

# AVEO Overview

January 2019

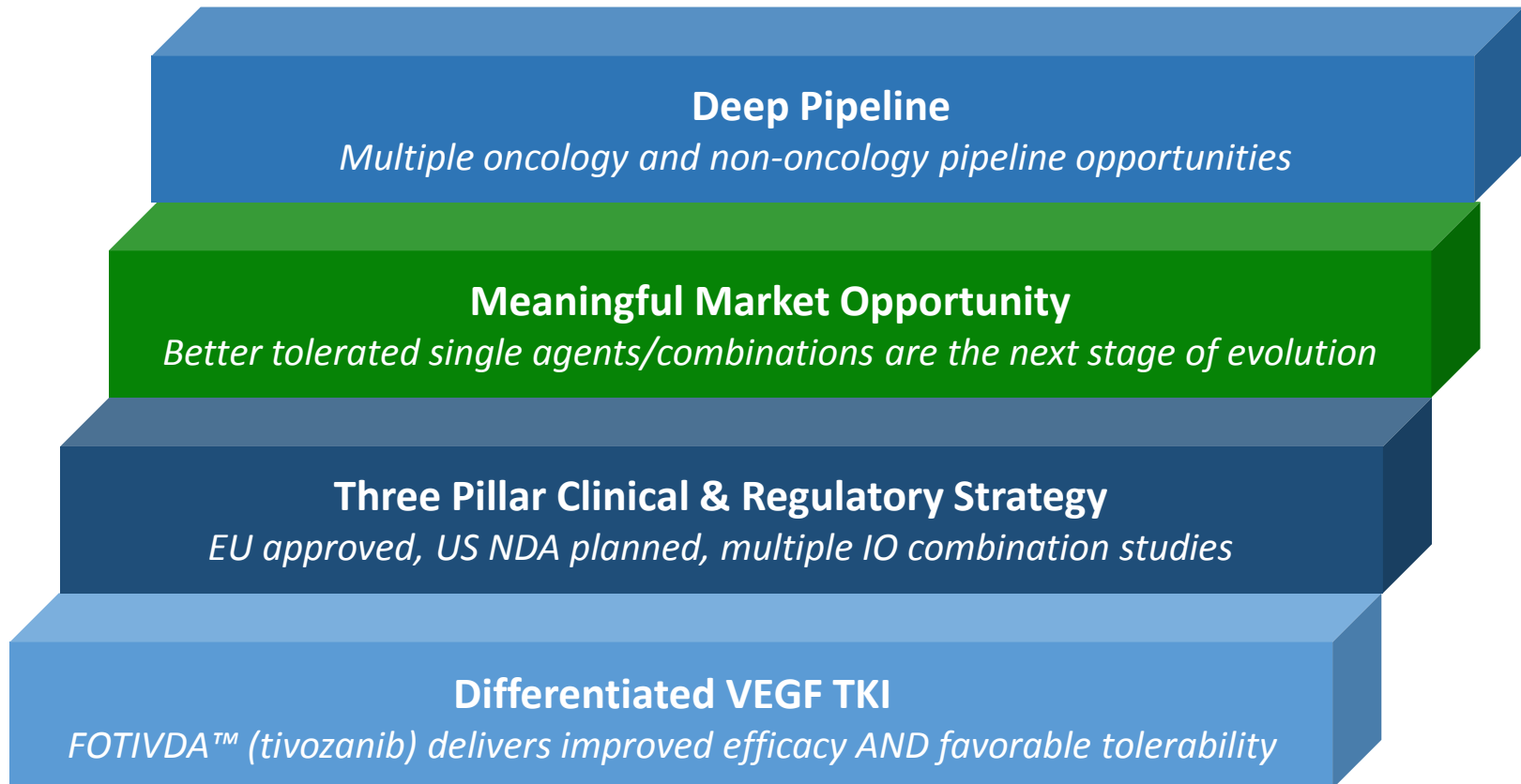


# Forward-Looking Statements




This presentation contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this presentation are forward-looking statements. The words “anticipate,” “believe,” “estimate,” “expect,” “intend,” “may,” “plan,” “predict,” “project,” “target,” “potential,” “will,” “would,” “could,” “should,” “continue,” “contemplate,” “seek,” “look forward,” “advance,” “goal,” “strategy,” or the negative of these terms or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements include, among others, statements about: AVEO’s goals and business strategy, prospects, plans and objectives; AVEO’s plans to submit a new drug application (NDA) to the U.S. Food and Drug Administration (FDA) for tivozanib; the timing, design and results of preclinical and clinical trials including its expectations regarding the timing for detailed topline results and the final overall survival analysis from the Phase 3 TIVO-3 study of tivozanib in RCC; the timing and outcome of meetings with and applications to regulatory authorities by AVEO and its partners; the competitive landscape for AVEO’s therapeutic candidates, the potential efficacy, safety and tolerability profile of tivozanib; and AVEO’s estimates for its cash runway.

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: the timing and costs of any product candidate that receives regulatory approval; AVEO’s ability to successfully implement its strategic plans; AVEO’s ability and the ability of its collaborators, licensees, and other strategic partners to successfully develop, test, gain regulatory approval and market its product candidates, including its companion diagnostics; the potential safety, efficacy, tolerability and other benefits of tivozanib as a single agent or in combination with other therapies; AVEO’s ability to obtain necessary financing required to perform its clinical trials and achieve its other goals; AVEO’s ability to establish and maintain strategic partnerships; AVEO’s ability to obtain and maintain intellectual property rights; AVEO’s ability, and the ability of its licensees, to demonstrate to the satisfaction of applicable regulatory agencies such as the FDA the safety, efficacy and clinically meaningful benefit of AVEO’s product candidates, including tivozanib; AVEO’s ability, and the ability of its licensees to successfully enroll and complete clinical trials, including the TIVO-3 and TiNivo trials and maintain compliance with all regulatory requirements applicable to its product candidates; competition; AVEO’s dependence on its strategic partners and other third parties; adverse general economic and industry conditions; and those risks discussed in the section titled “Risk Factors” 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 to update any of these statements, except as required by law.

# AVEO Oncology: Strategy for Value Creation



# Multiple Opportunities for Value Creation

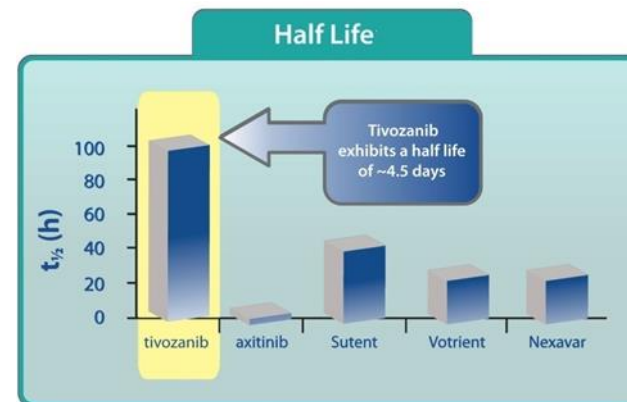
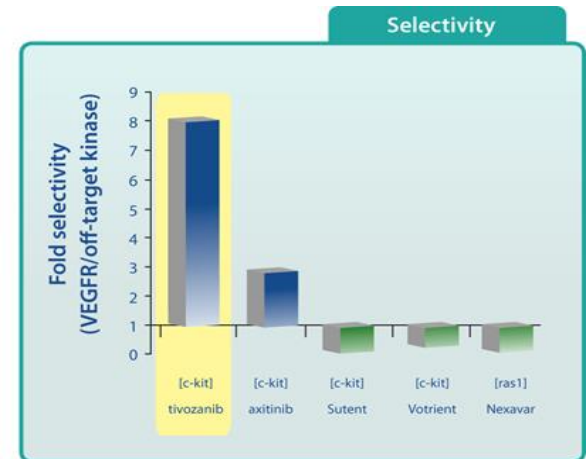
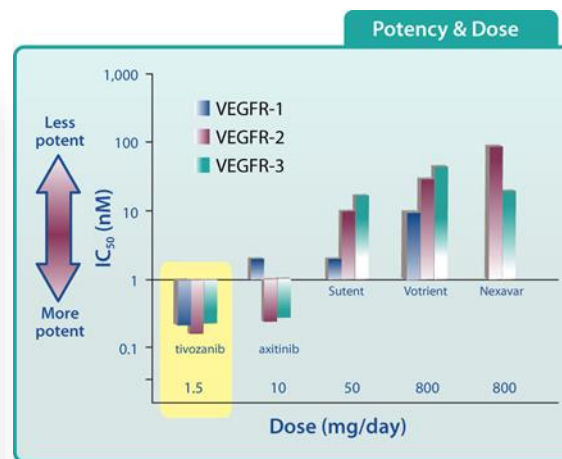
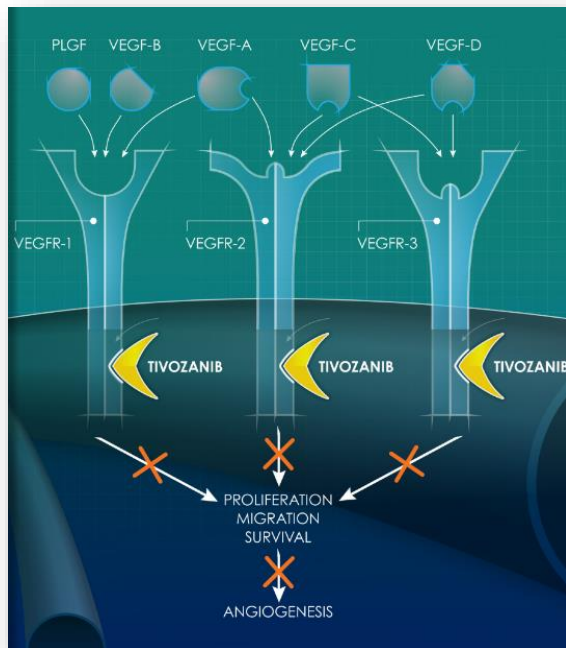
<b>Oncology</b>	Preclinical	Phase 1	Phase 2	Phase 3	Regulatory Filing	Marketed	Partner	
<b>Tivozanib</b> VEGFR 123 TKI	TIVO-1 (Phase 3 Registration Study in 1 <sup>st</sup> Line RCC)							 EUSA Pharma (Europe)
	TIVO-3 (Phase 3 Registration Study in 3 <sup>rd</sup> Line RCC)							
	TiNivo (+OPDIVO <sup>®</sup> RCC)							
	HCC (1 <sup>st</sup> line + IMFINZI <sup>®</sup> )							
<b>Ficlatuzumab</b> HGF MAb	SCCHN, Pancreatic, AML (Investigator)						 biodesix	
<b>AV-203 (CAN017)</b> ERBB3 MAb	Esophageal						 CANbridge	
<b>Non-Oncology</b>								
<b>Ocular Form</b> VEGFR 123 TKI	AMD						Licensable NA / EU Rights	
<b>AV-380</b> GDF15 MAb	Cachexia							
<b>AV-353</b> Notch 3 MAb	PAH						Seeking Partnership	

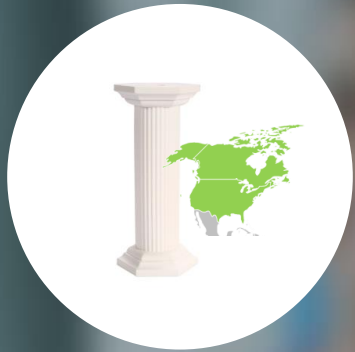
Ongoing or complete

In Planning

# Tivozanib: VEGFR 1, 2 and 3 Tyrosine Kinase Inhibitor

Potent, selective inhibitor of VEGFRs 1, 2 and 3 with a long half-life that is designed to optimize blockade while minimizing off-target toxicities<sup>1,2</sup>





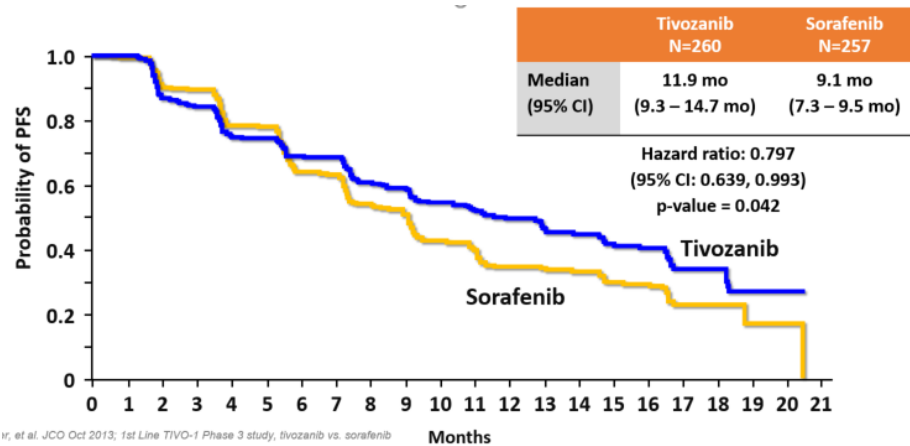
# FOTIVDA<sup>®</sup> (tivozanib)

US Commercial Opportunity

AVEO  
ONCOLOGY

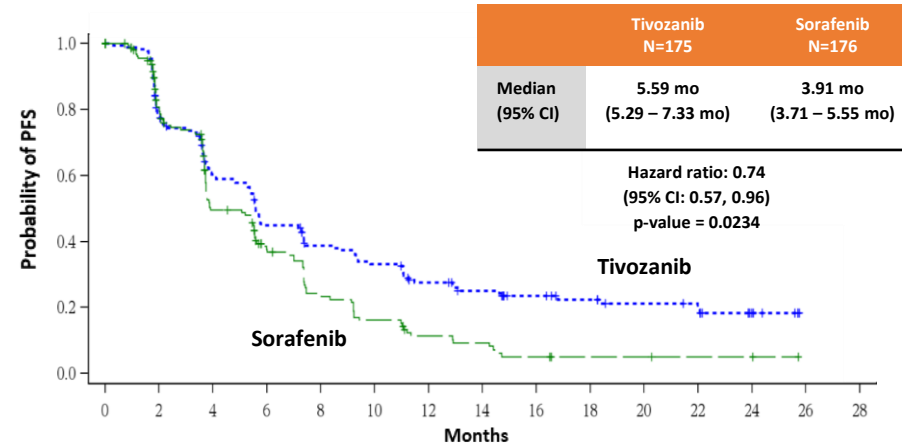
# Tivozanib: Superior PFS & Favorable Tolerability in Two Phase 3 RCC Studies

## TIVO-1



Phase 3 H2H study in 1<sup>st</sup> line RCC demonstrating superiority on primary PFS endpoint vs VEGF TKI\*

## TIVO-3

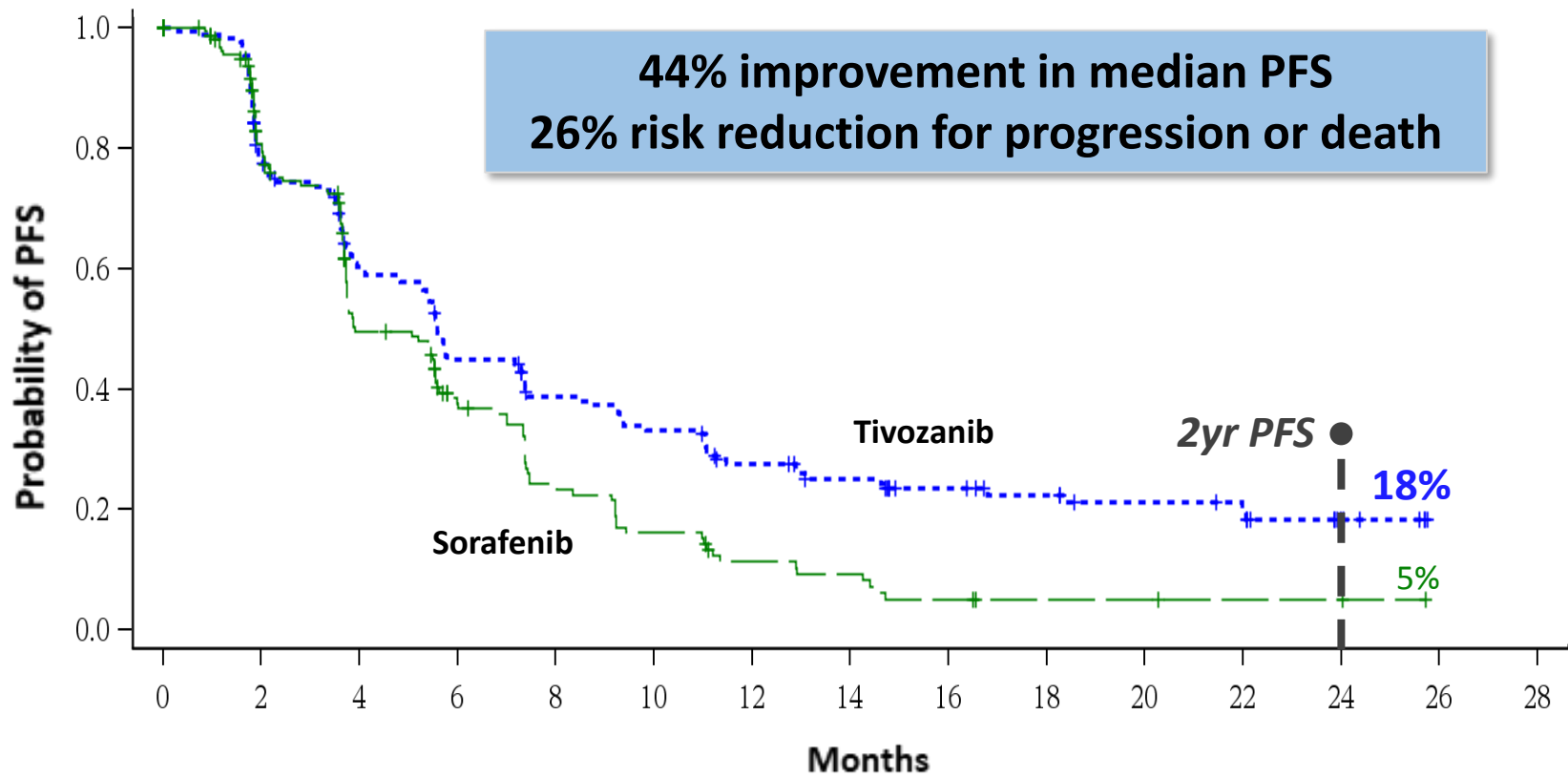


First and only Phase 3 study in 3<sup>rd</sup> and 4<sup>th</sup> line RCC to show a statistically significant PFS benefit over another VEGF TKI\*

\*vs Sorafenib (TIVO-1 & TIVO-3)

# Significant and Long Term Improvement in Disease Control

## TIVO-3

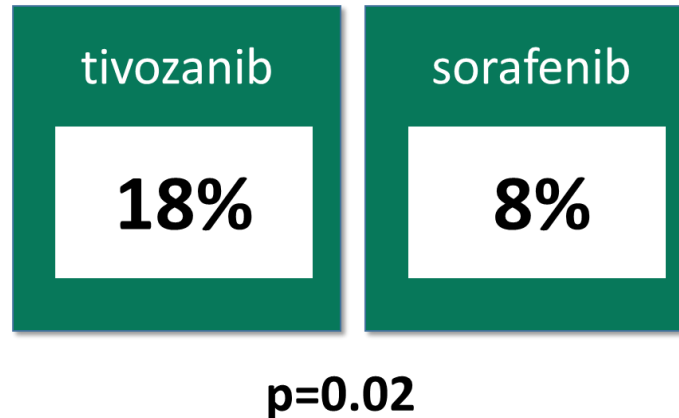




## Secondary Endpoints

TIVO-3

### ✓ Final Analysis - Superior Overall Response Rate



### ✓ Preliminary Analysis - OS Not Mature at Time of Final PFS Analysis

- Preliminary analysis (HR >1) represents approx. half of potential OS events
- OS data analysis and collection continues
- OS update to be presented at ASCO GU on February 16, 2019
- Final OS: Per protocol planned for August 2019

## Safety: Tivozanib Generally Well Tolerated

# TIVO-3

- ✔ Patients on the tivozanib arm received 95% of the targeted dose compared to 75% for sorafenib
- ✔ Grade 3 or higher adverse events for tivozanib are consistent with those observed in previous tivozanib trials
- ✔ Infrequent but severe adverse events reported in greater number in the tivozanib arm were thrombotic events similar to those observed in other tivozanib studies
- ✔ The most common adverse event in patients receiving tivozanib was hypertension, an adverse event known to reflect effective VEGF pathway inhibition
- ✔ Full dataset to be presented at a major medical meeting

# Low Rates of Toxicities Most Troublesome to RCC Patients



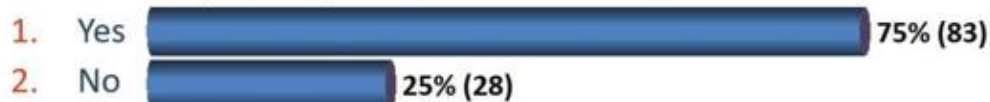
		Single Agent Toxicity All grade (Gr 3/4)	Sutent <sup>2</sup> (n=548)	Votrient <sup>2</sup> (n=554)	Inlyta <sup>3</sup> (n=189)	Nexavar <sup>1</sup> (n=257)	Cabometyx <sup>4</sup> (Int / poor risk pts) (n=78)	FOTIVDA® tivozanib <sup>1</sup> (n=259)
		Hypertension	41% (15%)	46% (15%)	49% (14%)	34% (18%)	81% (28%)	44% (27%)
The Most Troublesome Tolerability Effects of RCC Treatment <sup>5</sup>		Fatigue	63% (17%)	55% (10%)	33% (5%)	16% (4%)	86% (6%)	19% (5%)
		Hand-Foot Syndrome	50% (11%)	29% (6%)	26% (7%)	54% (17%)	42% (8%)	14% (2%)
		Diarrhea	57% (7%)	63% (9%)	50% (9%)	33% (7%)	72% (10%)	23% (2%)

Note: Data from separate pivotal studies



EIKCS EUSA Symposia April 2018

Does tolerability affect your treatment decision?



Total: 111

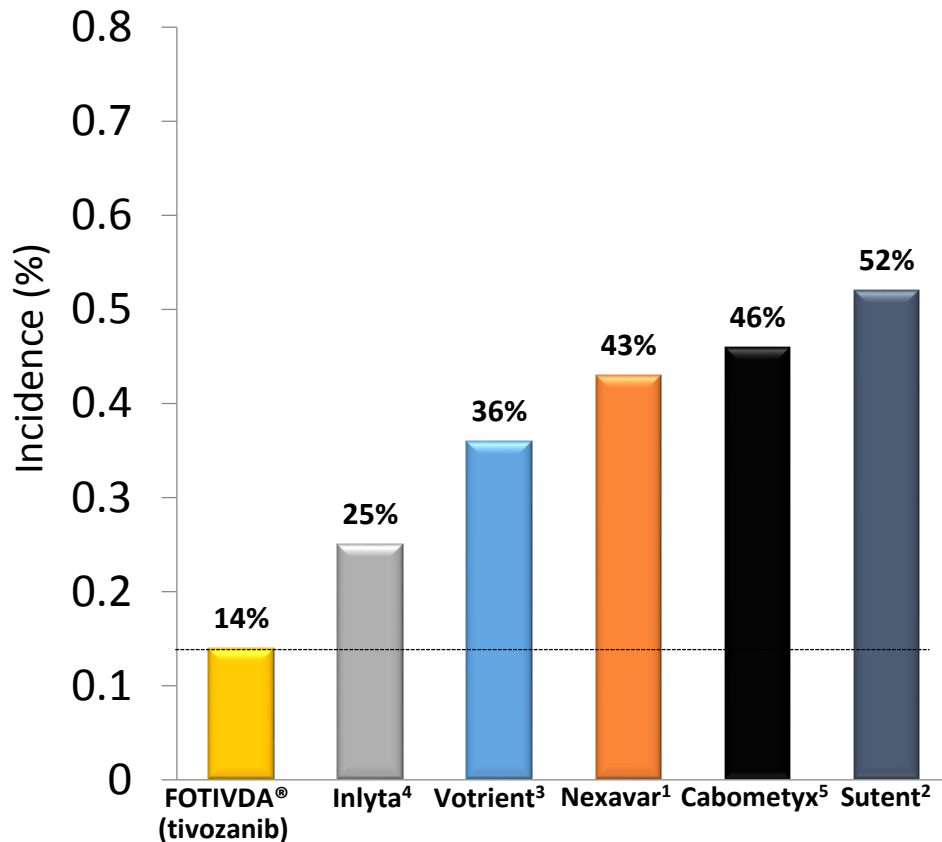


1. Motzer, et al. Tivozanib vs sorafenib as initial targeted therapy for patients with mRCC: Results from a Ph3 Trial, JCO 2013 31:30, 3791-3799
2. Motzer, et al. Pazopanib vs sunitinib in metastatic renal-cell carcinoma, N. Engl. J. Med., 369 (2013), pp. 722-731
3. Hutson, et al. LBA 348 GuCS 2013 (Ph3 axitinib versus sorafenib in 1<sup>st</sup> line RCC population)
4. Choueiri, et al. Cabozantinib vs sunitinib as initial targeted therapy for patients with mRCC of poor or intermediate risk" CABOSUN Trial, JCO 2016.70.7398 35, 591-597
5. Wong M, et al, J Med Econ 2012, 28 1-10

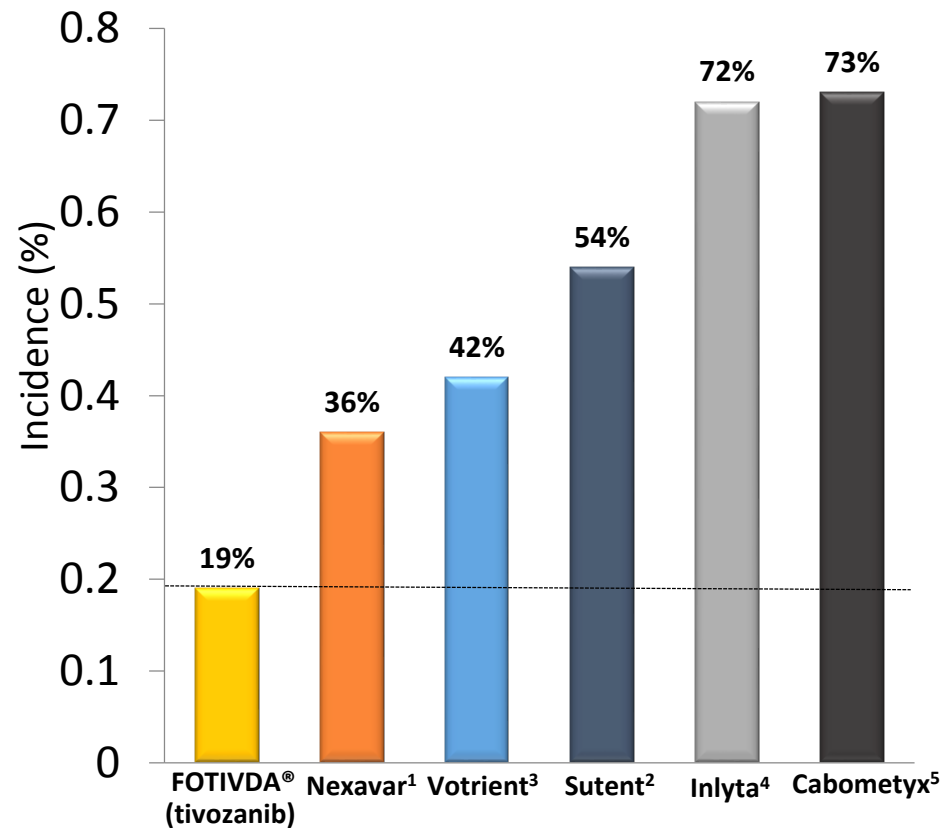
# Tolerability Translates into Low Rates of Dose Reductions and Interruptions

# TIVO-1

## Dose Reductions 1<sup>st</sup> Line



## Dose Interruptions 1<sup>st</sup> Line



1. Motzer, et al. Tivozanib vs sorafenib as initial targeted therapy for patients with mRCC: Results from a Ph3 Trial, JCO 2013 31:30, 3791-3799
2. Sutent US FDA Product Insert
3. Votrient US FDA Product Insert
4. Hutson, et al. LBA 348 GuCS 2013 (Ph3 axitinib versus sorafenib in 1<sup>st</sup> line RCC population)
5. Cabometyx US FDA Product Insert

**AVEO**  
ONCOLOGY

Note: Data from separate pivotal studies

## Upcoming Tivozanib Regulatory and Commercial Milestones

- ✓ Multiple large data sets spanning activity in 1st through 4th line RCC patients support potential NDA

**TIVO-1:** Phase 3 (n=517), 1st line RCC

**902:** Single arm (n=161), 2nd line RCC

**TIVO-3:** Phase 3 (n=350), 3rd & 4th line RCC

- Goal to submit a NDA to the U.S. Food and Drug Administration in 1H 2019
- Potential U.S. regulatory decision expected in 2020

# Significant Potential Commercial Opportunity for Tivozanib in the United States



1<sup>st</sup> Line Market  
~\$1.3B<sup>1</sup>

2<sup>nd</sup> Line Market  
~\$900M<sup>1</sup>

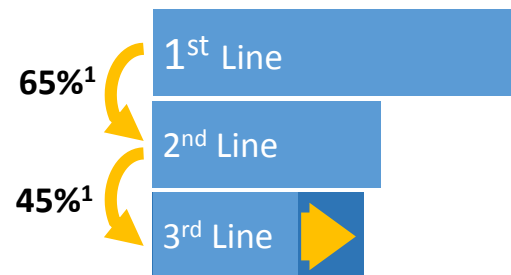
3<sup>rd</sup> Line+ Market  
~\$300M<sup>1</sup>

- Expanding opportunity
- Potential to be **first** agent indicated for 3<sup>rd</sup> & 4<sup>th</sup> line
- **Only** pivotal dataset in RCC stratified by prior PD-1

**1** >PFS with tivozanib may extend treatment duration

**2** Extended OS from IO may expand population eligible for 3<sup>rd</sup> line treatment

**3** Efficacy + tolerability may increase patients opting for 3<sup>rd</sup> line treatment



# Tivozanib Potentially Well Positioned in RCC Landscape



## ***Near Term - Immunotherapy is rapidly becoming standard of care in 1st line RCC***

- Extended OS increases need for new treatments with demonstrated activity in later lines
- Evidence gap exists for treatments after IO, a key subgroup in TIVO-3



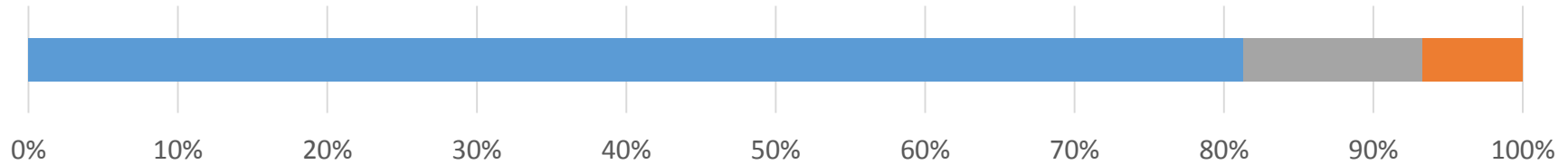
## ***Long Term – Combinations needed that enhance effectiveness without patient-challenging tolerability***

- Tivozanib selectivity has the potential to improve tolerability for IO combinations
- Tivozanib shown to reduce regulatory T-cells which could enhance activity
- Phase 2 TiNivo combination shows synergy in ORR

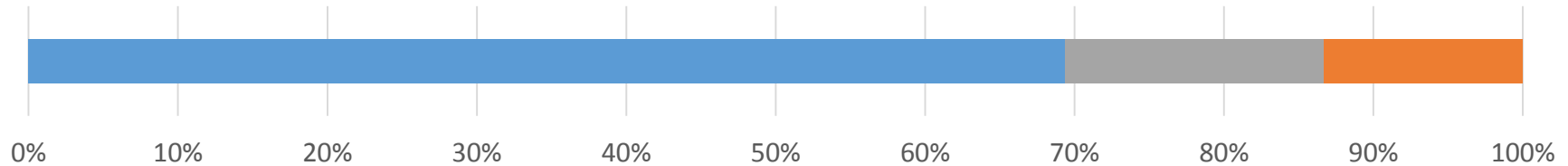
# Potential Relevance of Tivozanib in Refractory RCC

■ Agree ■ Neutral ■ Disagree

Treatments with proven efficacy are needed for patients who have failed 2 or more lines of treatment for RCC

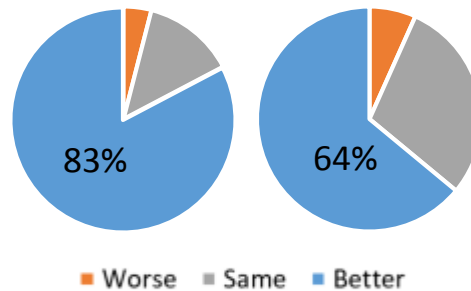


I prefer using drugs that do not often require me to adjust or interrupt dose due to patient tolerability issues

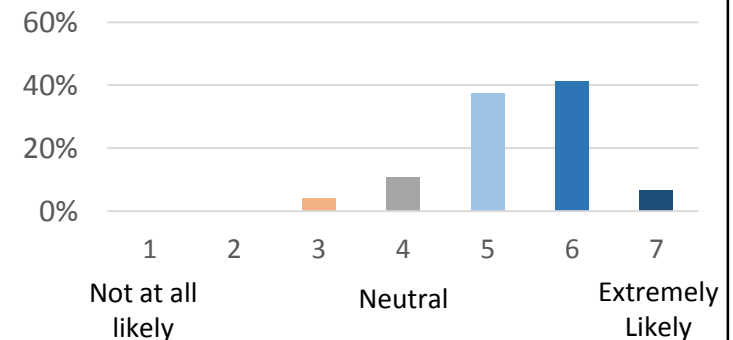


Blinded Tivo Profile Ratings compared to current treatment options in refractory patients

Efficacy Tolerability



Likelihood to Prescribe

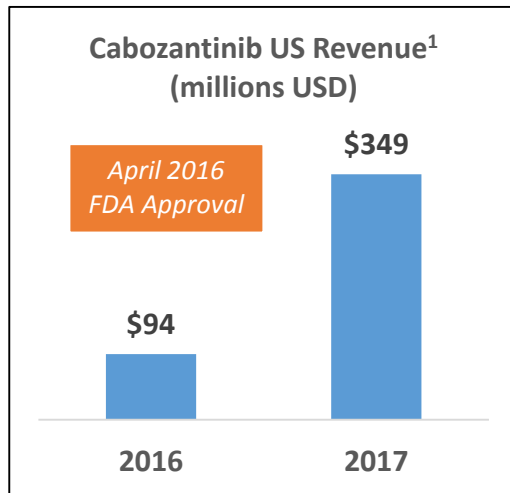






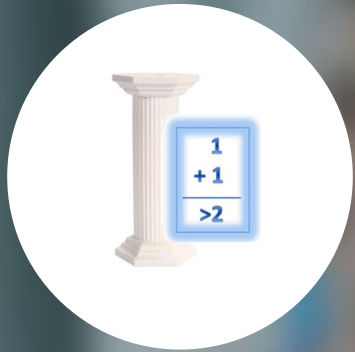
# Tivozanib Go-To-Market Strategy

- ✓ Key commercial leadership and launch plan in place
- ✓ Plan for focused salesforce of approximately 80 FTEs to provide broad market coverage and competitive share of voice
- ✓ Recent RCC analogues show potential for rapid adoption of differentiated therapy options (First 3<sup>rd</sup>/4<sup>th</sup> line positive study in RCC)



## Cabozantinib 2<sup>nd</sup> Line RCC Case Study<sup>2</sup>:

- 5<sup>th</sup> VEGF TKI approved in RCC, 2<sup>nd</sup> VEGF TKI approved in 2<sup>nd</sup> line
- Focused sales force of 80 FTEs<sup>2</sup>
- 38% New Patient Market Share in 2<sup>nd</sup> Line+ RCC within 18 months of approval<sup>3</sup>



# PD-1 Combination Opportunities

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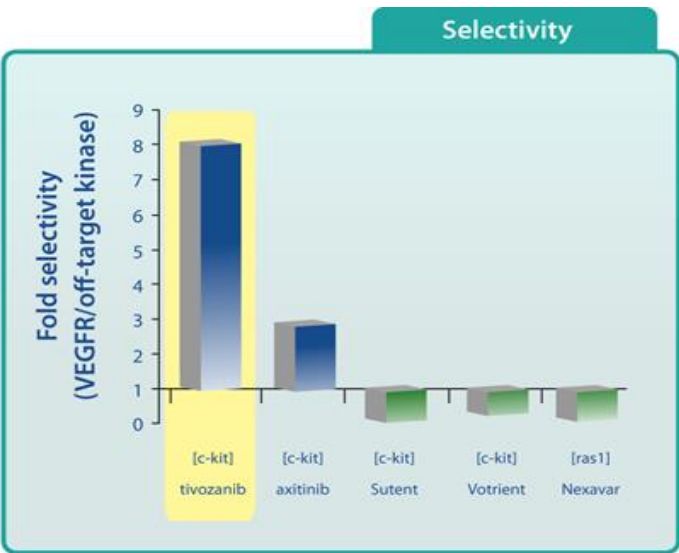
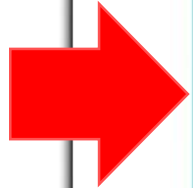
# Tivozanib High Selectivity<sup>1</sup> May Be a Significant Advantage ASCO 2017 – GU Oral Discussion<sup>2</sup>

>>Toxicity: Caution with PD1/PDL1 TKI combinations

But..

not all VEGF inhibitors are the same.

Case for more selective, potentially more combinable VEGF Inhibitors ?



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

### Selective TKIs

Axitinib plus Pembrolizumab (III)

Axitinib plus Avelumab (III)

Tivozanib plus Nivolumab

### Multitargeted TKI

Cabozantinib plus Nivolumab

Cabozantinib plus Nivo/Ipi (III)

Lenvatinib plus Pembrolizumab (III)

~~Pazopanib plus Nivolumab~~

~~Pazopanib plus Pembrolizumab~~

~~Sunitinib plus Nivolumab~~



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

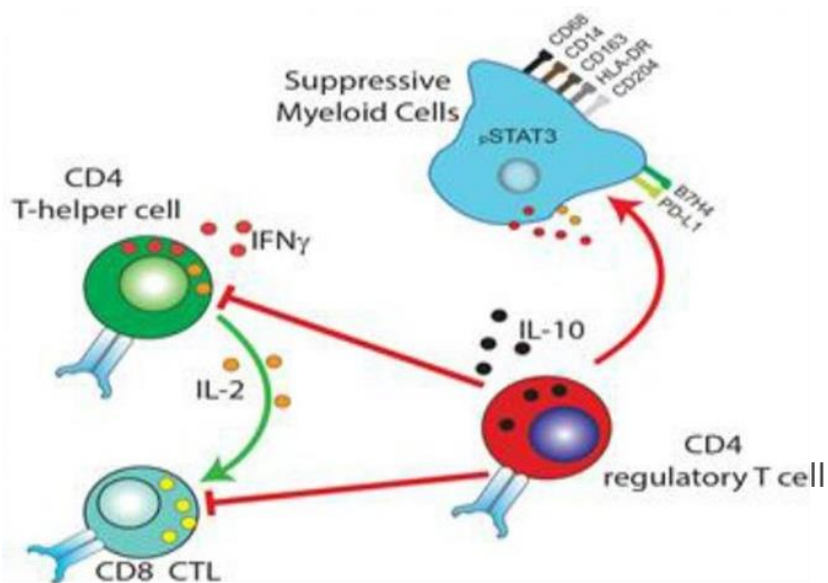


<sup>1</sup> Nakamura K et al. Cancer Res 2006;66:9134–9142.

<sup>2</sup> Hammers, Emerging VEGF-I/O Combinations: Efficacy and Toxicity, ASCO 2017

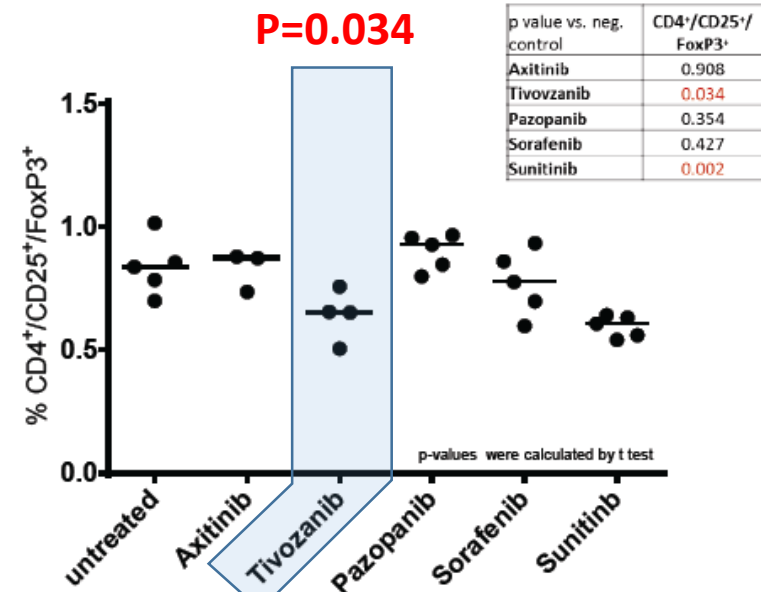
# Tivozanib has Immunomodulatory Properties: Regulatory T Cell Reduction May Enhance PD-1 Activity

Regulatory T cells suppress or downregulate induction and proliferation of effector T cells (e.g. CD4 and CD8)



## -/ EXPERIMENT I REGULATORY T CELLS

## RESULTS 1



### Influence on regulatory T cells

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

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

# ESMO 2018: Favorable Safety Results



**Table 1. Baseline patient characteristics in all enrolled patients**

	Patients (N=25)
<b>Median age, y (range)</b>	64 (37-75)
<b>Sex, n (%)</b>	
Male	19 (76)
Female	6 (24)
<b>Prior therapy, n (%)</b>	
0	12 (48)
1	11 (44)
2+	2 (8)
<b>ECOG PS, n (%)</b>	
0	15 (60)
1	10 (40)

**Table. Grade 3+ Treatment-related AEs**

	Grade 3/4 AEs, n (%)
Total	15 (60)
Hypertension	10 (40)
Malignant hypertension	2 (8)
Palmar-plantar <u>erythrodysesthesia</u> syndrome	2 (8)
ALT increased	1 (4)
Amylase increased	1 (4)
AST increased	1 (4)
Blood alkaline phosphatase increased	1 (4)
Blood pressure increased	1 (4)
<u>Gamma-glutamyltransferase</u> increased	1 (4)
Lipase increased	1 (4)
Rash	1 (4)
Acute coronary syndrome	1 (4)
Fatigue	1 (4)
Pain in extremity	1 (4)

ALT = alanine aminotransferase; AST = aspartate aminotransferase.

- 60% of patients experienced treatment related grade 3/4 adverse event
- Excluding uncomplicated hypertension, only 44% of patients experienced grade 3/4 adverse event
- Minimal off-target AEs observed, likely due to high specificity of tivozanib





# Preliminary Data for the Combination of PD-1 + VEGF TKIs: Promising Responses with Challenging Toxicity

	50% Pre-treated	100% Pre-treated	60% Pre-treated	Treatment Naive	Treatment Naive	Treatment Naive
<b>Efficacy N (%)</b>	<b>Tivozanib + Nivolumab<sup>1</sup> Total N=25</b>	<b>Pembro + Lenvatinib<sup>4</sup> Total N=30</b>	<b>Cabo<sup>^</sup> + Nivo or IpiNivo<sup>5</sup> Total N=13</b>	<b>Axitinib + Pembro<sup>2</sup> Total N=52</b>	<b>Axitinib + Avel<sup>3</sup> Ph3 Total N=442 (ITT)</b>	<b>Bev + Atezo<sup>6</sup> Ph3 Total N=454 (ITT)</b>
CR	1 (4)	0 (0)	0 (0)	4 (8)	(3)	(5)
PR	13 (52)	20 (67)	7 (54)	34 (65)	(48)	(31)
ORR	14 (56)	20 (67)	7 (54)	38 (73)	(51)	(37)
PFS / OS	NR	18.0 mo	18.4 mo / NR	20.9 mo / NR	13.8 mo	11.2 mo / NR
<b>Safety (%)</b>	<b>Tivozanib + Nivolumab<sup>1</sup> Total N=25</b>	<b>Pembro + Lenvatinib<sup>4</sup> Total N=30</b>	<b>Cabo<sup>^</sup> + Nivo or IpiNivo<sup>5</sup> GU Tumors Total N=78 (49-CN; 29-CNI)</b>	<b>Axitinib + Pembro<sup>2</sup> Total N=52</b>	<b>Axitinib + Avelumab<sup>3</sup> Total N=434</b>	<b>Atezo + Bev<sup>6</sup> Total N=451</b>
Gr 3/4 AEs (Tx Related)	(60) (44*)	(73)	CN (57) CNI (72)	(65)	(71)	(40)

\*Excl Uncomplicated HTN

<sup>^</sup>Reduced dose (40mg) recommended for combination

1. Barthelemy, et al. Tivozanib Combined With Nivolumab: Phase Ib/II Study in mRCC, ESMO 2018; 2. Atkins, et al., Axitinib in combination with pembrolizumab in patients with advanced renal cell cancer: a non-randomised, open-label, dose-finding, and dose-expansion phase 1b trial, The Lancet Oncology, Volume 0, Issue 0; 3. Motzer, et al. 1<sup>st</sup> line avelumab + axitinib therapy in patients with aRCC: Ph3, ESMO 2018; 4. Lee, et al. A Phase 1b/2 Trial of Lenvatinib + Pembrolizumab in Patients With Renal Cell Carcinoma, ASCO 2018; 5. Nadal, et al. Ph1 study of cabozantinib + nivolumab (CaboNivo) alone or with ipilimumab (CaboNivoIpi) in GU tumors, ASCO GU 2018; 6. Motzer, et al., IMmotion151: A Ph3 Study of Atezolizumab Plus Bevacizumab vs Sunitinib in RCC, ASGO GU 2018; NR=not reached.



Note: Data from separate studies

## Immuno-Oncology Clinical Collaboration with AstraZeneca

- Clinical Rationale: Potential to show enhanced efficacy and best in class tolerability profile for an IO/TKI combination
- Monotherapy tivozanib POC in HCC<sup>1</sup>
  - ORR 21%, PFS 5.5mo, OS 7.5mo
- Monotherapy durvalumab POC in HCC<sup>2</sup>
  - ORR 10%, PFS 2.7mo, OS 13.2mo
- Planned Ph1/2 study: costs shared equally and clinical drug supplied by each company

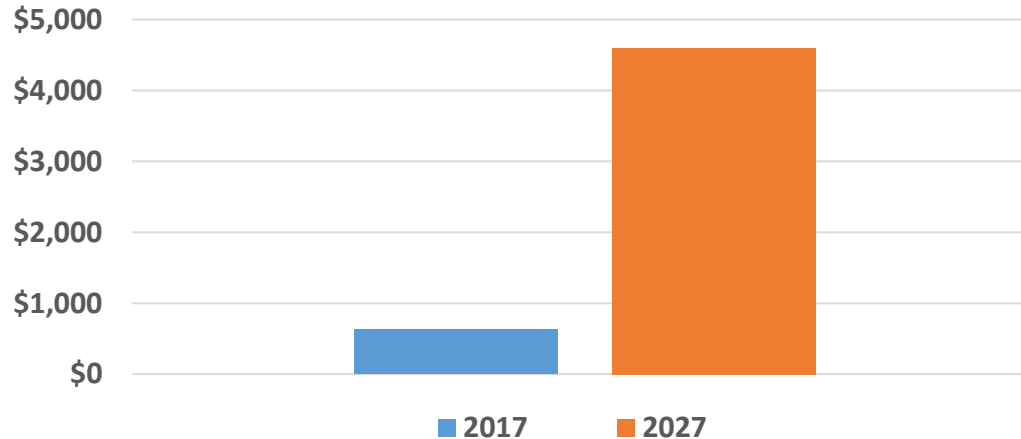
<sup>1</sup> Lee, ASCO GI 2018 Poster 364

<sup>2</sup> Wainberg, ASCO 2017 Poster 4071



# HCC Combination has Significant Market Potential

HCC Revenue Projections - Major Markets (Millions USD)<sup>1</sup>



***Dramatic market growth driven by adoption of IO therapies and improvement in patient outcomes.***

## HCC Market – Key Opportunity<sup>1</sup>

- Developing combination regimens comprising drugs of different mechanisms of action as first-line treatment can generate significant commercial rewards.



# FOTIVDA<sup>®</sup> (tivozanib)

European Commercial Opportunity

AVEO  
ONCOLOGY

# EUSA Agreement: Fotivda Economics

## Payments Earned to Date

- **\$8.5M** in Upfront and R&D reimbursement
- **\$4M** Milestone for UK & DE reimbursement approval
- Royalty revenue with EU launch in Q4 2017

## \$20M in Potential R&D Reimbursement and 50% Cost Sharing for I/O Combinations<sup>^</sup>

## Commercially Focused Milestones & Royalties

- Tiered royalties range from **low double digits to mid twenties**\*
- **\$6M** milestones for reimbursement approval in three outstanding EU5 countries\*
- **\$335M** in tiered commercial milestones based on sales thresholds\*
- **\$23M** in milestones based on approvals for additional indications and countries\*

\*Royalty to KHK: EU/ROW payments received by AVEO subject to 30% sublicense revenue obligation

<sup>^</sup>No sublicense revenue obligation to KHK on R&D Reimbursement, subject to certain limitations

*Milestone and royalty payments subject to the successful development or commercialization of the product*

# EU Launch Territories: Germany, the U.K., Austria, the Netherlands and Sweden



ESMO Guidelines updated to include Fotivda (tivozanib)<sup>2</sup>

## EU5 Launch Territories

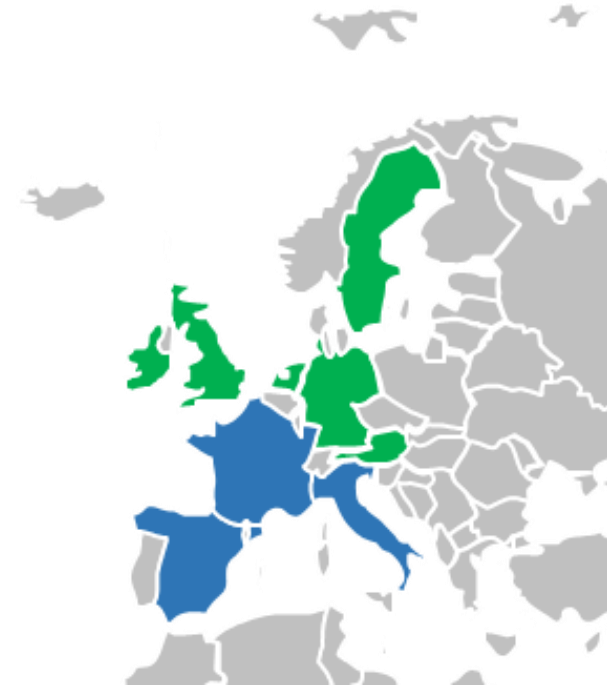


- ~\$200M Market (2017); 50% Sutent/Votrient<sup>1</sup>
- \$2M milestone payment Nov 18



- \$2M milestone payment Feb 18
- ~\$100M Market (2017) with 50% of sales from Sutent and Votrient<sup>1</sup>

## Upcoming EU5 Launch Territories



Anticipated milestone payments from EUSA up to \$6.0 million for potential reimbursement approvals in France, Italy, and Spain

1. Decision Resources Pharmacor Market Projections Dec 2017  
 2. <https://www.onkopedia.com/de/onkopedia/guidelines/nierenzellkarzinom-hypernephrom/@@view/html/index.html>

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# Pipeline and Financials Highlights



# Pipeline

## **Ficlatuzumab** HGF Inhibitory Antibody with Optimal Blockade of c-Met

biosix 

- **SCCHN:** Randomized Phase 2 Trial Ongoing (Ficlatuzumab + Erbitux vs. Ficlatuzumab)
- **Pancreatic Cancer:** Phase 1/2 Trial Ongoing (Ficlatuzumab + Nab-paclitaxel + Gemcitabine)
- **AML:** Phase 1b/2 Trial Ongoing (Ficlatuzumab + High Dose Cytarabine (HiDAC))
- COM and other IP to at least 2027

## **CAN017 (AV-203)** Anti-ERBB3 Mab with Broad Therapeutic Potential

 CANbridge

- CANbridge to fund clinical development through Phase 2a POC study
- Additional \$40M development and regulatory/\$90M commercial milestone
- Tiered royalties from low double-digit to low-teens, for ex-NA rights
- Planned indication: squamous cell esophageal cancer (IND accepted in China August 2018)
- COM and other IP ranging from 2031 to 2032

## **AV-380** First-in-Class, Anti-GDF15 Mab for Cachexia

- Affects approximately 5 million patients in the US alone; up to 80% of advanced cancer patients and is responsible for 20-30% of all cancer deaths
- COM through 2033\* and in licensed methods of use patent
- Moving AV-380 into IND-enabling preclinical development

\* Does not include potential PTE up to 5 yr max

1. Morley et al; Am J Clin Nutr 2006;83:735– 43

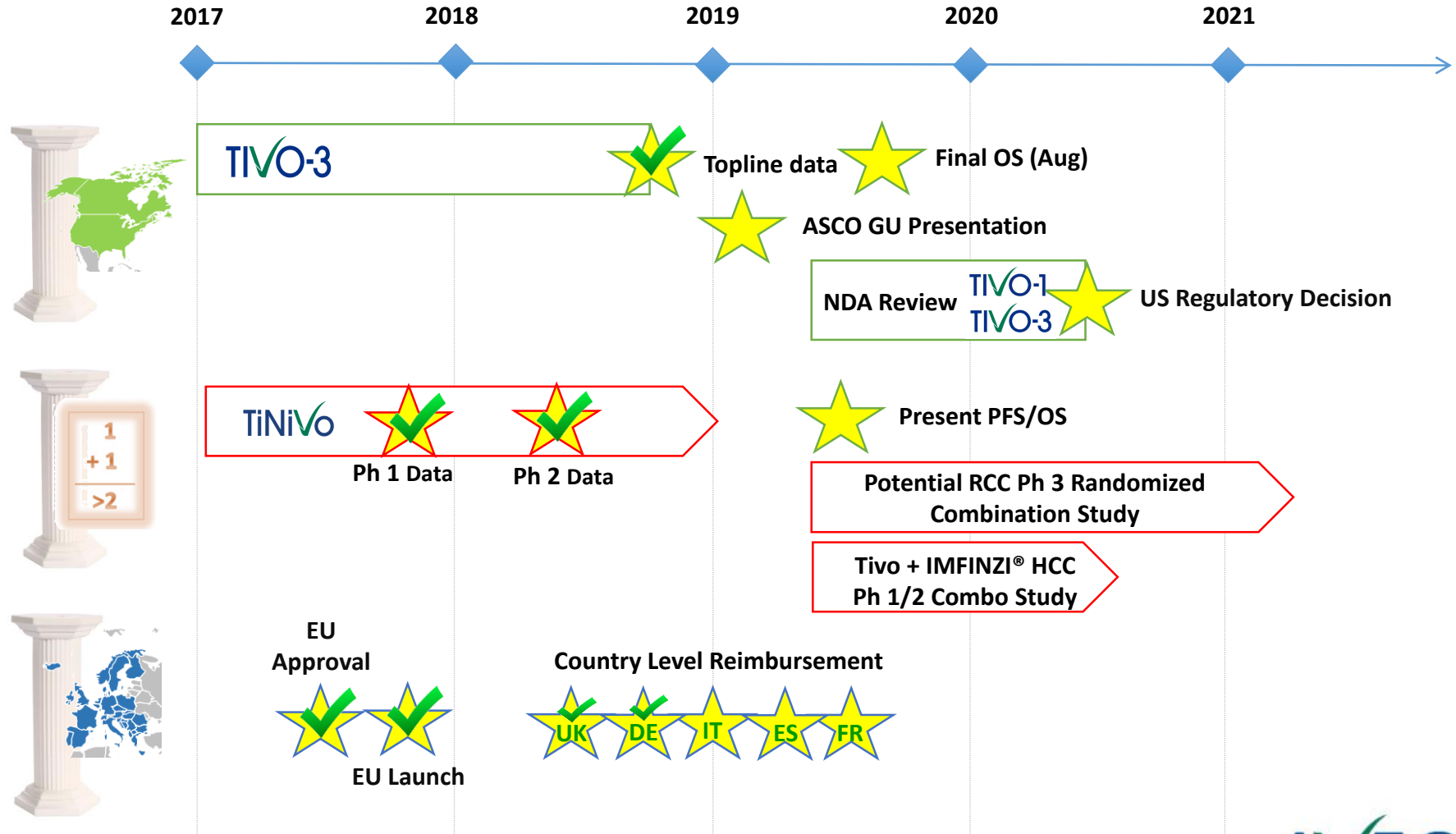
2. Lerner, et al. MAP3K11/GDF15 axis is a critical driver of cancer cachexia, [J Cachexia Sarcopenia Muscle](#). 2016 Sep; 7(4): 467–482.

# Financial Highlights

- **\$20.4M in cash, cash equivalents, and investments as of 3Q 2018**
  - Additional \$8.4 million raised through sales agreement in Oct/Nov
  - \$2M reimbursement milestone from EUSA for Germany incurred in Nov 2018
  - Fund planned operations into 3Q 2019\*
- **Restructured debt provides +cash flow in 2018-19 without increasing principal**
  - 6-mos interest-only extension (Dec 2018) principal to begin Aug 2019
- **EUSA royalties and potential milestones:**
  - Tiered low double-digit to mid-twenties royalties on FOTIVDA<sup>®</sup> (tivozanib) net sales in Europe, Latin America, and Australia
  - \$6M in milestones for reimbursement approvals in France, Italy, and Spain
  - \$20M in R&D reimbursement for access to TIVO-3 data, if optioned
  - \$335M in tiered commercial milestones
- **Streamlined, experienced team with a headcount of ~20**

\* Guidance assumes no receipt of additional milestone payments from our partners, no additional funding from new partnership agreements, no additional equity or debt financings, and no sales of equity through the exercise of our outstanding warrants.

# FOTIVDA® (tivozanib) Key Upcoming Milestones



Composition of matter patent into 2022 with potential for extension into 2027 for both Europe and North America



# AVEO Overview

January 2019

