3: Secondary Endpoint, ORR & DoR
Statistically Significant Improvement vs Sorafenib

	Tivozanib		Sorafenib
ORR	**18%**		**8%**
ORR p-value		0.02	
Median DoR	Not reached (12.9, NR)		5.7 months (5.6, NR)



Response rate final analyses, Oct 4, 2018

TIVO-3: Demonstrated Superior PFS & ORR in CPI Subgroup



Prior Checkpoint Inhibitor (CPI) + VEGFR TKI

	Tivozanib (n=47)	Sorafenib (n=44)
Median PFS months (95% CI)	**7.3** (4.8, 11.1)	**5.1** (3.2, 7.4)
HR (95% CI)	**0.55** (0.32, 0.94)	
P-value	0.028	
ORR	24.4%	6.8%

Porta et al. ASCO 2019

Final analyses, Oct 4, 2018

TIVO-3: Treatment-Related Adverse Events

TRAEs ≥ 20% frequency in either arm*

	Tivozanib (N=173)^		Sorafenib (N=170)^	
Preferred Term	**All Grades %**	**Grade 3/4 %**	**All Grades %**	**Grade 3/4 %**
Treatment Related AEs	84	46	94	55
Hypertension	38	21	25	14
Diarrhea	33	2	50	9
Fatigue	29	4	19	5
Decreased Appetite	27	4	21	2
Dysphonia	24	1	8	0
Asthenia	22	5	17	4
PPE/HFSR**	16	1	39	10
Rash	5	0	24	8

>10% difference between arms

Analysis as of Aug 15, 2019
***Palmar-plantar erythrodysesthesia (PPE), also known as hand-foot skin reaction (HFSR)*
^Safety population

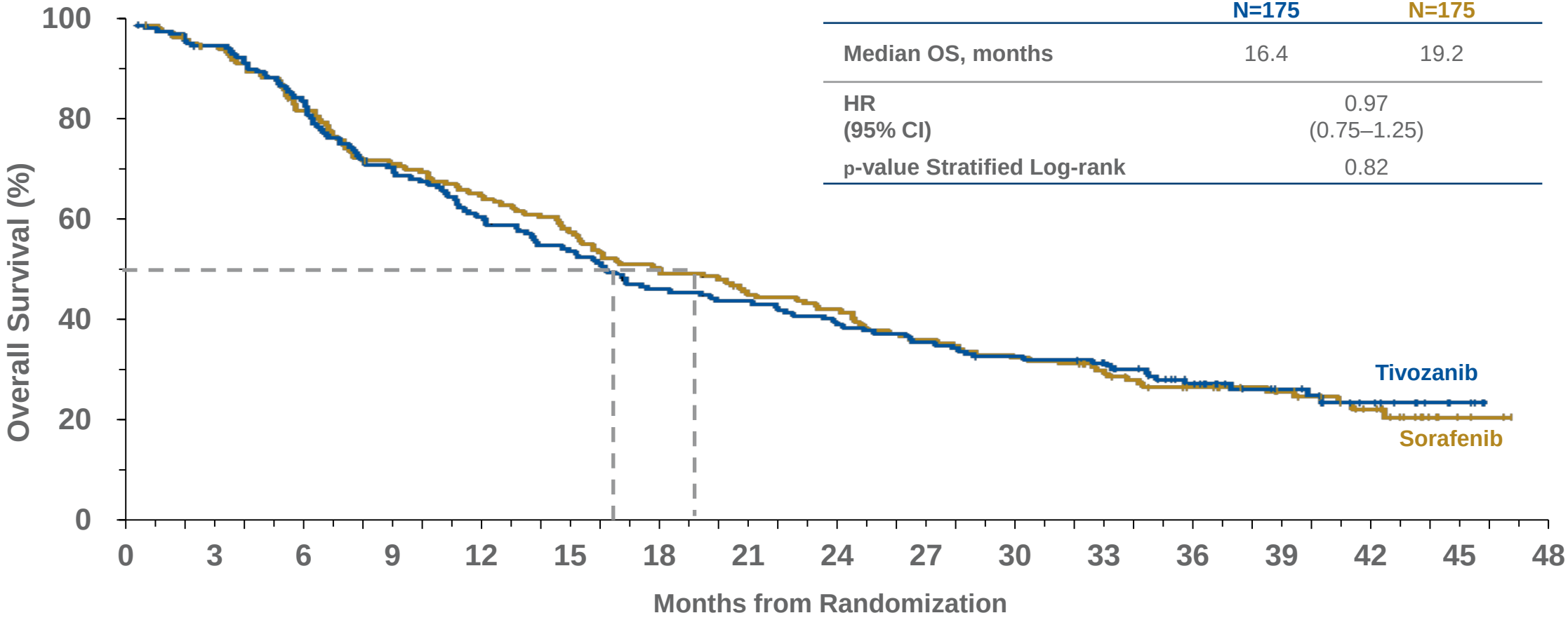
TIVO-3: Dose Modifications

Characteristic	Tivozanib (N=173)^		Sorafenib (N=170)^
Mean Number of Cycles Initiated	**11.9**		**6.7**
AEs Leading to Dose Reductions (%)	25	P=0.0147	39
AEs Leading to Dose Interruption (%)	50	P=0.0164	64
ADRs Leading to Permanent Discontinuation (%)	8		15
Treatment Related SAEs (%)	12		11
Treatment Related Deaths (%)	0		0
Deaths within 30 days of Tx (N)	15		13
Exposure Adj Deaths per Month of Tx	0.72%		1.11%

^*Safety population*

Final Overall Survival – May 2020

	Tivozanib N=175	Sorafenib N=175
Median OS, months	16.4	19.2
HR (95% CI)	0.97 (0.75–1.25)	
p-value Stratified Log-rank	0.82	



Conclusions

- **In this final analysis of survival in the TIVO-3 trial, tivozanib demonstrated clinically meaningful and statistically significant improvement in PFS with similar OS in patients with highly relapsed or refractory metastatic RCC**
  - Patients treated with a prior CPI and VEGFR TKI or 2 VEGFR TKIs derived the most PFS benefit from tivozanib (HR of 0.55 and 0.57, respectively) relative to sorafenib
- **To our knowledge, TIVO-3 is the first randomized phase 3 study to show PFS superiority over another VEGFR TKI in the third- and fourth-line treatment setting, and is the first study to prospectively and comparatively evaluate treatment following CPI**
- **Consistent with other large studies in RCC comparing VEGFR TKIs, the OS HRs did not show significant OS differences between agents**
- **Collectively, these data support tivozanib as an evidence-based treatment option for patients with RCC, including for patients whose disease has progressed after previous CPI treatment**

Regulatory Update & Considerations

Tivozanib New Drug Application

- **FDA dialogue actively proceeding**
  - NDA filed for R/R RCC March 31, 2020
  - Final OS data submitted as last component of the NDA
  - Application Orientation Meeting (AOM) completed

- **NDA submission is based on the TIVO-3 trial and supported by three additional trials**
  - Active comparator-controlled Phase 3 first line study, TIVO-1, comparing tivozanib to sorafenib
  - Phase 2 open-label crossover study, Study 902, of tivozanib for patients who progressed on sorafenib in TIVO-1
  - Phase 2 placebo-controlled study, Study 201, in first line RCC patients

- **Target indication is relapsed or refractory renal cell carcinoma**

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Positive Risk/Benefit Profile for Relapsed or Refractory RCC

- **Limited evidence for sequencing therapies in highly refractory RCC or after treatment with a checkpoint inhibitor**
- **TIVO-3 provides first Phase 3 dataset in a 3rd and 4th line patient population**
  - First large randomized study to evaluate treatment following a checkpoint inhibitor
- **Superior disease control (PFS, ORR & DoR) vs. VEGFR TKI comparator in two large Phase 3 studies**
  - Efficacy demonstrated in large single arm study in VEGFR TKI refractory RCC population
- **Safety and OS profile consistent with the VEGFR TKI class**
  - RCC monotherapy clinical trial safety data >1,000 patients
  - TIVO-3 confirms no adverse effect on overall survival
  - Years of EU post-marketing treatment experience
- **Superior tolerability compared to sorafenib**
  - Fewer dose reductions, interruptions and discontinuations due to AEs

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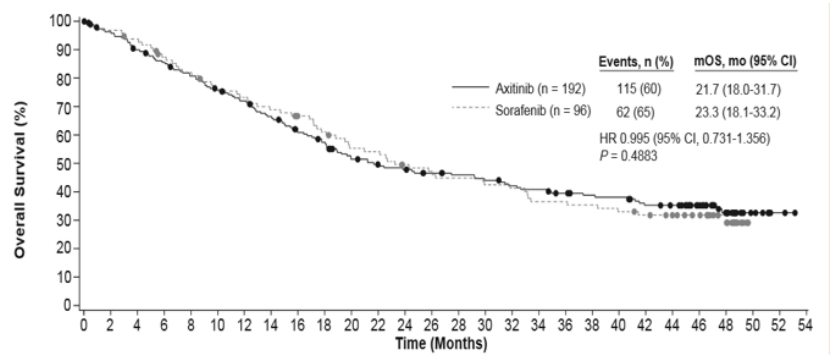
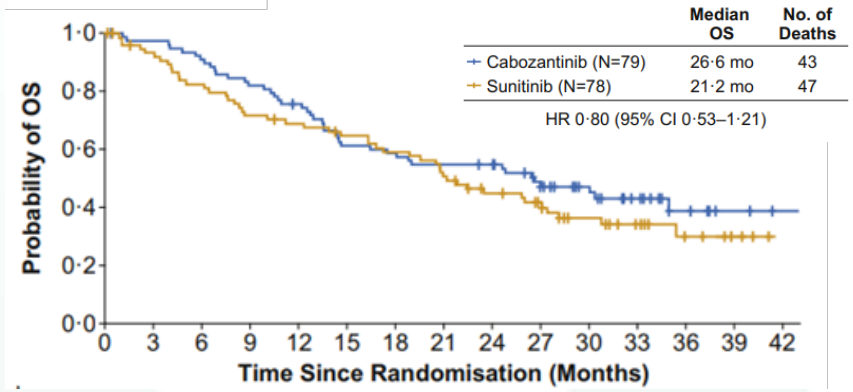
No VEGFR TKI Has Shown an OS Advantage Over Another in RCC

Axitinib vs Sorafenib 1st line[1]

All Randomized Patients

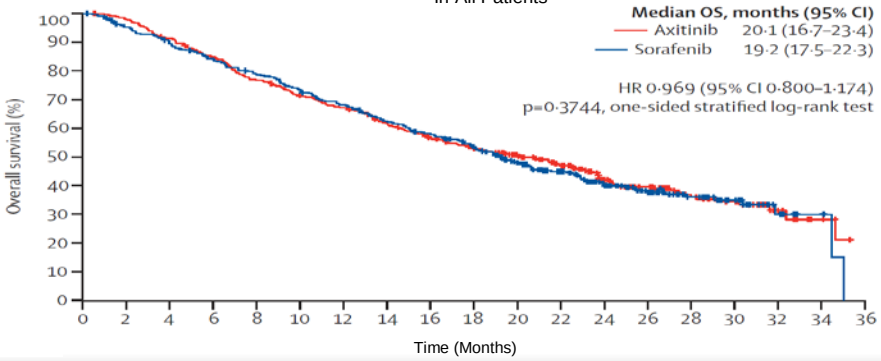


Cabozantinib vs Sunitinib 1st line[2]

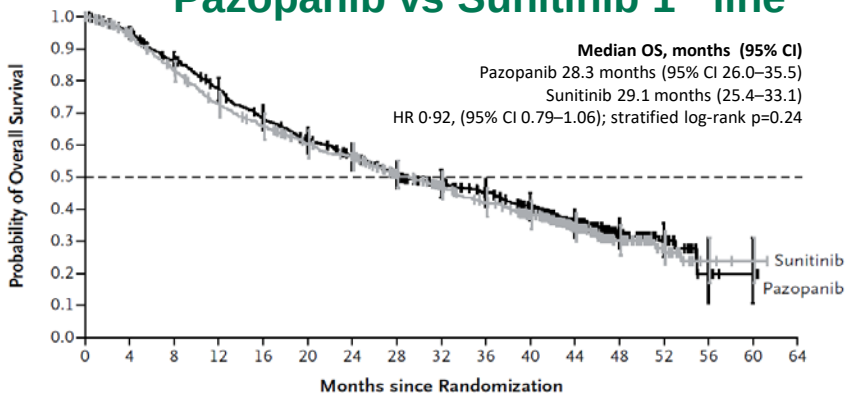


Axitinib vs Sorafenib 2nd Line[3]

In All Patients



Pazopanib vs Sunitinib 1st line[4]



Note: Data from separate studies

1) Hutson et al. Clinical Genitourinary Cancer; Vol. 15, No. 1, 72-6. 2) Choueiri et al. European Journal of Cancer 2018; 94: 115e125

3) Motzer et. al. Lancet Oncol 2013; 14: 552–62. 4) Motzer, et al. N Engl J Med. 2014;370(18):1769-1770.

Commercial Opportunity

If Approved, Significant Potential Commercial Opportunity for Tivozanib in the United States

2nd Line Market *(est. 2020)*
~$700M[1]

3rd Line+ Market *(est. 2020)*
~$300M[1]

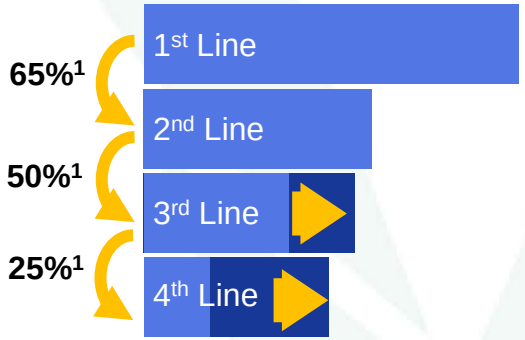
- Expect opportunity to expand
- Potential to be **first** agent indicated for 3rd & 4th line
- **Only** pivotal dataset in RCC stratified by *prior PD-1*

NA royalties to KHK are low- to mid-teens on net sales

1 >PFS with tivozanib may extend treatment duration

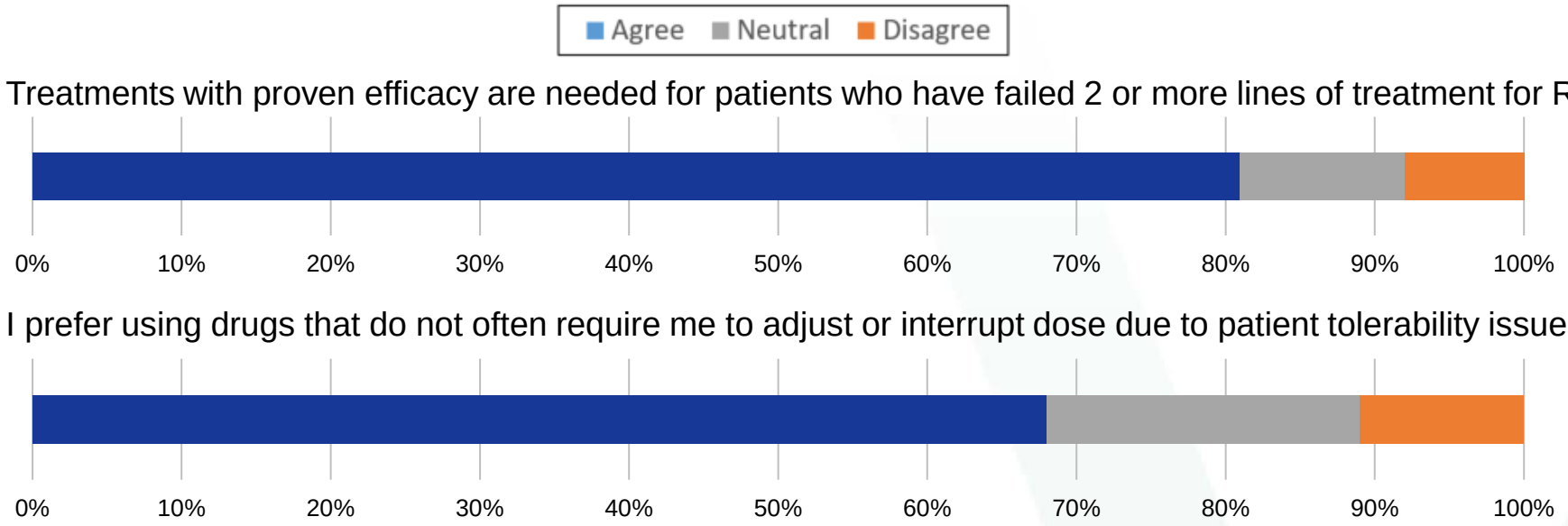
2 Extended OS from IO may expand population eligible for 3rd line treatment

3 Efficacy + tolerability may increase patients opting for 3rd and 4th line treatment

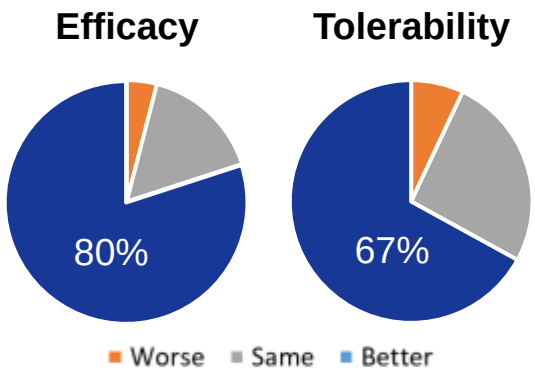


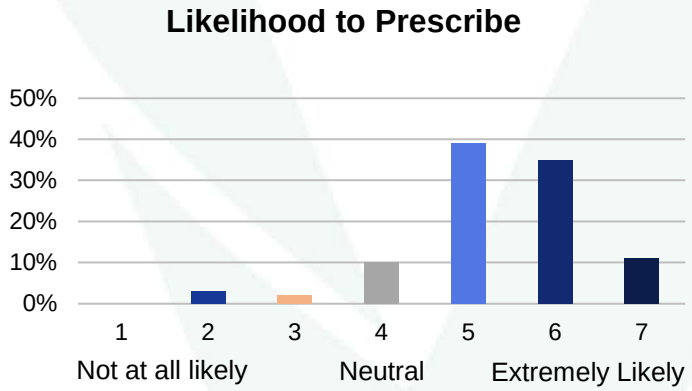
1 Decision Resources Pharmacor 2020 Market Projections July 2019

Potential Relevance of Tivozanib in Refractory RCC



Blinded Tivo Profile Ratings compared to current treatment options in refractory patients





Source: AVEO blinded Third-Party U.S. Oncologist Market Research using approximate TIVO-3 PFS and AE profile - Dec 2018 n=100

Tivozanib Properties May Provide Advantages in Combination with IO Therapy

>>Toxicity: Caution with PD1/PDL1 TKI combinations

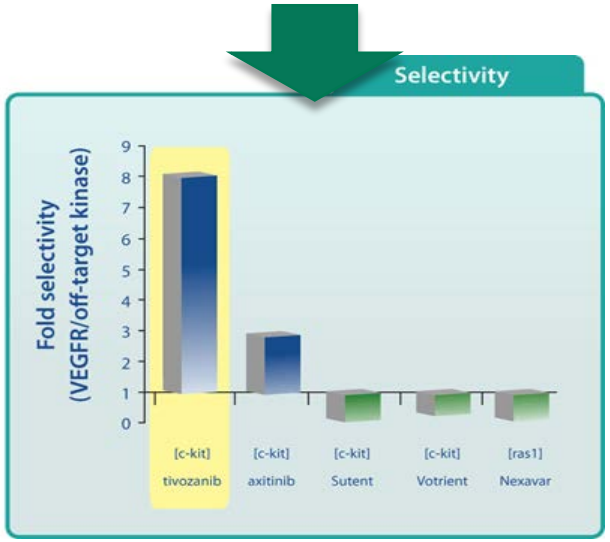
But..

not all VEGF inhibitors are the same.

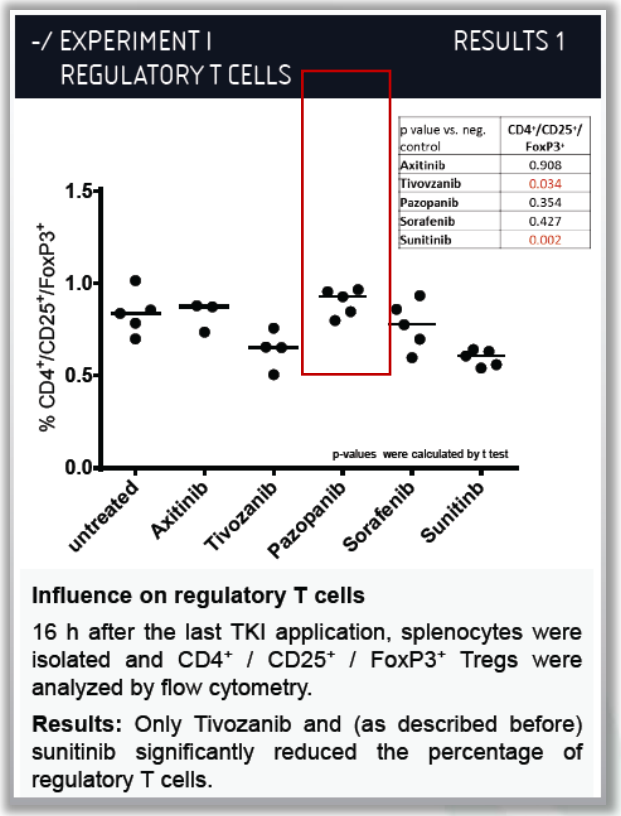
Case for more selective, potentially more combinable VEGF Inhibitors ?

ASCO ANNUAL MEETING '17 | #ASCO17 Discussed by: Hans Hammers, MD, PhD

Hammers, Emerging VEGF-I/O Combinations, ASCO 2017



Nakamura K et al. Cancer Res 2006;66:9134–9142.



Influence on regulatory T cells

16 h after the last TKI application, splenocytes were isolated and CD4+ / CD25+ / FoxP3+ Tregs were analyzed by flow cytometry.

Results: Only Tivozanib and (as described before) sunitinib significantly reduced the percentage of regulatory T cells.

Pawlowski N et al. AACR 2013. Poster 3971.

TiNiVo

A Phase 1/2, Open-Label, Multi-Center Study of Tivozanib in Combination with Nivolumab (OPDIVO®) in Subjects with Advanced Renal Cell Carcinoma

DEDUCTIVE

A Phase 1/2, Open-Label, Multi-Center Study of Tivozanib in Combination with Durvalumab (IMFINZI®) in Subjects with Hepatocellular Carcinoma Who Have Not Received Prior Systemic Therapy

Phase 2 Initiated

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Summary

- **FDA dialogue actively proceeding**
  - NDA filed for R/R RCC March 31, 2020
  - Application Orientation Meeting (AOM) completed
- **Tivozanib is well positioned for the changing R/R RCC landscape**
  - R/R RCC is a significant monotherapy market opportunity: $1b and growing
  - TIVO-3 is the first positive Phase 3 in 3/4th line and first Phase 3 data to inform sequencing after immunotherapy
  - Foundation for commercial readiness in place
- **Expanding into IO combination**
  - TiNivo RCC Phase 2 combination with nivolumab (presented ESMO 2019)
  - DEDUCTIVE HCC Phase 1/2 combination with durvalumab now in Phase 2
- **Potential partnership & pipeline catalysts on the horizon**
  - EUSA (ex-NA oncology partner) TIVO-3 data buy-in of $20M, European and non-European approvals of $6M
  - KKC (tivozanib non-oncology partner) regulatory and development milestones
  - Ficlatuzumab (HGF mAb) and AV-203 (ERBB3 mAb) clinical milestones in 2021, AV-380 (Anti-GDF15 mAb) IND in 2020

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Q&A

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