EX-99.2 4 lsacu-ex992_8.htm EX-99.2

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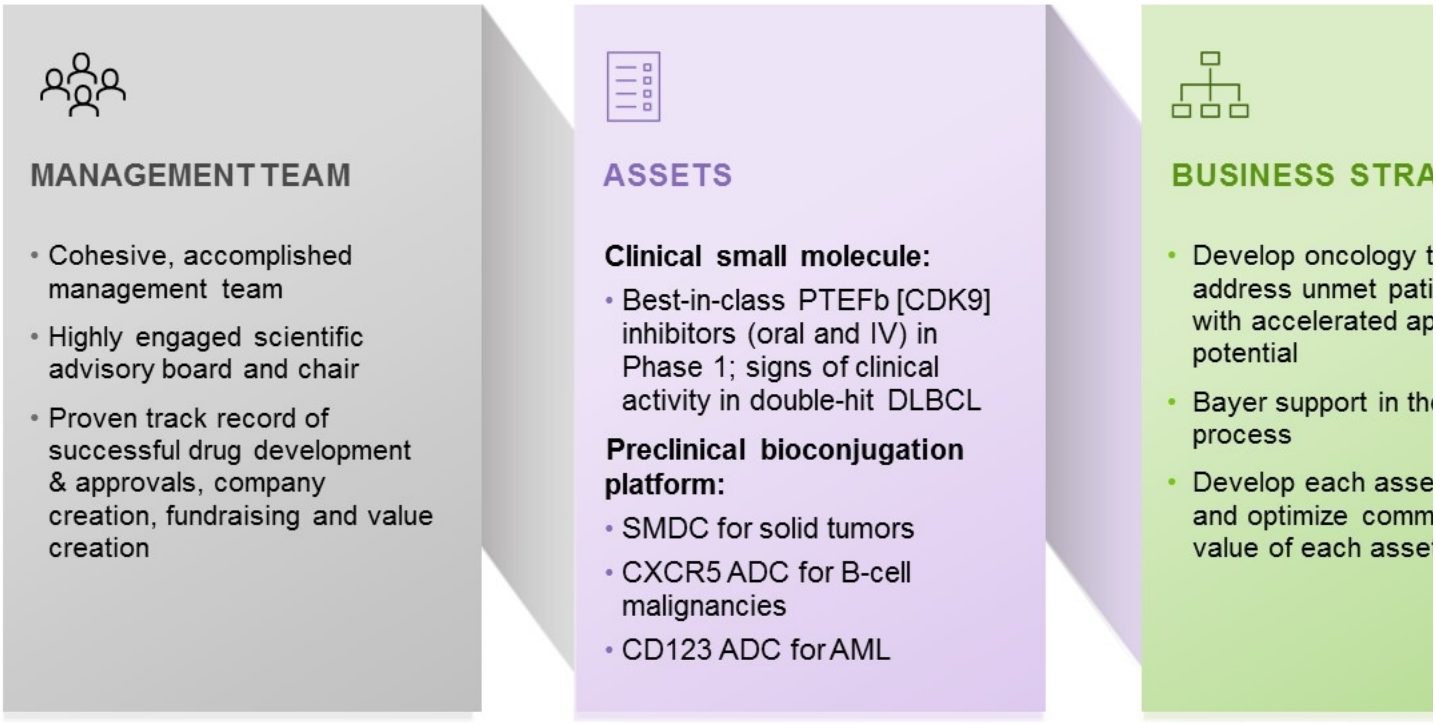
OUR VISION
We aspire to conquer cancer by addressing
needs of our patients with paradigm-shif
Vincera
PHARMA

Vincera Pharma Highlights



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Vincera Founders

AHMED HAMDY, MD
CEO

- Cofounder of Acerta Pharma
- Former CMO of Pharmacyclics, leading developer of Imbruvica®
- Proven track record for assembling experienced teams that deliver from INDs to NDAs

RAQUEL IZUMI, PhD
COO

- Cofounder of Acerta Pharma
- Former Sr Director of Clinical Development of Pharmacyclics
- Extensive drug development experience from preclinical stages through NDA submission

TOM THOMAS, JD

- Outside general counsel
- Extensive experience in venture, finance, M&A & IPO
- Partner, Pillsbury Winthrop

STUA
VP Bus

- Biote devel
- Lead Quad in par M&A
- Led c R&D Cor T and U

5

Management Team Experience Proven Track F

CALQUENCE (acalabrutinib) 100 mg capsules

$7B acquisition by AstraZeneca in 2016 for acalabr

Management Team's Contribution

- Founded Acerta with acala
- Accelerated approval in 4 y

2013	2014	2016	
Acerta founded	1st patient dosed	AZ acquisition	Acce

imbruvica (ibrutinib) 140mg capsules

$975M partnership with Janssen in 2011 [$150 upfr

$21B acquisition of Pharmacyclics by AbbVie in 20

Management Team's Contribution

- Developed ibrutinib from p
- All three Phase 2 studies
  Accelerated Approvals

Magrolimab

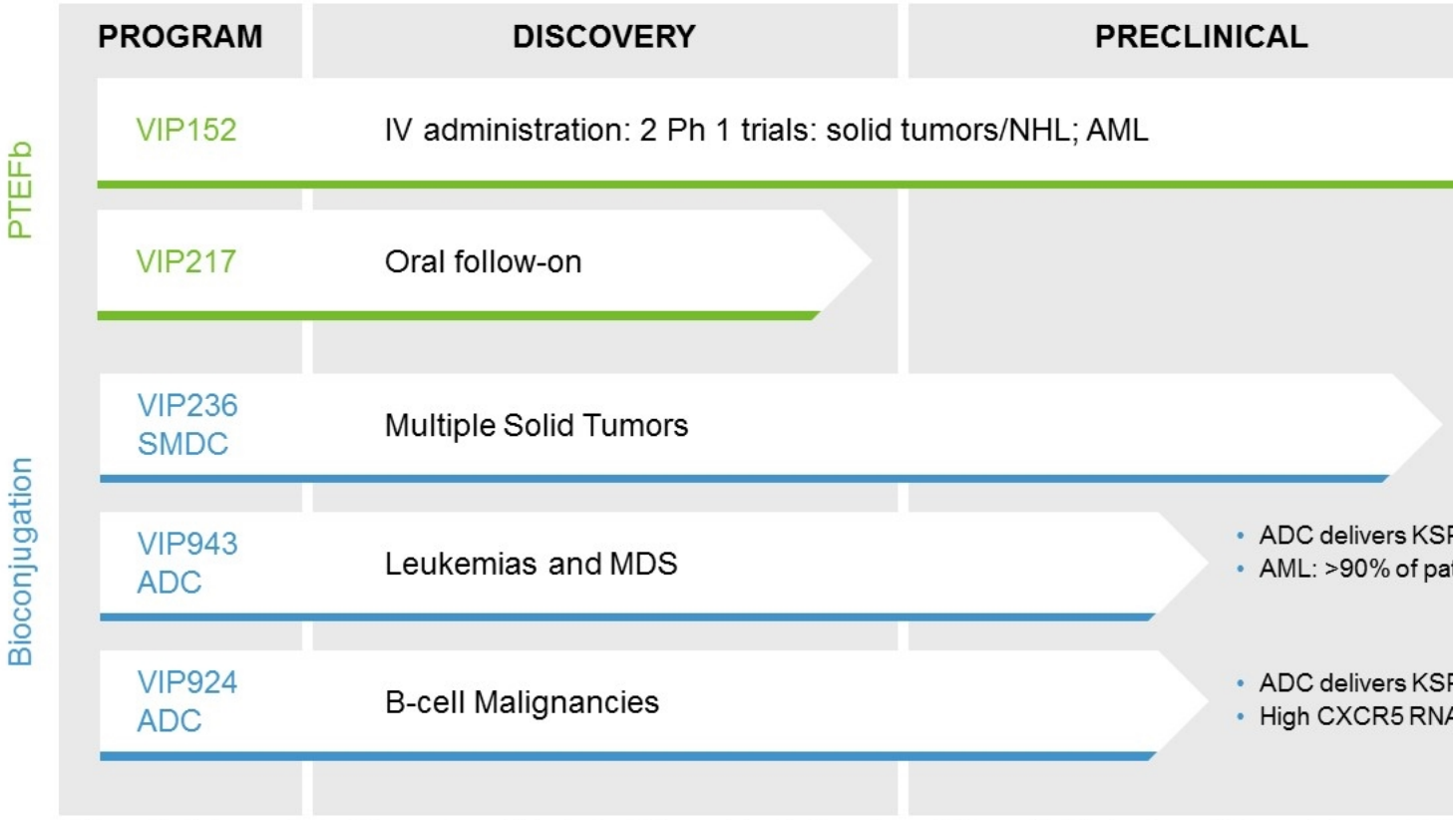
$4.9B acquisition of Forty Seven Inc by Gilead in 20

Management Team's Contribution

- Developed magrolimab Cl
- Complete and comprehen

6

Vincera Pipeline*



ADC = antibody-drug conjugate; AML = acute myeloid leukemia; MDS = myelodysplastic syndromes; NHL = nonHodgkin lymphoma; PoC = proof of concept; PTE molecule drug conjugate

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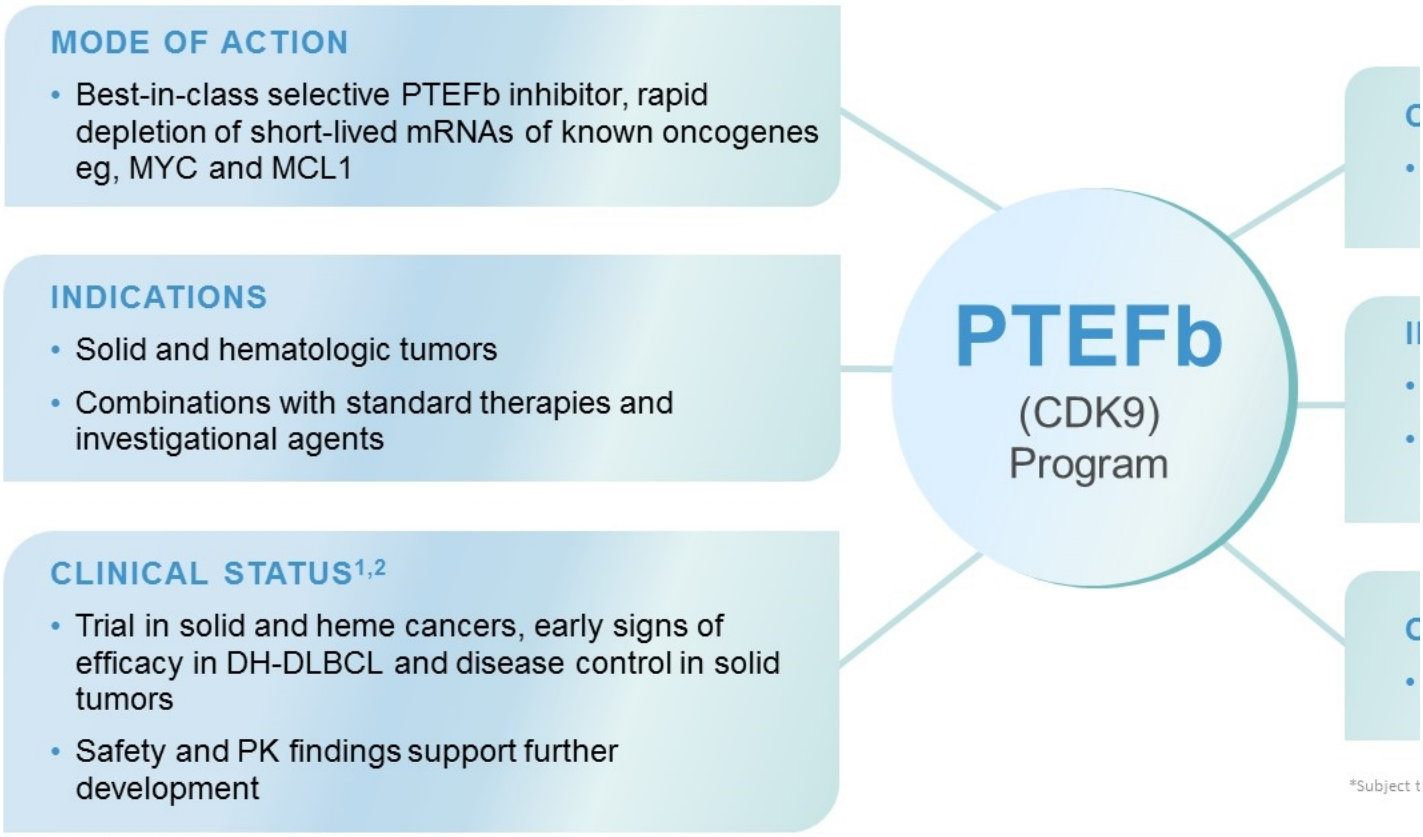
PTEFb PROGRAM

VIP152 IV (Phase 1)
VIP217 Oral (Discovery)

Vincera PHARMA

Summary of PTEFb (CDK9) Portfolio – Clinical & D



1. Blood (2018) 132 (Supplement 1): 4055.
2. JCO (2018) 36 (15): 2507.

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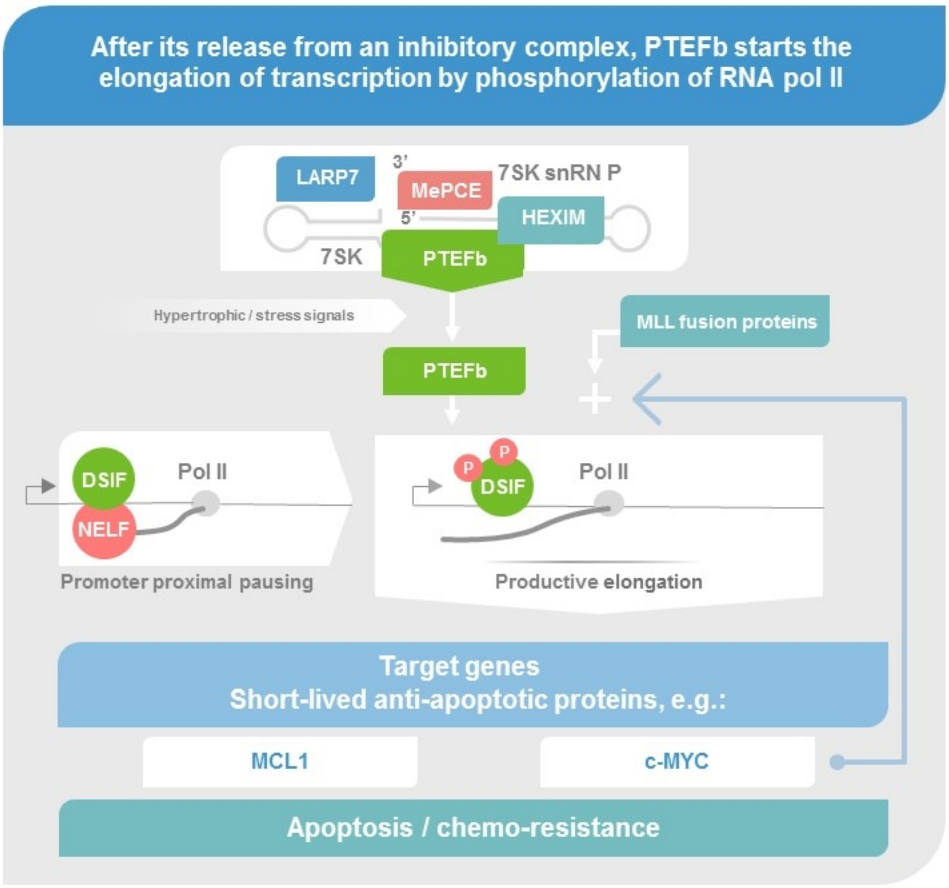
PTEFb: A Novel Target for Oncology



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PTEFb [CDK9]

- Positive transcript transcription throu
- A key target to ad
- Inhibition causes of known oncoge

Role of MCL1

- Drives tumor growth resistance to apoptos various heme and so entities
- Potential PD biomark Induction of apoptosi
- Inhibitors currently in

CDK9 is a Clinically Validated Target

	VIP152 Vincera	Dinaciclib Merck	Alvocidib (Flavopiri Tolero
Patients	Double hit DLBCL [MYC driven]	r/r CLL [MCL1 driven]	r/r CLL [MCL1 driven]
Treatment	VIP152 monotherapy	Dinaciclib monotherapy vs ofatumumab	Alvocidib monotherapy
Trial	Phase 1/1b dose escalation and dose expansion	Randomized Phase 3 (stopped early)	Two Phase 2's
Response	ORR: 29% (2/7), both PET-negative CRs	Dinaciclib ORR: 40% (8/20) Ofatumumab ORR: 8% (2/24)	Study 1 ORR: 54% (34/64) Study 2 ORR: 25% (41/164)
Durability	2.3 to 3.6 years	Dinaciclib mPFS of 13.7 mo Ofatumumab mPFS of 5.9 mo	Study 1: mPFS of 8.6 mo Study 2: mPFS of 7.6 mo

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VIP152 is the Most Selective CDK9 Inhibitor in

Programs	**VIP152** Vincera	**AZD4573** AZ	**Dinaciclib** Merck	**CYC065** Cyclacel
Selectivity	CDK9	CDK1/9	CDK1/2/5/9	CDK2/3/5/9
Development Stage	P1	P1	P3 mono P2 combo	P1
Type of tumor	Hematologic & Solid tumors	Hematologic	CLL stopped Solids combo with IO	AML, CLL, ALL Solid tumors
IC_{50} on CDK9	3 nM	14 nM	1-4 nM	26 nM
Half life	4 h	<3 h	3 h	~1 h
Route of admin	IV	IV	IV	Oral & IV

12

VIP152 Highly Selective and Potent CDK9 Inhi

Assay	VIP152
IC_{50} CDK9 [nM] low ATP	3
IC_{50} CDK9 [nM] high ATP	4

High potency is independent of [ATP]

Kinase	**Kd** [nM] @ DiscoverRx	**IC_{50}** [nM @ Millipo
CDK9	1.3	13**
CDK1	n.a.	192
CDK2	710	158
CDK3	540	318
CDK4-cyclinD1	120	n.d.
CDK4-cyclinD3	68	n.d.
CDK5	4900	286
CDK6	n.a.	1048
CDK7	24*	>10000
CDK8	25000	n.d.
CDK11	not active	n.d.

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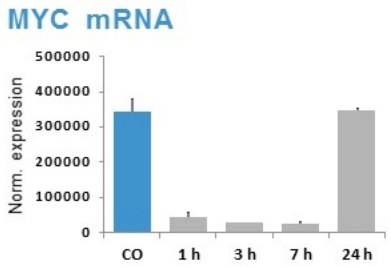
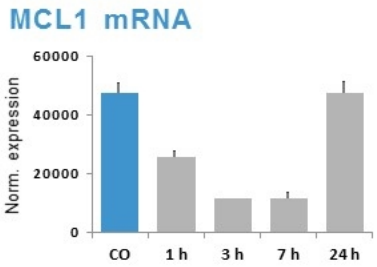
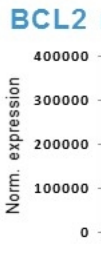
* No cyclin co-expression
** Probably lower limit of quantification

MoA – VIP152 Inhibits the Transcription of MY

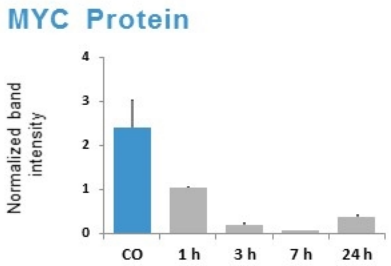
Reduction of MYC & MCL1 mRNA levels



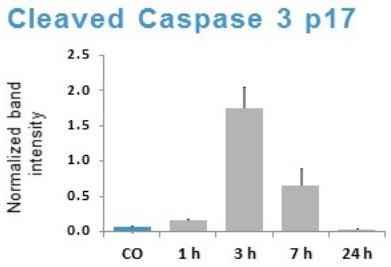


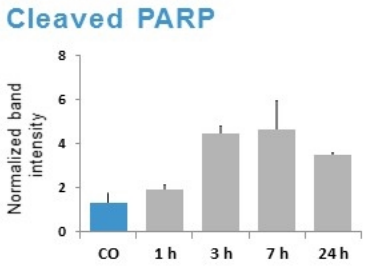


Durable reduction of MYC protein levels



Induction of apoptosis





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VIP152 (IV) - Clinical Trial Design & Status

Two Phase 1 clinical trials

FIRST-IN-HUMAN STUDY (17496; NCT02635672)

Dose escalation (N=31) → MTD → Expansion

- Once weekly IV; 30-min infusion
- 21-day cycles
- No biomarker selection patient population (ie, all-comer advanced cancer)

- At recomm
- Double-hi

AML study (18117; NCT02745743)

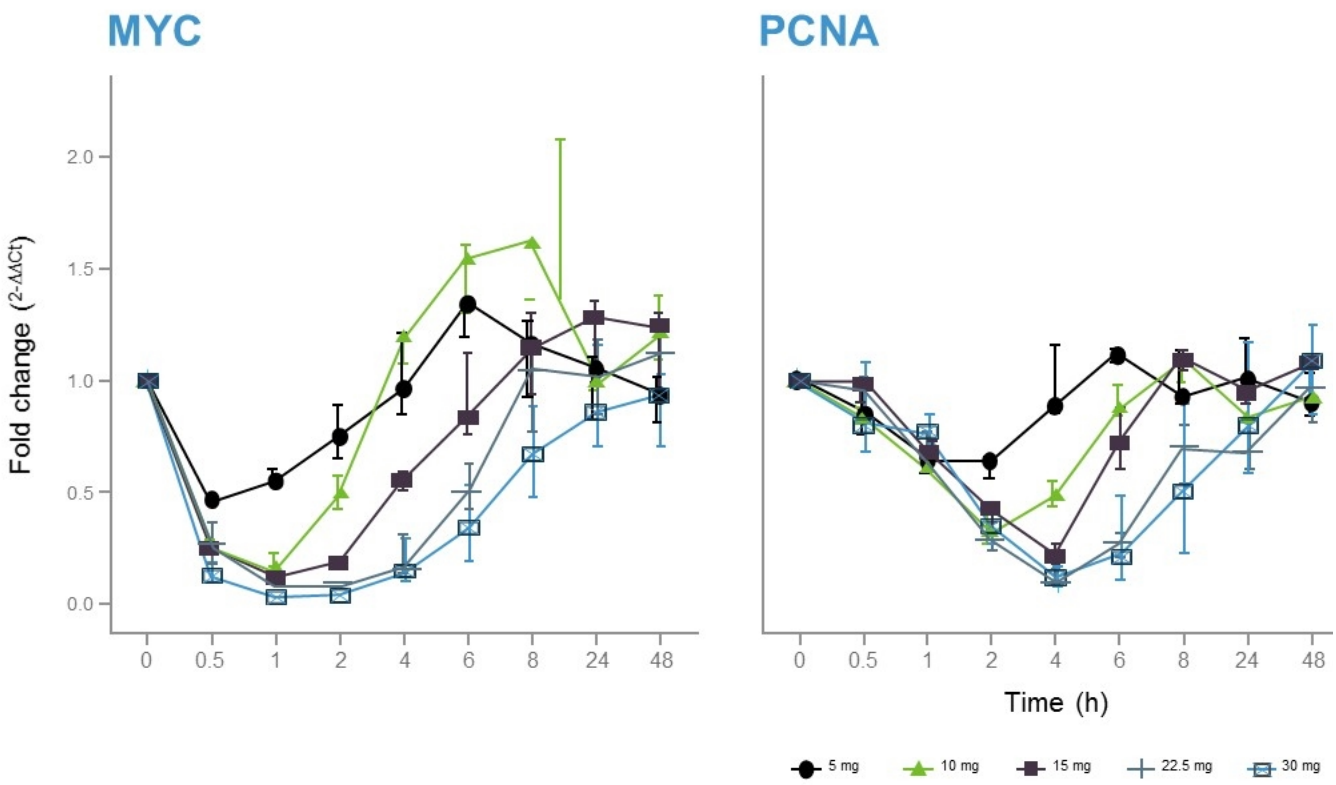
Dose escalation (N=21) — Completed

- Once weekly IV; 30-min infusion
- 21-day cycles
- No biomarker selection in patients with AML

15

VIP152 Pharmacodynamic Activity in Patient S

PD biomarker assessment: mRNA expression in whole blood, cycle 1, d
Inhibition of MYC, MCL1 and cell proliferation (PCNA)



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Manageable Safety Profile

Neutropenia manageable; Long-term CRs highlight tolerability profile

Adverse Events (>15%)	Grade 1	Grade 2	Grade 3	Grade
Nausea	17 (55)	9 (29)	0 (0)	0 (
Vomiting	15 (48)	5 (16)	0 (0)	0 (
Anemia	6 (19)	5 (16)	3 (10)	0 (
Neutropenia	0 (0)	3 (10)	**5 (16)**	**4 (1**
Fatigue	2 (6)	8 (26)	0 (0)	0 (
Diarrhea	8 (26)	1 (3)	0 (0)	0 (
Constipation	4 (13)	2 (6)	0 (0)	0 (
Thrombocytopenia	4 (13)	2 (6)	0 (0)	0 (
Abdominal pain	0 (0)	2 (6)	3 (10)	0 (
Anxiety	4 (13)	1 (3)	0 (0)	0 (
Fever	4 (13)	0 (0)	1 (3)	0 (

17

Early Signs of Monotherapy Efficacy in Phase

Dose escalation trial (solid tumors and NHL)	• 31 patients, ≥3 prior systemic chemotherapies in 97% of patients • No biomarker selection
Early clinical signs of efficacy in DH-DLBCL	• 1 patient with DH-DLBCL in dose escalation achieved a PET-negative CR* • DH-DLBCL patients have MYC rearrangements and either BCL2 or BCL6 rearrangements
Expansion cohort ongoing in DH-DLBCL	• 1/6 patients in the expansion cohort achieved a PET-negative CR*

Disease control observed in heavily pretreated solid tumor patients (1 pancreatic cancer and 1 salivary gland cancer pt)

Pat

*Per investiga

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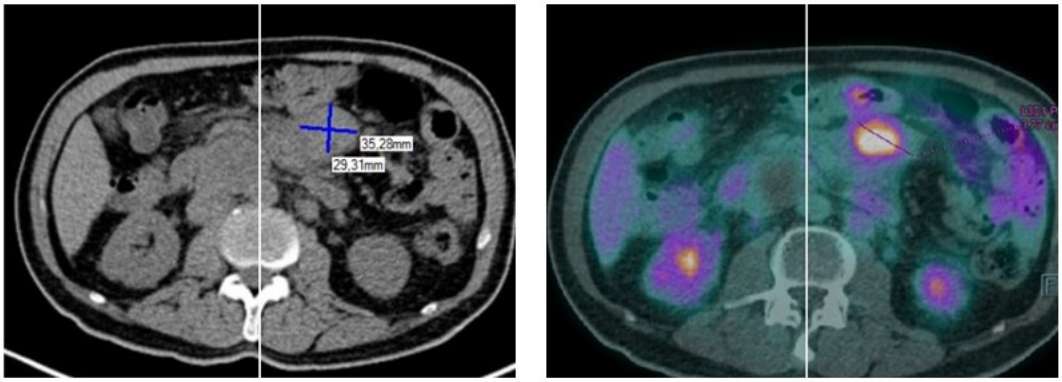
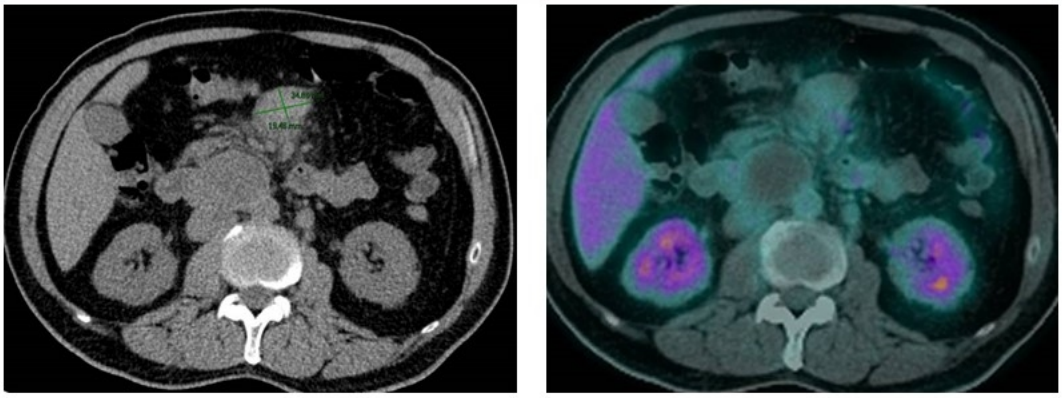
Complete Metabolic Response Observed in Pa with Treatment-refractory Double-hit DLBCL

Baseline PET/CT



PET/CT cycle 10



Treatment

- GCB m
- *BCL2* a
- BCL2, I MYC IH
- Founda panel s mutate

Prior Ther

1. R-EPOC
2. R-DHAP
3. Palliativ best res

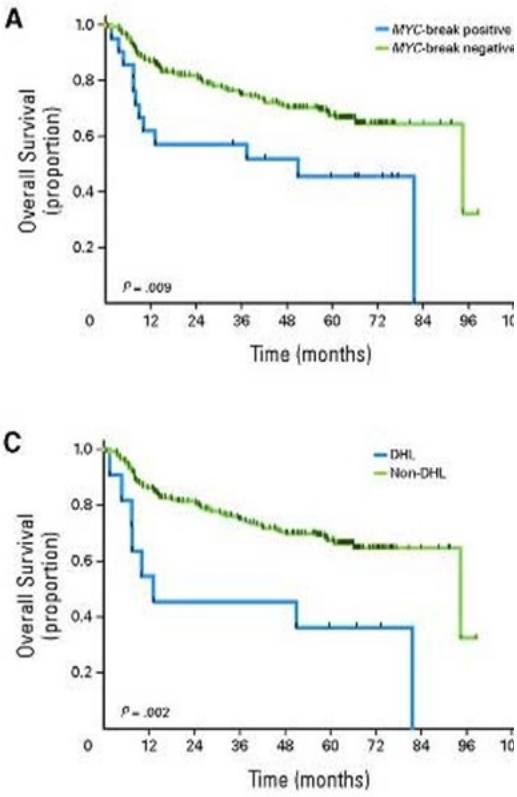
IHC, immunohistochemistry; PET / CT, positron emission tomography/computed tomography; TTP, time to progression

Poor Prognosis in Double-hit Lymphoma

Double-hit (DH)-DLBCL

- Activation of MYC and BCL2/BCL6 genes
  - Rearrangements
  - Overexpression
- 25% of r/r-DLBCL[1]
  - Median PFS 11 months[2]
  - Median OS 22 months[2]

R-CHOP in unselected DLBCL pts: >80% reach a PFS of 6-year[3]



Overall survival (OS) and progression-free survival (PFS) after tr
large B-cell lymphoma (DLBCL) harboring gene breaks in MYC,
breaks versus 168 patients with DLBCL who were negative for M
Kaplan-Meier curves of (B) OS in 47 patients with DLBCL who w
significant association with OS (P = .159). Kaplan-Meier curves o
DLBCL show that combined breaks in MYC and BCL2 are signifi
Published in: Green et al JCO 2012;30: 3460-67 Copyright © 20

1. Tumati et al Int J Radiation Oncol Biol Phys 2018;100:1126-32
2. Petrich et al Blood 2014;124:2354-61
3. Pfreundschuh et al Lancet Oncol 2011;12:1013-22

Potential Indications

MYC and MCL1 overexpression is a hallmark of multiple aggressive, res
representing a wide-ranging unmet medical need

B-cell Lymphoma MYC dependent (DH-DLBCL, Transformed FL, RS, blastoid MCL)	• Broad sensitivity to VIP152 ac • Opportunity for significantly im or BCL-2 (venetoclax)
Leukemias MCL1 Dependent (CLL, AML, MDS)	• Initial indication double refract with BTK/BCL2 inhibition • Potential combinations (eg, BC
Myeloma highly expresses and is dependent on MCL1 & CDK9 for survival (MM)	• Opportunity for significantly im
Solid Tumors (ovarian, TNBC, CRPC incl NEPC)	• MYC and MCL1 driven solid tu • Opportunity for addressing dru

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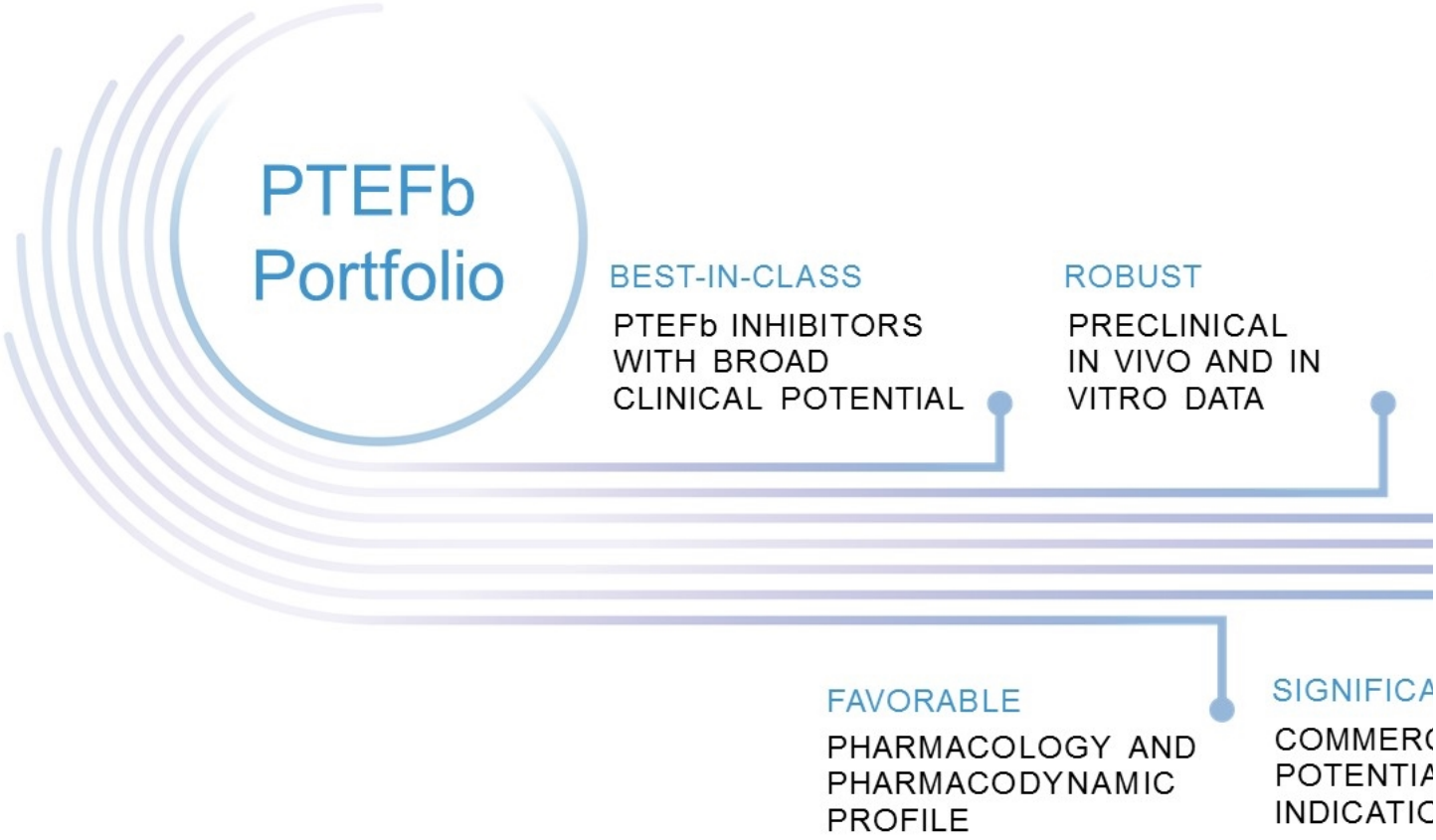
VIP152: Clinical Development Plan

Multiple Accelerated Approval Opportunities

Phase	Design	Population
1b	Myc driven heme tumors	DH-DLBCL, Transformed MCL
1b	Myc driven solid tumors	Ovarian, TNBC, CRPC [ir
1b	Double refractory/relapse (BTK & VEN)	R/R CLL

Summary: PTEFb Portfolio*



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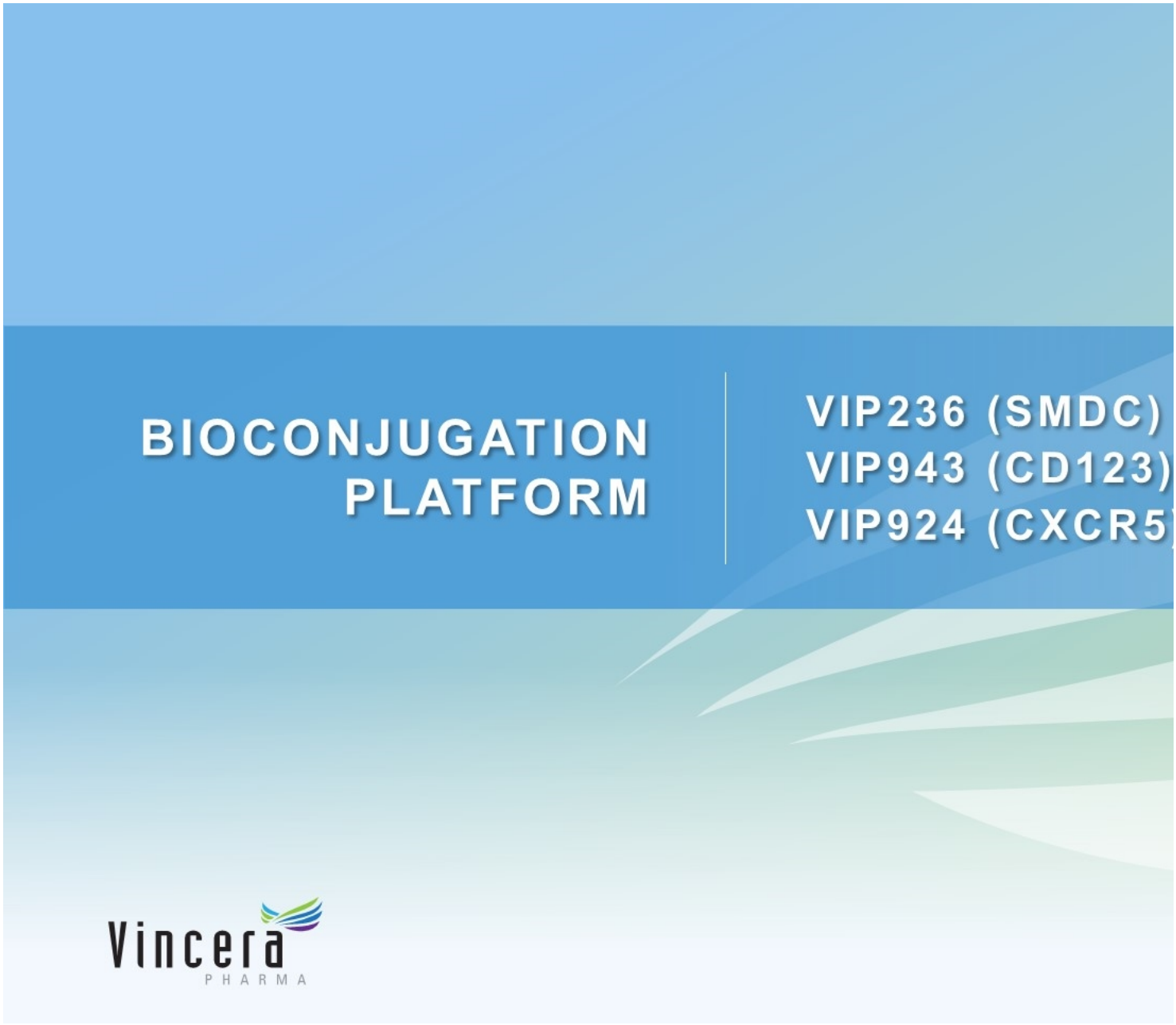
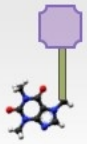

BIOCONJUGATION
PLATFORM
VIP236 (SMDC)
VIP943 (CD123)
VIP924 (CXCR5)
Vincera
PHARMA

Vincera's Proprietary Bioconjugate Platforms – Sh

Turning 10 years of Bayer discovery know-how into break-through tre

SMALL MOLECULE DRUG CONJUGATE

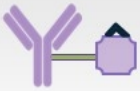
SMDC



- Conjugate design for highly aggressive adva
- Targets cell surface cancer markers
- Drug release in tumor stroma
- Tailored warhead design

NEXT GEN ADC PLATFORM

ADC



- 2 candidates for heme malignancies
- Proprietary linker-payload technology
- Preferential activation in tumors increase the
- Extension to solid tumors for best-in-class tr modalities

DISCOVERY PROGRAMS

- New antibodies with KSPi linker-payload tec
- Multiple combinations of modular platform c

*Subject to signing and effectiveness of Bayer License Agreement

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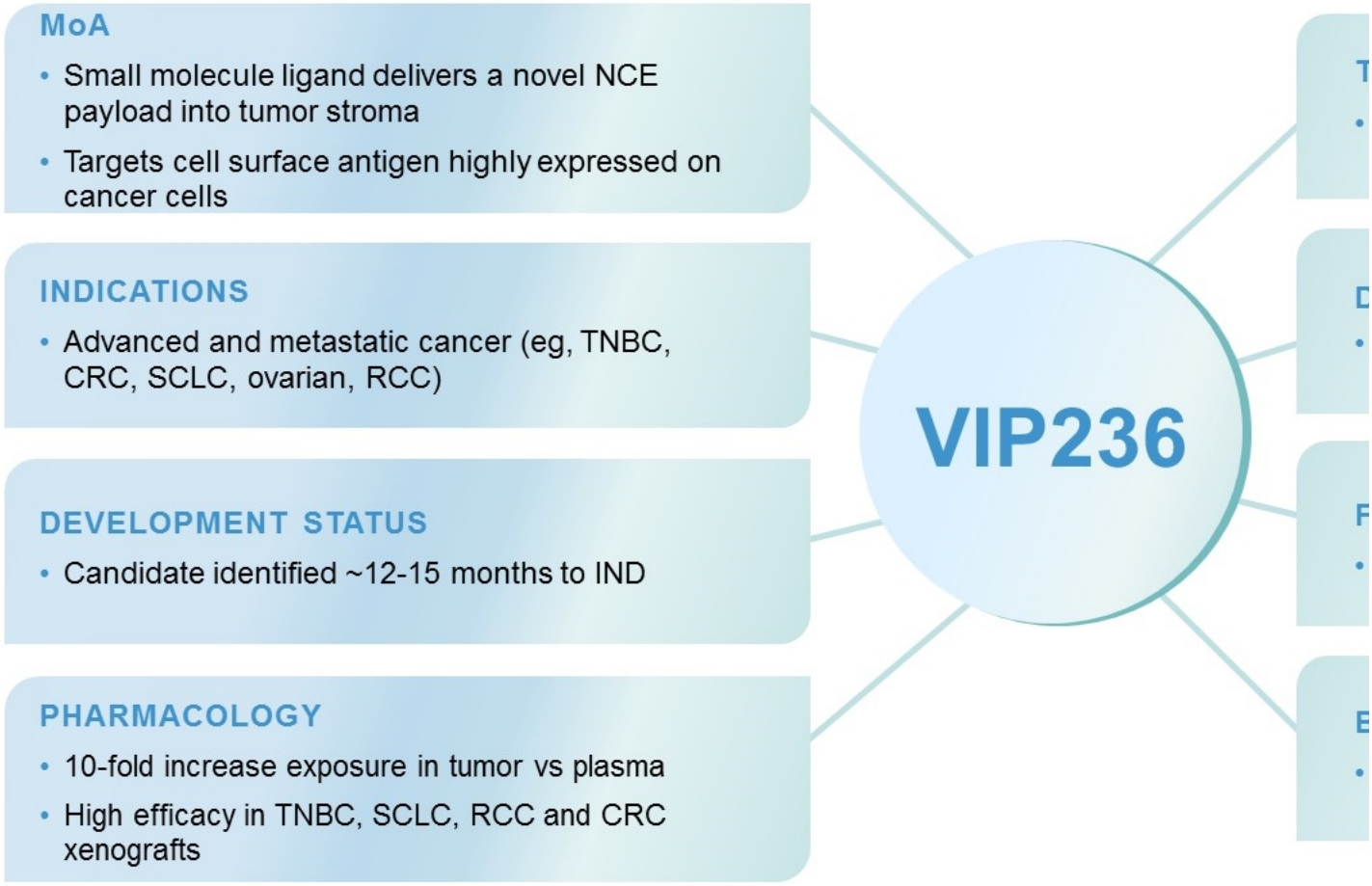
SMALL MOLECULE DRUG CONJUGATE (SMDC)

VIP236

Vincera PHARMA

Key Features of VIP236, Cancer Cell Surface T



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SMDC Dual Targeting Rationale

Tumor Stroma Activated Conjugate

Targeting moiety

- Ligand binds cancer selective markers
- Stable non-peptidic ligand
- Proven tumor homing

Linker enables tumor specific release of active payload

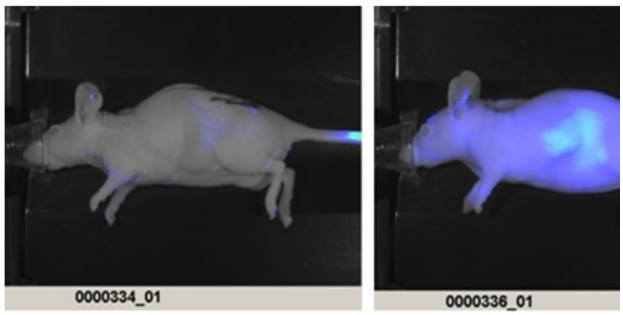
- Extracellular cleavage in tumor stroma
- Non-cleavable isomer is inactive

Differentiated profile

- Target: Cancer cell-surface marker
- Linker: Cleaved by protease in tumor stroma
- Payload: NCE with an improved profile
- In vivo proof of concept in multiple solid tumor models (colon, breast, SCLC, RC)
- Well tolerated after repeated dosing

Imaging shows efficient targeting of

Unconjugated dye IR800 Neg ctrl ligand-



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NEXT GEN ADC PLATFORM

VIP943
VIP924

Vincera PHARMA

Vincera's Next Generation ADC Technology S

Problems of ADCs	NextGen Design Features [1]	Impact/E
High-potency payloads have narrow therapeutic index	**KSP inhibitor** is a novel payload class in ADCs	**Low/no to** **High pote** **Flexibility**
Off-target toxicities due to leaking and unspecific cleavage of highly toxic, cell-permeable toxophores	**Stable linker specifically cleaved by legumain**, a tumor associated protease **Impermeable payload – Cell Trapper™** attached to KSPi to reduce membrane permeability	**Unique cl** **Second le** **Safety:** No **Efficacy:** H
Highly lipophilic payloads cause aggregation and unspecific pinocytosis of ADCs	**KSPi payload with Cell Trapper™** is hydrophilic and does not cause aggregation	**Safety:** No **Efficacy:** A **CMC:** Less

*Subject to

1. https://dx.doi.org/10.1021/asc.bioconjchem.0c00357

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Key Features of VIP943, an IL3RA-KSPi ADC

MoA

- ADC delivers highly potent KSP inhibitor to IL3RA+ (CD123+) tumors
- AML: >90% of patients express CD123 on blasts and leukemic stem cells
- High levels associated with aggressive disease and poor prognosis (p53 mutated, secondary AML & high risk MDS)

INDICATIONS

- CML/AML/MDS/T-ALL (blastic plasmacytoid dendritic cell neoplasm, B-ALL, hairy cell leukemia, cHL)

DEVELOPMENT STATUS

- Preclinical; IND enabling studies to be initiated. IND in ~18-36 months

PHARMACOLOGY[1]

- High efficacy in AML and in Hodgkin lymphoma xenograft models
- Dose-proportional, typical IgG PK profile

CURRENT STATUS

VIP943

TO

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DR

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- C

1. Cancer

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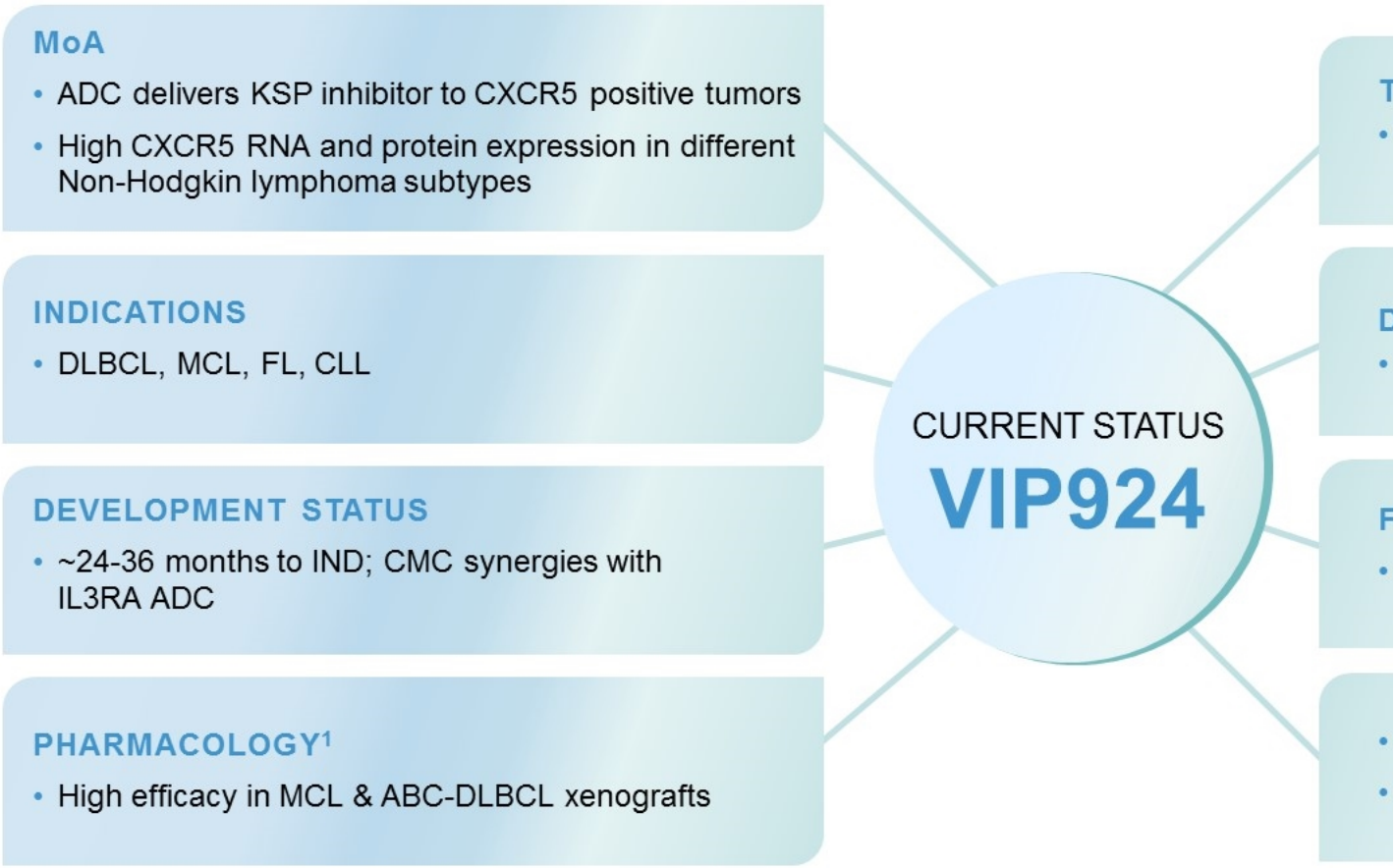
Key Features of VIP924, a CXCR5-KSPi ADC



1. Cancer Res (2019) 79 (13 suppl): 4825

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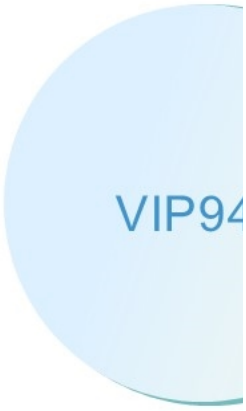
Expected Upcoming Milestones

- Q1 2021 – Begin Phase 1b study for Myc driven hematologic malignancies
- Q1 2021 – Begin Phase 1b study for Myc driven solid tumors
- Q1 2021 – Begin Phase 1b study for R/R D CLL
- Late 2021 – Initial clinical data from Phase 1b studies

- H1 2022 – Begin FIH study for solid tumors



- H2 202
  2024 –
  study fo
  hemato
  maligna

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Vincera Summary

A strong management team with a proven track record of successes

- Publicly traded company (PCYC): Co-development w JNJ, $1B; Sale to Abbvie, $21B
- Private company (Acerta) founded company on preclinical asset and took it to approval and sale of company: M&A $7B, AZN
- >20 years of experience in CDK9 space
- >10 years of ADC development experience from discovery to clinical development

Innovative, next-generation bioconjugation platform

- Modular technology designed to address specific challenges of current
- KSPi-ADC safety profile has been de-risked in cyno tox studies with pc & best-in-class opportunity
- SMDC is ready for IND after GLP tox

*Subject to signing and effectiveness of Bayer License Agreement

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