Tuspetinib Clinical Update and KOL Data Review

Hosted in conjunction with the European School of Haematology (ESH)
6th International Conference being held in Estoril, Portugal

October 30, 2023

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PRECISION ONCOLOGY FOR THERAPIES OF TOMORROW

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KOL BIOGRAPHIES

Naval G. Daver, MD is Professor, Director Leukemia Research Alliance Program, in the Department of Leukemia at the University of Texas MD Anderson Cancer Center. He completed his medical school from Grant Medical College and Sir J group of Hospitals Mumbai, followed by a residency and fellowship in hematology-oncology from Baylor College of Medicine. He is a clinical investigator with a focus on molecular and immune therapies in AML and Myelofibrosis and is principal investigator on >25 ongoing institutional, national and international clinical trials in these diseases. These trials focus on developing a personalized therapy approach by targeting specific mutations or immune pathways expressed by patients with AML, evaluating novel combinations of targeted, immune and cytotoxic agents, and identifying and overcoming mechanism of resistance. He is especially interested in developing monoclonal and bispecific antibodies, immune checkpoint and vaccine based approaches in AML, MDS, and myelofibrosis and is leading a number of these trials at MDACC. Dr. Daver has published >150 peer-reviewed manuscripts and is on the editorial board of numerous hematology specific journals. He has also authored numerous abstracts at national and international conferences.

Rafael Bejar, MD, PhD is an internationally recognized physician scientist with extensive research and clinical experience in hematologic malignancies. Dr. Bejar joined Aptose from UC San Diego where continues to serve as an Associate Professor of Clinical Medicine, cares for patients, and maintains a research laboratory focused on translational studies of myeloid malignancies. At UCSD, he founded the MDS Center of Excellence and led the Hematology Disease Team. There he has directed several clinical studies and served as an advisor for numerous companies including Celgene, Takeda, AbbVie, Astex, Genoptix, Forty Seven, PersImmune, and Daiichi-Sankyo. Outside UCSD, Dr. Bejar sits on the Scientific Advisory Board for the MDS Foundation, is a prior member of the National Comprehensive Cancer Network Guidelines Committee and has led projects for the International Working Group for MDS. He is frequently invited to speak at national and international meetings and has published articles in a variety of journals, including *The New England Journal of Medicine*, *Journal of Clinical Oncology*, *Leukemia*, *Blood*, and *Blood Advances*. Dr. Bejar has been board certified in Hematology and Oncology since completing his fellowship at the Dana-Farber Cancer Institute. He completed his internship in Internal Medicine at the University of Chicago followed by his residency at the Brigham and Women's Hospital in Boston where he later served as a Medical Chief Resident and an Instructor in Hematology. He holds an MD degree and Neuroscience PhD from UCSD and a BS in Physics from MIT.

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Dr. William G. Rice: Chairman and CEO, Aptose

- Introduction to KOLs
- Tuspetinib Overview

Dr. Rafael Bejar, Chief Medical Officer, Aptose

- Tuspetinib (TUS) Single Agent Clinical Findings in R/R AML Patients
- Tuspetinib/Venetoclax (TUS/VEN) Drug Combination Clinical Findings in R/R AML Patients

Dr. Naval Daver, MD Anderson Cancer Center

- Q and A Session

Overview

- **Tuspetinib (TUS) | once daily oral kinase inhibitor | demonstrated robust single agent activity and excellent safety as a treatment for relapsed/refractory acute myeloid leukemia (R/R AML)**
  - Tuspetinib is more than a FLT3 inhibitor for AML, it also hits SYK, $FLT3^{WT/MUT}$, KIT^{MUT}, JAK1/2, RSK2, TAK1-TAB1
  - Potential application in the large higher-risk myelodysplastic syndromes (HR-MDS) indication
- **AML care shifted to Venetoclax (VEN) combinations → Emerging wave of difficult-to-treat VEN failures**
- **Tuspetinib's safety/efficacy/mechanistic/convenience properties ideal for combination therapy**
- **Tuspetinib directly targets VEN resistance mechanisms**

  TUS may mechanistically re-sensitize VEN failures to VEN | TUS/VEN may successfully treat these VEN failures
- **Potential accelerated approval path for TUS/VEN in prior-VEN failure R/R AML**
- **Multiple data readouts and events ahead of us**
  - TUS/VEN incremental data readout (Nov data cut) in R/R AML planned: ASH 2023
  - TUS/VEN further data on duration of response in R/R AML: 1Q & 2Q2024
  - TUS/VEN/HMA planned initiation of pilot study in 1L AML: 1H2024
  - Extension into HR-MDS and CMML planned: 4Q2023

Tuspetinib Single Agent Update

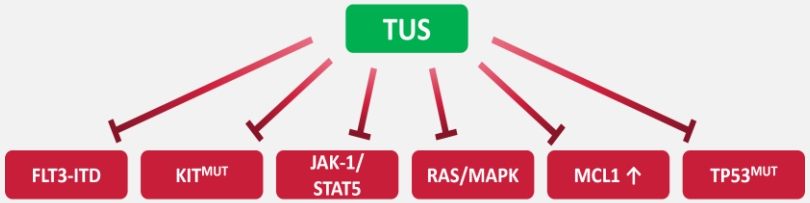
- **Established excellent safety and tolerability – ideal for combination therapies**
  - No drug-related myelosuppression in remission, QTc changes, muscle damage, or differentiation syndrome
- **Tuspetinib 80mg RP2D as a single agent**
  - Highly active across diverse subgroups with adverse genetics ($TP53^{MUT}$, RAS^{MUT}, $RUNX1^{MUT}$, $FLT3^{MUT/WT}$)
  - VEN-naïve AML patients: 42% CR/CRh Overall | 60% CR/CRh in $FLT3^{MUT}$ | 29% CR/CRh in $FLT3^{WT}$
- **Above 80mg dose level, response rates unexpectedly changed midway through the Phase 1 trial**

Tuspetinib Dose	% VEN Failure	ORR (%)	n
80mg	30%	35.3%	17
120mg	> 80%	19.0%	21

  - Patients enrolled at higher dose levels above 80mg represented a different population – primarily VEN failures
  - VEN failures more difficult-to-treat and have dramatically lower response rates to single agent therapies
- **Addition of Venetoclax to Tuspetinib jumps the 19% ORR in VEN failure patients back up to 44% ORR, demonstrating TUS/Ven Doublet can solve the problem**

Tuspetinib Can Directly Target Venetoclax Escape Mechanisms

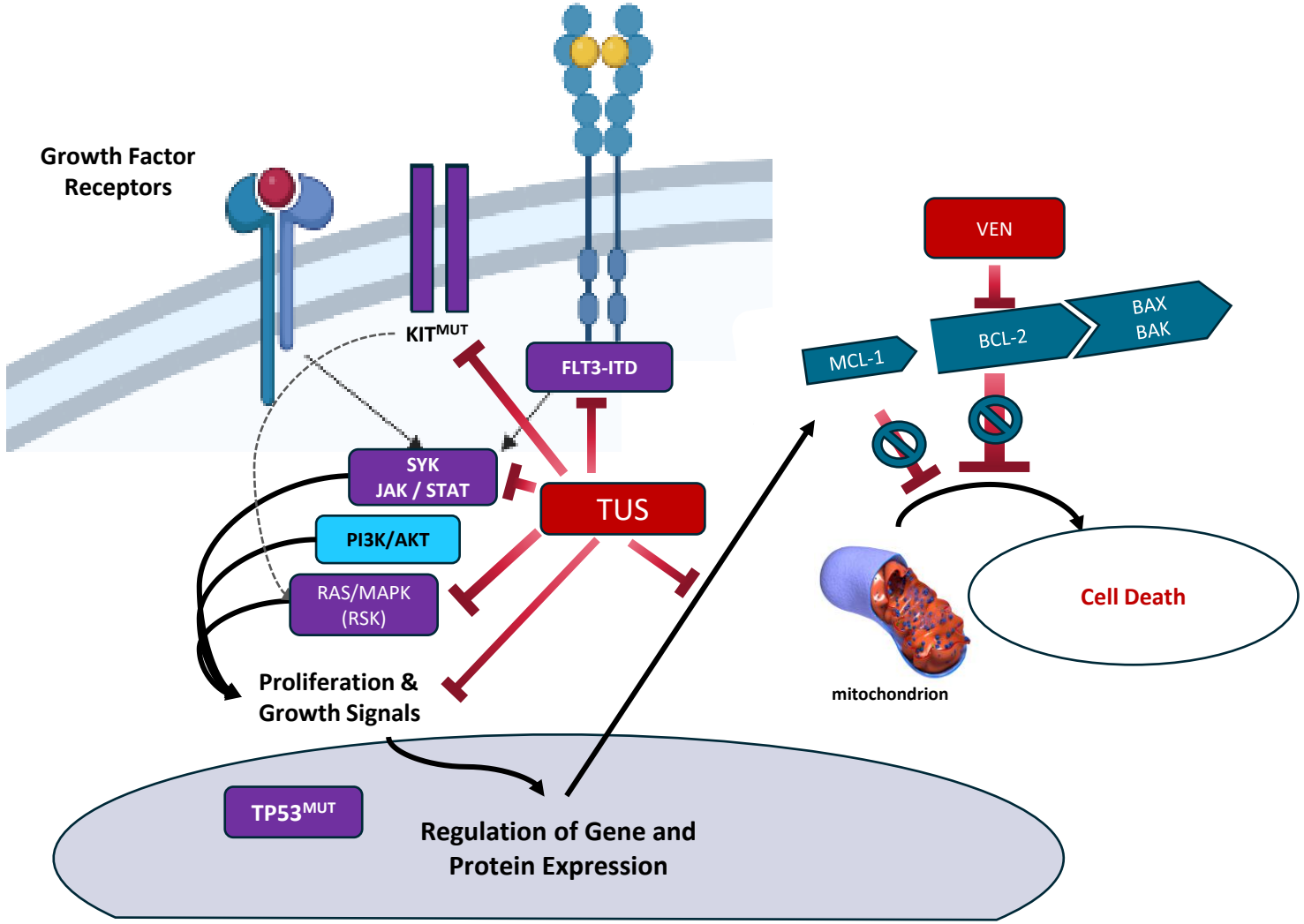
Tuspetinib directly targets pathways involved in resistance to Venetoclax



VEN resistance involves mutations in multiple pathways to evade BCL-2 blockade

By shutting down escape pathways, TUS may re-sensitize prior-VEN failures to venetoclax

- Strong evidence for combination therapy with tuspetinib and venetoclax
- ESH Poster: *Tuspetinib oral myeloid kinase inhibitor creates synthetic lethal vulnerability to venetoclax*



TUS/VEN Well-Tolerated and Active in Prior-VEN Failure AML Patients

- **EXPECTATION: 30 Patients Dosed by ESH**
- **ACTUALITY: 49 Patients Dosed by ESH (Oct 29, 2023)**
  Investigator Enthusiasm
- **TUS/VEN in APTIVATE trial maintained favorable safety and tolerability**

- Many dosed in Sep/Oct
- Many patients very early in Tx
  | Expect responses to mature

Overall Response Rates (%)			
Patient Population	**Aug 1, 2023 10 patients evaluable of 15 dosed**	**Sep 1, 2023 15 patients evaluable of 26 dosed**	**Oct 23, 2023 31 patients evaluable of 49 dosed**
VEN Failures	**44% (4 of 9)**	**38% (5 of 13)**	**44% (11 of 25)**
FLT3-Mutant	67% (2 of 3)	67% (4 of 6)	60% (6 of 10)
FLT3-Wildtype	43% (3 of 7)	33% (3 of 9)	43% (9 of 21)
Overall	50% (5 of 10)	47% (7 of 15)	48% (15 of 31)
Response Types	1CR|3CRi|1CRp	1CR|6CRi	2CR|7CRi|6PR

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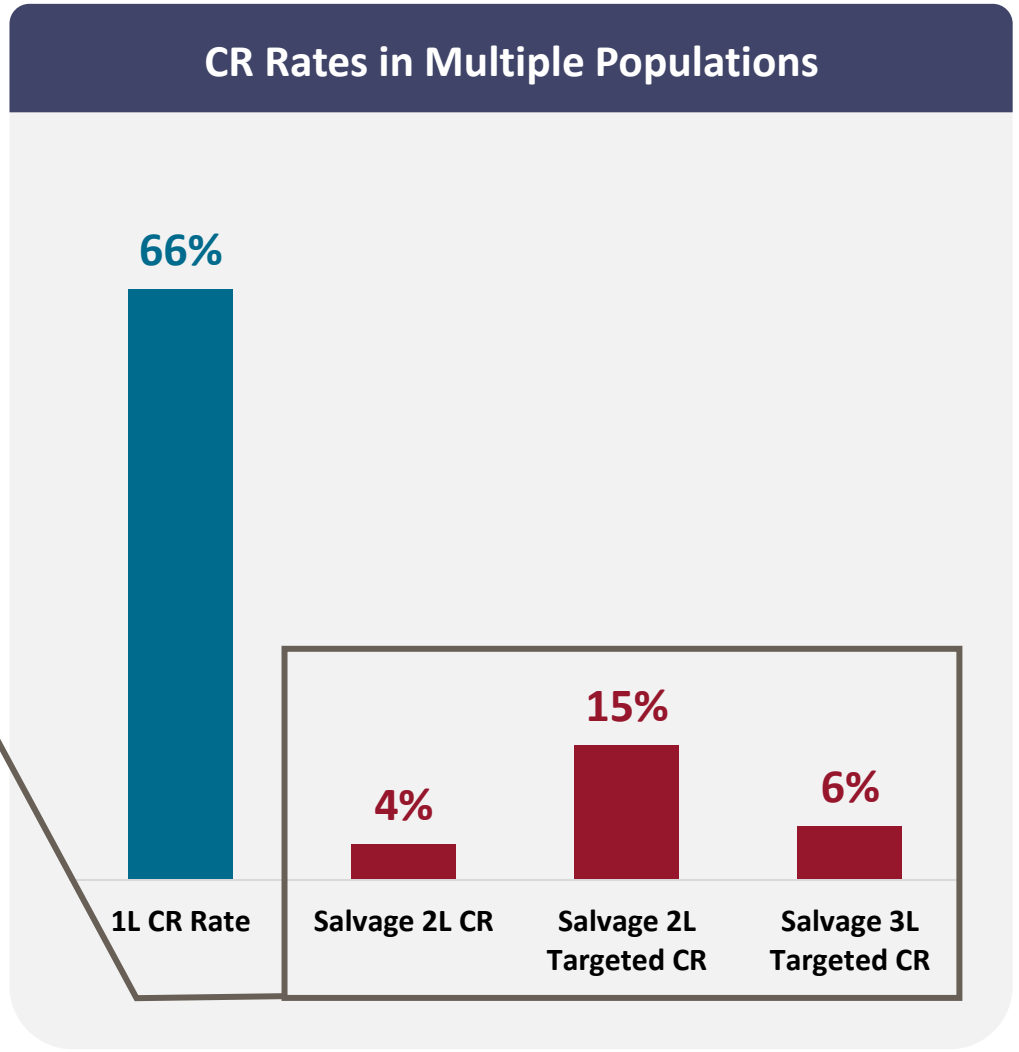
Need for Improved Combination Therapy for R/R Prior-VEN Failure AML

- **R/R AML Setting: AML care shifted toward Venetoclax (VEN) containing combination regimens and a new population of difficult-to-treat VEN failures is emerging**
- **After failing venetoclax, AML is highly refractory to salvage therapy[1,2,3,4]**
  - Prior-VEN failures have "dismal" response rates to salvage therapy
  - Resistance involves alterations in multiple pathways (FLT3, NRAS, KIT, TP53, JAK1/STAT5, MCL-1)

Need Improved Therapy for R/R Prior-VEN Failures

Greatest emerging need in AML is for a new, safe and effective combination salvage therapy

TUS/VEN combination is safe & active in VEN failures



1 Pei, Cancer Discos 2020); 2 DiNardo, Blood 2020); 3 (Maiti et al., Haematologica 2021); 4 (Mannis et al., Leukemia Research 2023); 5 Datamonitor Healthcare AML forecast July 2023; Also, Bewersforf et al., Leukemia Research 2022; 122: 106942.

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Clinical Path to Support Clinical Development and Registrational Plans

Dose Escalation Ph 1/2 Trial in R/R AML

- Demonstrated tuspetinib single agent activity
- Favorable safety and tolerability

EOP1 Meeting with FDA

- Successful meeting and outcomes
- RP2D = 80mg once daily
- All approval paths remain available

APTIVATE Expansion Trial in R/R AML

- Tuspetinib or TUS/VEN
- TUS/VEN favorable safety profile and highly active including prior-VEN failure difficult-to-treat subgroup

TUS/VEN Differentiation from Other Therapies

- TUS/VEN impressive response rate in R/R prior-VEN AML
- ~80% R/R prior-VEN patients entering APTIVATE trial
- May enable accelerated approval development path

Tuspetinib Single Agent

Phase 1/2 Clinical Study

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Tuspetinib Single Agent Phase 1/2 Study in R/R AML

Successfully completed with broad efficacy and favorable safety

Dose Escalation (A), Exploration (B), Expansion (C) (n = 91)				Dose	n=	
Cohort 1: 20 mg QD				20mg	2	
Cohort 2: 40 mg QD	40 mg QD	CRs	No DLT	40mg	17	
Cohort 3: 80 mg QD	80 mg QD	CRs	No DLT	80mg	20	RP2D
Cohort 4: 120 mg QD	120 mg QD	CRs	No DLT	120mg	32	Mostly Prior-VEN
Cohort 5: 160 mg QD	160 mg QD	CRs	No DLT	160mg	16	Mostly Prior-VEN
Cohort 6: 200 mg QD 1 DLT				200mg	4	

- Extensive dose exploration to address Project Optimus over 6 dose levels
- Clinical Responses (CRs) achieved at 4 dose levels (40, 80, 120, 160mg) with no DLT
- CRs in patients with highly adverse genetics, including mutated TP53 and RAS and $FLT3^{WT}$

Data as of 01 September 2023

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TUS Single Agent Favorable Safety Profile and Broad Therapeutic Window

Favorable Safety Profile

- No drug related AE of QTc prolongation
- No drug related non-hematologic SAE
- No drug related deaths or discontinuations
- No observed differentiation syndrome
- No DLT from 20mg level through 160mg level
  - One DLT of muscle weakness at 200mg
    - Occurred in patient with high exposure
    - Not rhabdomyolysis (muscle destruction)
    - No AEs of elevated creatine phosphokinase (CPK)
- Avoids many of the typical toxicities observed with other FLT3, IDH1/2 and menin inhibitors

Treatment-Emergent AEs (TEAEs), Safety Analysis Set, Single Agent Parts A, B, C (N = 91)

Patients Experiencing TEAEs	TUS (N=91, n[%])
Any	87 (95.6%)
Most Frequent TEAEs (>15% of patients)	
Pneumonia	30 (33.0%)
Nausea	18 (19.8%)
Diarrhea	17 (18.7%)
Pyrexia	17 (18.7%)
≥ Grade 3	66 (72.5%)
SAEs	52 (57.1%)
Leading to treatment termination	12 (13.2%)
Leading to death	18 (19.8%)
Patients Experiencing related TEAEs	
Any	29 (31.9%)
Most Frequent Related TEAEs (>10% of patients)	
Diarrhea	10 (11.0%)
Nausea	8 (8.8%)
White blood cell count decreased	2 (2.2%)
Grade ≥ 3	9 (9.9%)
Neutrophil count decreased or Neutropenia	3 (3.3%)
Muscle weakness	2 (2.2%)
White blood cell count decreased or Leukopenia	3 (3.3%)
Nausea	1 (1.1%)
Febrile neutropenia	1 (1.1%)
Hypertransaminasaemia	1 (1.1%)
Platelet count decreased or Thrombocytopenia	1 (1.1%)
Pneumonia	0 (0%)
Vomiting	0 (0%)
SAEs	1 (1.1%)
Leading to death	0 (0%)
Dose Limiting Toxicity (DLT)	1 (1.1%)

Data as of 01 September 2023

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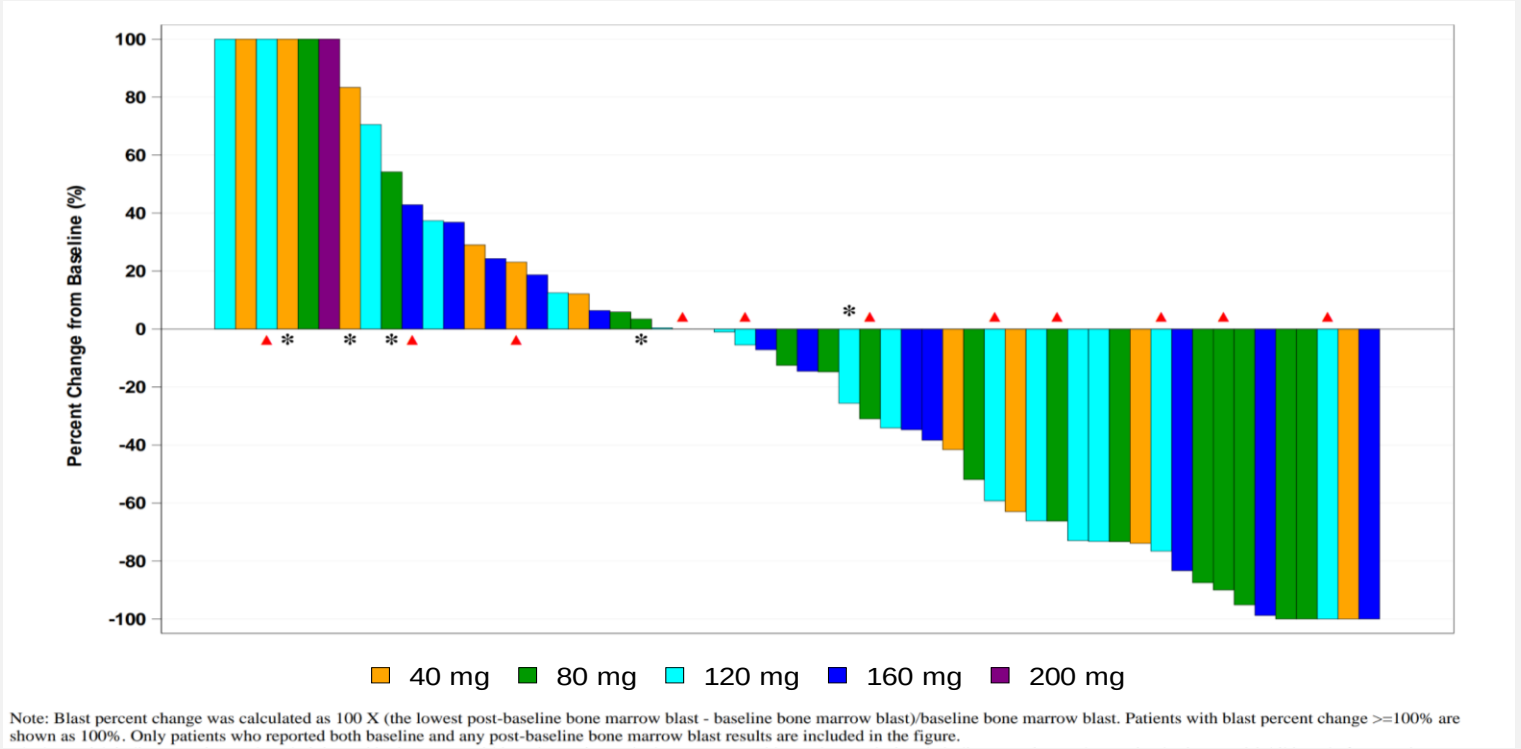
Tuspetinib Single Agent Bone Marrow Blast Reductions in R/R AML Patients

Blast Reductions | ALL Patients Percent Change from Baseline



Note: Blast percent change was calculated as 100 X (the lowest post-baseline bone marrow blast - baseline bone marrow blast)/baseline bone marrow blast. Patients with blast percent change >=100% are shown as 100%. Only patients who reported both baseline and any post-baseline bone marrow blast results are included in the figure.

- Significant blast reductions with 40mg, 80mg, 120mg, 160mg single agent tuspetinib
- Blast reductions observed across AML subgroups with tuspetinib

* Black asterisk indicates patients who administered hydroxyurea within 7 days prior to the lowest marrow blast value
▲ Red triangle indicates patients who received prior FLT3 inhibitors before starting HM43239, including gilteritinib, midostaurin, and/or sorafenib

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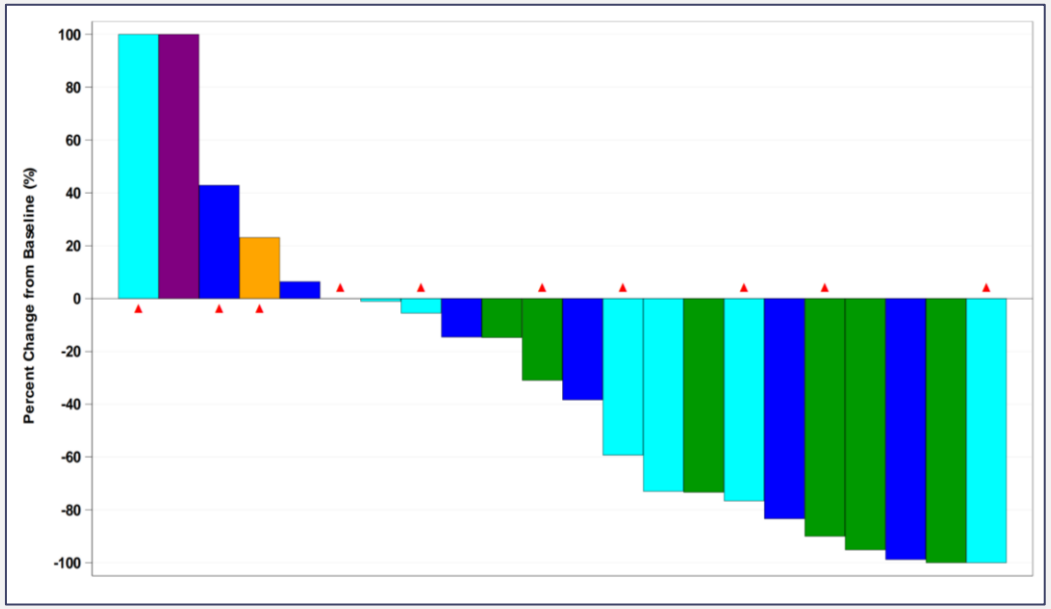
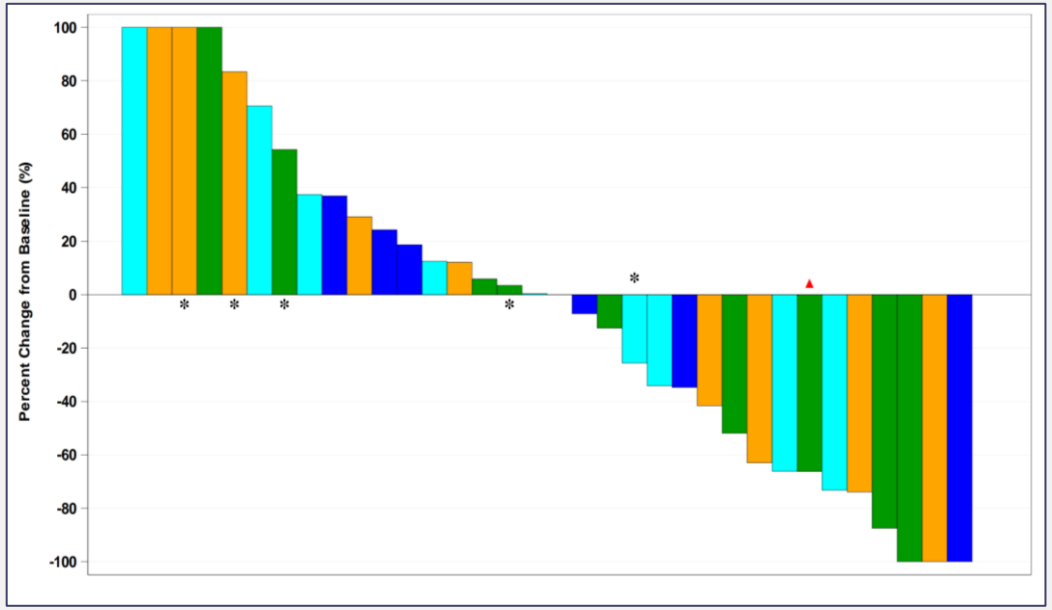
Tuspetinib Single Agent Bone Marrow Blast Reductions in R/R AML Patients

Blast Reductions | FLT3 Mutated
Percent Change from Baseline



40 mg 80 mg 120 mg 160 mg 200 mg

Blast Reductions | FLT3 Wildtype
Percent Change from Baseline



40 mg 80 mg 120 mg 160 mg 200 mg

- Blast reductions in FLT3MUT (with prior FLT3i exposure ▲) and FLT3-Wildtype/Unmutated AML

* Black asterisk indicates patients who administered hydroxyurea within 7 days prior to the lowest marrow blast value
▲ Red triangle indicates patients who received prior FLT3 inhibitors before starting HM43239, including gilteritinib, midostaurin, and/or sorafenib

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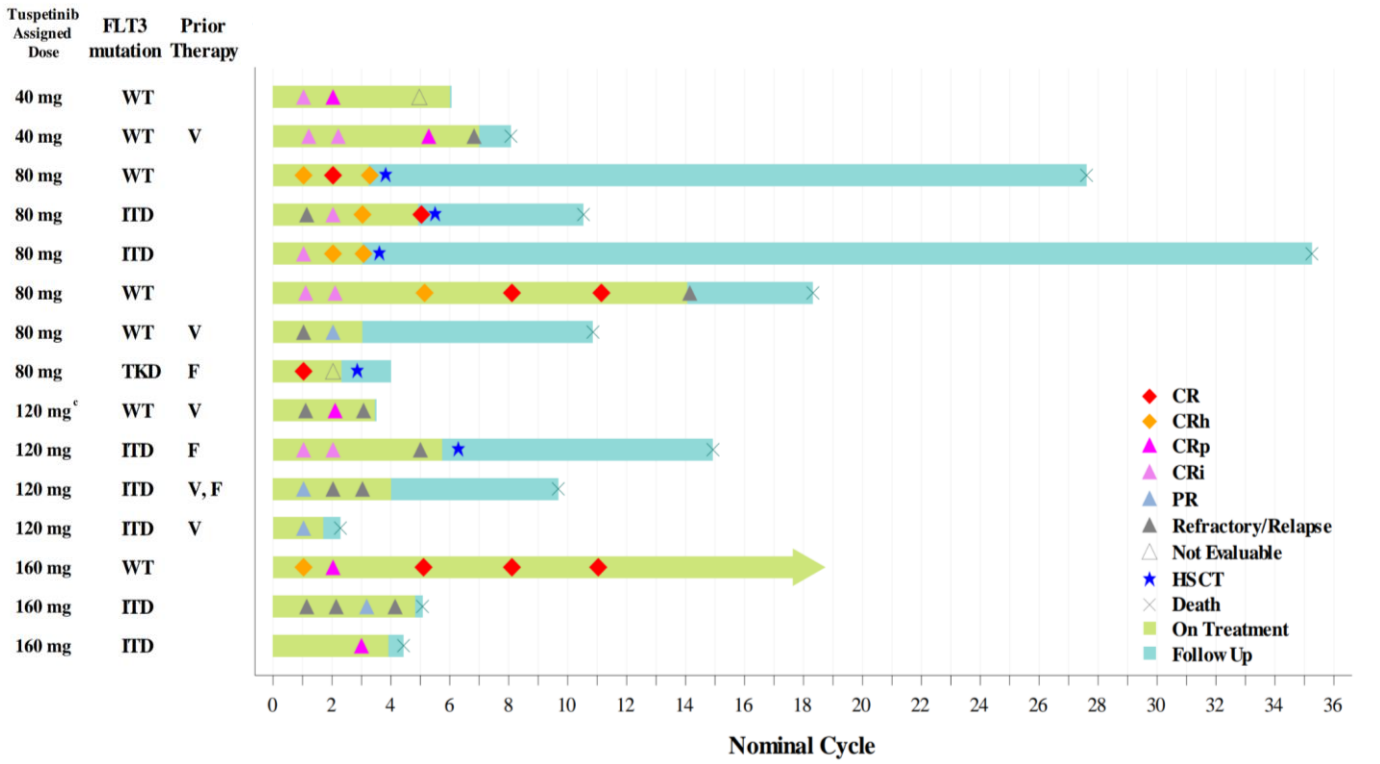
R/R AML Patients Achieving Clinical Responses with Tuspetinib Single Agent

Data as of September 1, 2023 and inclusive of Parts A, B, C

Responder Analysis

- Responses achieved across four dose levels
- Responses mature over time with ongoing continuous dosing
- Many bridged to potentially life-saving transplant (HSCT★)
- Durability observed when HSCT unavailable



Abbreviation: CR, complete response; CRh, complete response with partial hematologic recovery; CRi, complete response with incomplete hematologic recovery; CRp, complete response with incomplete platelet recovery; HSCT, hematopoietic stem cell transplantation; PR, partial remission.
Note: The bone marrow aspiration/biopsy date was used as response date. Actual time relative to the first dose date was used to plot events. The right arrow at the end of horizontal bar indicates patients are still ongoing, whereas without the right arrow indicates patients discontinued from study. The nominal cycle is calculated in 28 days increment in study days.
Note: For the prior therapy, 'V' indicates prior venetoclax usage and 'F' indicates prior FLT3 inhibitor usage.
[c] Indicates patients in Part C.

Path: Z:¥SASShare¥HM43239¥HM-FLTI-101¥Prog¥f_response_to_trt_actualtime.sas Executed: 05OCT2023 11:08:24 Data filtered through: 01SEP2023

Tuspetinib Single Agent Response Rates Compare Favorably to GILT FLT3i

Compare* RP2D of Each | No Prior-VEN Therapy | FLT3-Mutated and FLT3-Wildtype

	FLT3-Mutated R/R AML	
	Tuspetinib 80mg Phase 1/2 Trial (R/R, n=5)	GILT 120mg Admiral Phase 3 Trial[1,2] (2L, n=243)
CR/CRh	60%	23%

FLT3-Mutated R/R AML

- Tuspetinib appears highly active in FLT3-mutated AML

	FLT3-Wildtype R/R AML	
	Tuspetinib 80mg Phase 1/2 Trial (R/R, n=7)	GILT 120mg Phase 1b Trial[3] (R/R, n=14)
CR/CRh	29%	0%

FLT3-Wildtype R/R AML

- Tuspetinib also active in FLT3-wildtype AML
- Important data that unlock the potential for tuspetinib to treat additional 70-75% of the AML population ($FLT3^{WT}$) not available to GILT

*Inter-trial comparison

1 Pulte, and Pazdur and colleagues, FDA Approval Summary: Gilteritinib for Relapsed or Refractory Acute Myeloid Leukemia with a FLT3 Mutation. Clinical Cancer Research 2021;27(13): 3515; 2 Gilteritinib US package insert May 2019; 3 Perl and colleagues, Selective Inhibition of FLT3 by Gilteritinib in Relapsed/Refractory Acute Myeloid Leukemia: a Multicenter, First-in-human, Open-label, Phase 1/2 Study. Lancet Oncol. 2017;18(8):1061.

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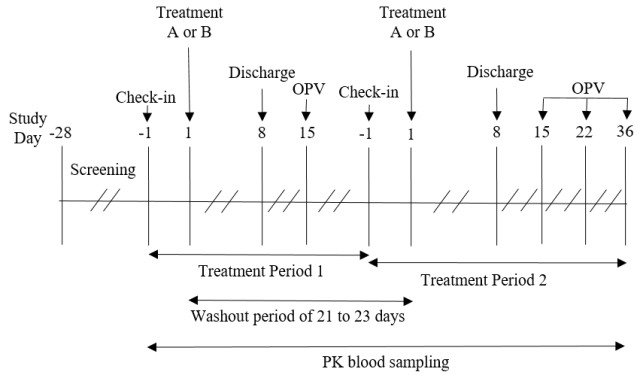
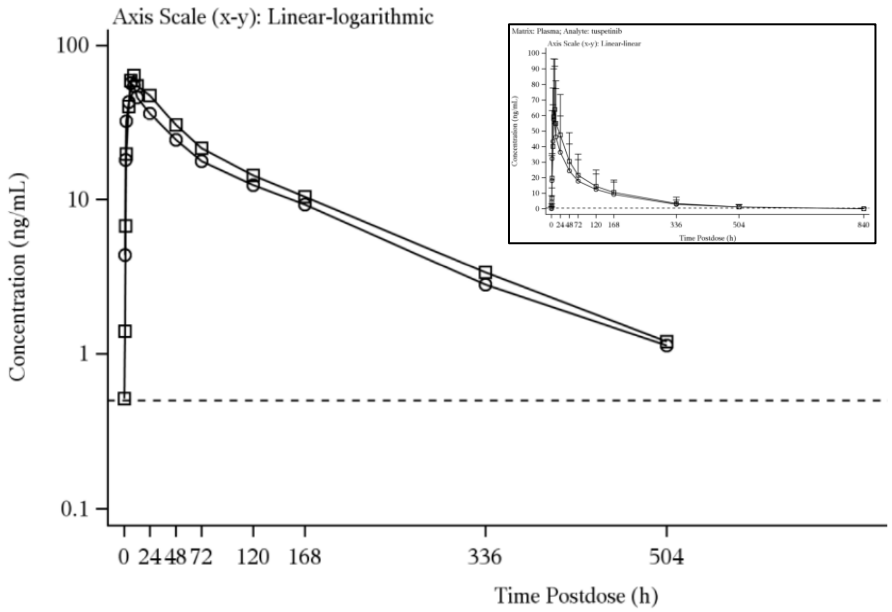
Tuspetinib Fed vs Fasted Food Effect Study in Healthy Human Volunteers

Planning ahead for combination therapies



- **21 subjects** | 10 Fed → Fasted , 11 Fasted → Fed | No SAE reported
- **Cross-over design:** Each subject received one dose of 80mg tuspetinib with food and one dose of 80mg without food, with 21-day washout period between doses
- **Data analysis:** Concentration-time profiles and statistical analysis of PK parameters
- **Ratio of Fed to Fasted:**

$AUC_{0-\infty}$(h*ng/mL)	1.26
C_{max} (ng/ml)	1.19



- **Tuspetinib can be administered with or without food, and foresee no clinically meaningful difference**
- **Important finding for patient convenience:**
  - Venetoclax (VEN) is dosed with food (~4X exposure)
  - Findings enable simultaneous TUS+VEN administration

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APTIVATE Trial

TUS/VEN Expansion Trial in R/R AML

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TUS/VEN Favorable Safety Profile

PK supports safety with no changes over venetoclax known profile

Favorable Safety Profile

- No new or unexpected safety signals observed with the TUS/VEN relative to venetoclax alone
- No drug related AE of QTc prolongation
- No observed differentiation syndrome
- No drug related deaths
- Avoids many of the typical toxicities observed with other FLT3, IDH1/2 and menin inhibitors

Treatment-Emergent AEs (TEAEs), Safety Analysis Set, Parts A, B, C (N=117)

Patients Experiencing TEAEs	TUS (N=91, n[%])	TUS/VEN (N=26, n[%])	
Any	87 (95.6%)	23 (88.5%)	
Most Frequent TEAEs (>15% of patients)			
Pneumonia	30 (33.0%)	3 (11.5%)	
Nausea	18 (19.8%)	5 (19.2%)	
Diarrhea	17 (18.7%)	3 (11.5%)	
Pyrexia	17 (18.7%)	1 (3.8%)	
Anaemia	5 (5.5%)	4 (15.4%)	
Febrile neutropenia	11 (12.1%)	7 (26.9%)	
WBC count decreased	4 (4.4%)	4 (15.4%)	
≥ Grade 3	66 (72.5%)	16 (61.5%)	
SAEs	52 (57.1%)	12 (46.2%)	
Leading to treatment termination	12 (13.2%)	1 (3.8%)*	
Leading to death	18 (19.8%)	0 (0%)	
Patients Experiencing Related TEAEs	**Related to TUS**	**Related to TUS**	**Related to VEN**
Any	29 (31.9%)	11 (42.3%)	11 (42.3%)
Most Frequent Related TEAEs (>10% of patients)			
Diarrhea	10 (11.0%)	2 (7.7%)	1 (3.8%)
Nausea	8 (8.8%)	4 (15.4%)	3(11.5%)
WBC count decreased	2 (2.2%)	3 (11.5%)	3 (11.5%)
Grade ≥ 3	9 (9.9%)	6 (23.1%)	7 (26.9%)
Neutrophil count decreased or Neutropenia	3 (3.3%)	2 (7.7%)	2 (7.7%)
Muscle weakness	2 (2.2%)	0 (0%)	0 (0%)
WBC count decreased or Leukopenia	3 (3.3%)	2 (7.7%)	2 (7.7%)
Nausea	1 (1.1%)	0 (0%)	0 (0%)
Febrile neutropenia	1 (1.1%)	0 (0%)	0 (0%)
Hypertransaminasaemia	1 (1.1%)	0 (0%)	0 (0%)
Platelet count decreased or Thrombocytopenia	1 (1.1%)	1 (3.8%)	1 (3.8%)
Pneumonia	0 (0%)	0 (0%)	1 (3.8%)
Vomiting	0 (0%)	1 (3.8%)	1 (3.8%)
SAEs	1 (1.1%)	0 (0%)	1 (3.8%)
Leading to death	0 (0%)	0 (0%)	0 (0%)
Dose Limiting Toxicity (DLT)	1 (1.1%)	NA	NA

Data as of 01 September 2023: * SAE leading to treatment termination is for both drug; VEN & TUS

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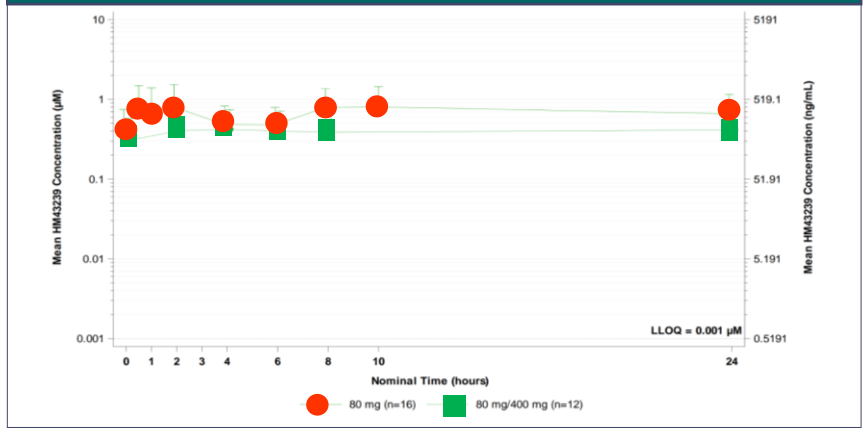
PK Analysis : Mean Plasma Concentration-time Profile at Steady State

TUS and VEN retain their individual single agent PK properties when dosed in the TUS/VEN Doublet

Steady state PK properties of Tuspetinib as a single agent (TUS, orange spheres) are roughly the same as when it is dosed in combination with Venetoclax (TUS/VEN, green squares)

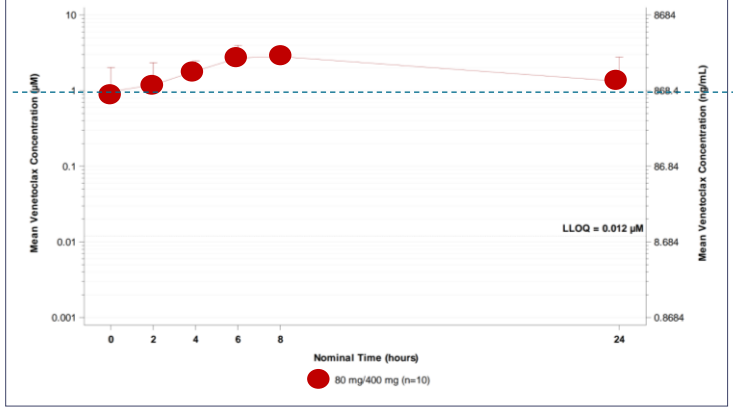
Tuspetinib PK as TUS or TUS/VEN at 80mg Multiple Dose PK Profile



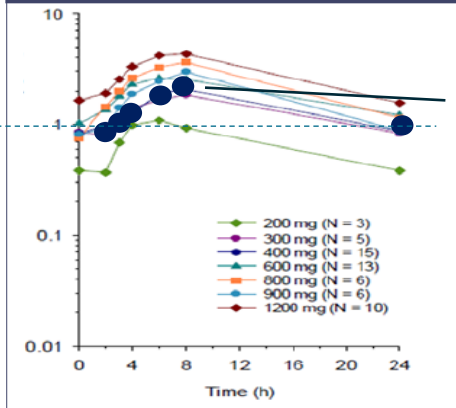
Steady state PK properties of Venetoclax from our APTIVATE study dosed as the TUS/VEN doublet (red spheres) appear roughly the same as the PK properties of Venetoclax reported for single agent VEN dosing in the published FDA Venetoclax NDA 208573 Review Package

(Formal assessment ongoing)

Venetoclax PK in TUS/VEN Multiple Dose PK Profile



Venetoclax Single Agent Multiple Dose PK Profile (NHL Pts)



400mg VEN

FDA Venetoclax NDA 208573 Review Package

Response Rates (ORR) in Efficacy Evaluable Patients Across Subgroups: Tuspetinib and TUS 80mg / VEN 400mg

Overall Response Rate (ORR, %)		
Subgroups	**TUS % ORR (n=63)**	**TUS /VEN % ORR (n=31)**
Overall	24% (15/63)	**48% (15/31)**
VEN Naïve	**34% (10/29)**	67% (4/6)
Prior VEN	15% (5/34)	**44% (11/25)**
FLT3-Mutated	33% (8/24)	**60% (6/10)**
VEN Naïve	**55% (6/11)**	100% (1/1)
Prior VEN	15% (2/13)	**56% (5/9)**
Prior FLT3i	21% (3/14)	50% (4/8)
FLT3-Unmutated	18% (7/39)	**43% (9/21)**
VEN Naïve	**22% (4/18)**	60% (3/5)
Prior VEN	14% (3/21)	**38% (6/16)**

Data as of 23 October 2023

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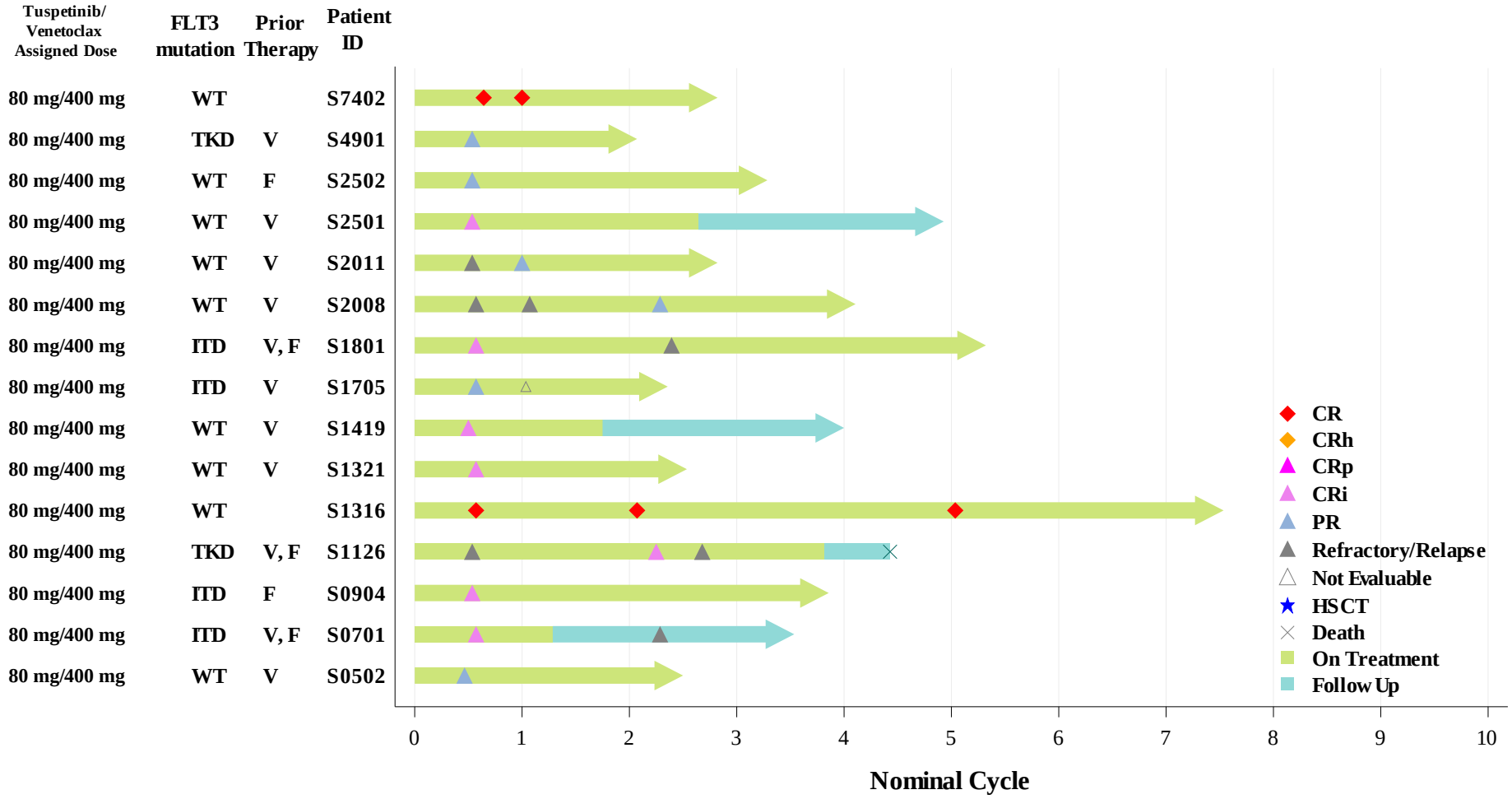
Swimmer Plot of Responders Receiving TUS/VEN

Responses Achieved in Heavily Pretreated R/R AML Patients as of Oct 23, 2023



Abbreviation: CR, complete response; CRh, complete response with partial hematologic recovery; CRi, complete response with incomplete hematologic recovery; CRp, complete response with incomplete platelet recovery; HSCT, hematopoietic stem cell transplantation; PR, partial remission.
Note: The bone marrow aspiration/biopsy date was used as response date. Actual time relative to the first dose date was used to plot events. The right arrow at the end of horizontal bar indicates patients are still ongoing, whereas without the right arrow indicates patients discontinued from study. The nominal cycle is calculated in 28 days increment in study days.
Note: For the prior therapy, 'V' indicates prior venetoclax usage and 'F' indicates prior FLT3 inhibitor usage.

Data as of 23 October 2023.

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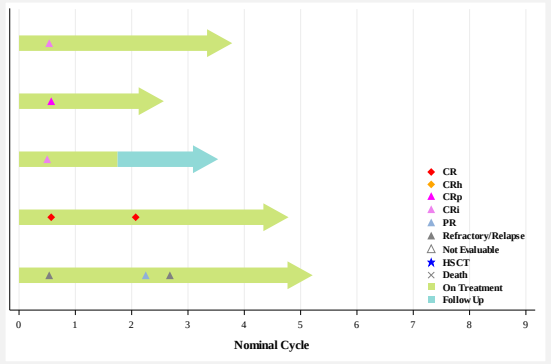
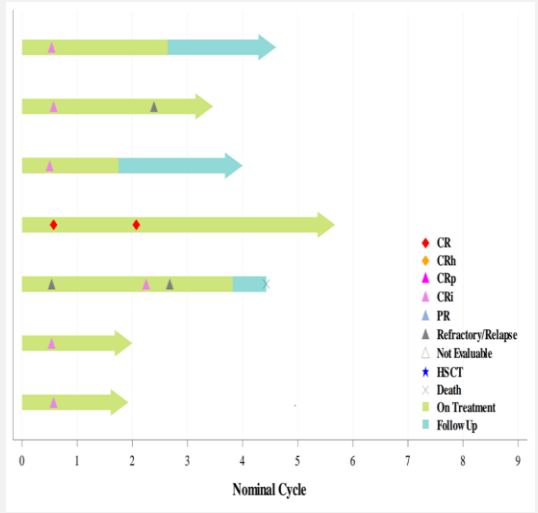
Swimmer Plot Evolution Over Time of Responders Receiving TUS/VEN

Responses Achieved in Heavily Pretreated R/R AML Patients

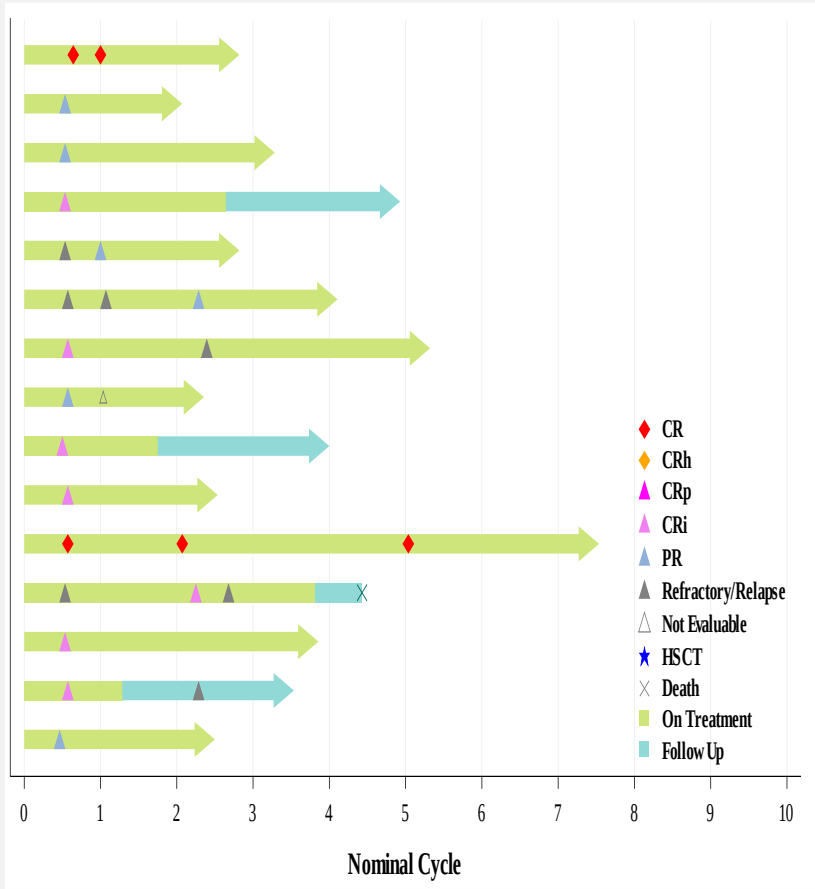
Aug 01, 2023



Sep 01, 2023



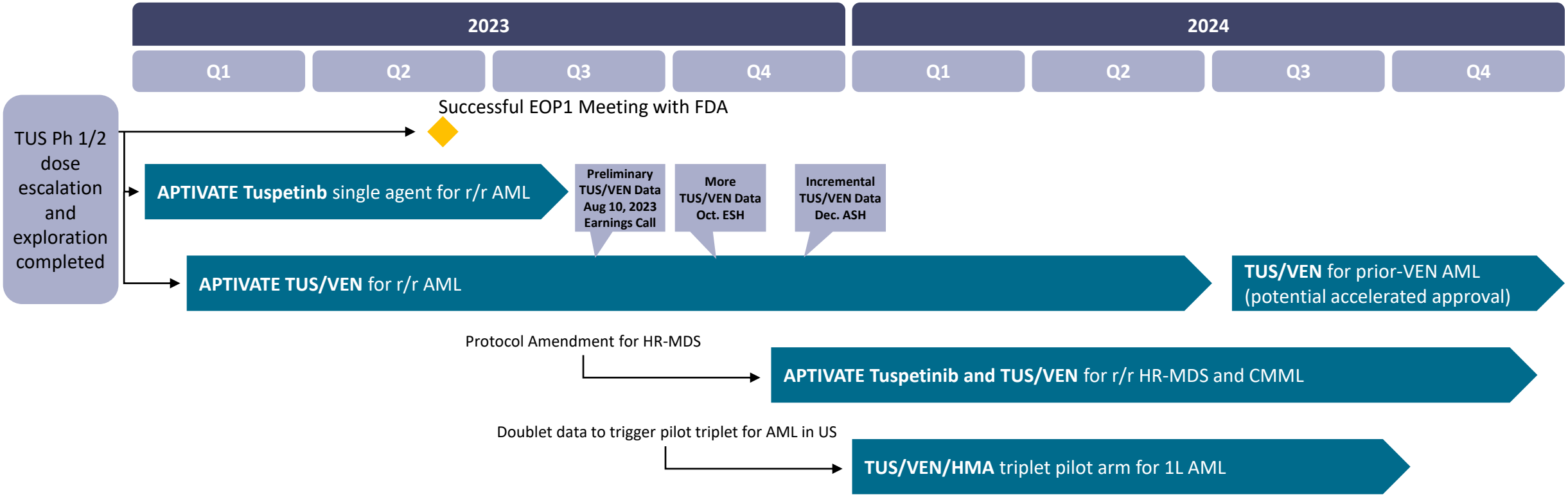
Oct 23, 2023



Data as of 23 October 2023.

Tuspetinib Development Plan

- **2L AML (failed 1L VEN/HMA and no approved targeted agents available) | 3L AML (failed 1L VEN/HMA and failed approved targeted agents in 2L)**
- **High enthusiasm from investigators, as competing off-label regimens likely have greater toxicity and more narrow populations than a TUS/VEN regimen**



Q&A Session

Dr. Naval Daver

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Thank You

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