BiVictriX THERAPEUTICS

Engineered to target the cancer, not the patient

LEVERAGING FRONTLINE CLINICAL EXPERIENCE FOR THE DEVELOPMENT OF NEXT GENERATION CANCER THERAPIES

Immuno-Oncology Summit Europe
May 2022

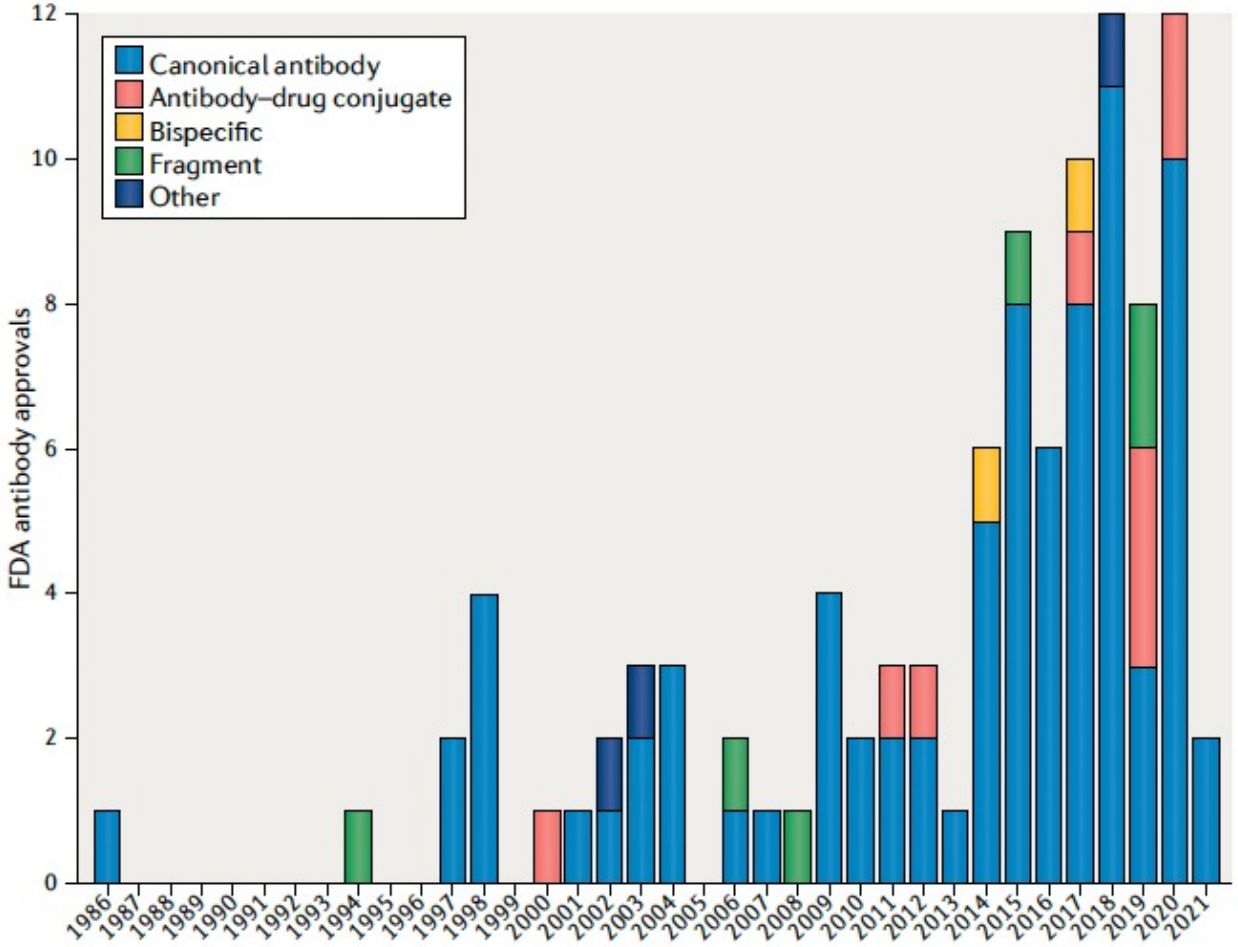
INTRODUCING BIVICTRIX

- UK-based drug development company **aimed at addressing one of the longest standing issues** limiting our ability to successfully combat cancer - the lack of true cancer selectivity of anti-cancer drugs
- Derived from frontline clinical experience, BiVictriX has developed the **Bi-Cygni® platform** to enable the development of a broad pipeline of **first-in-class therapeutics** which exhibit **superior cancer selectivity**, facilitating higher dosing - and therefore greater efficacy - even in the most vulnerable patient cohorts
- **Bi-Cygni® approach applied to one of the fastest growing markets** in the sector to develop the next-generation of highly cancer-selective Antibody Drug Conjugates

- **AIM listed public company** since August 2021 with HQ in Alderley Park, Cheshire
- Growing therapeutic pipeline of ***'twin antigen fingerprint'*** projects all in oncology – data of a PoC in AML being presented today.

FDA APPROVES 100TH MONOCLONAL ANTIBODY

- Significant expertise & momentum gained in developing therapeutic Abs
- ca.½ of approved Abs entered marked in last 6 years
- mAbs still dominate, but other formats are following suit (potentially with expedited approval curve)
- Approval rate/year continues to pace despite more stringent FDA CBER approval hurdles



https://www.nature.com/articles/d41573-021-00079-7

UNMET NEED

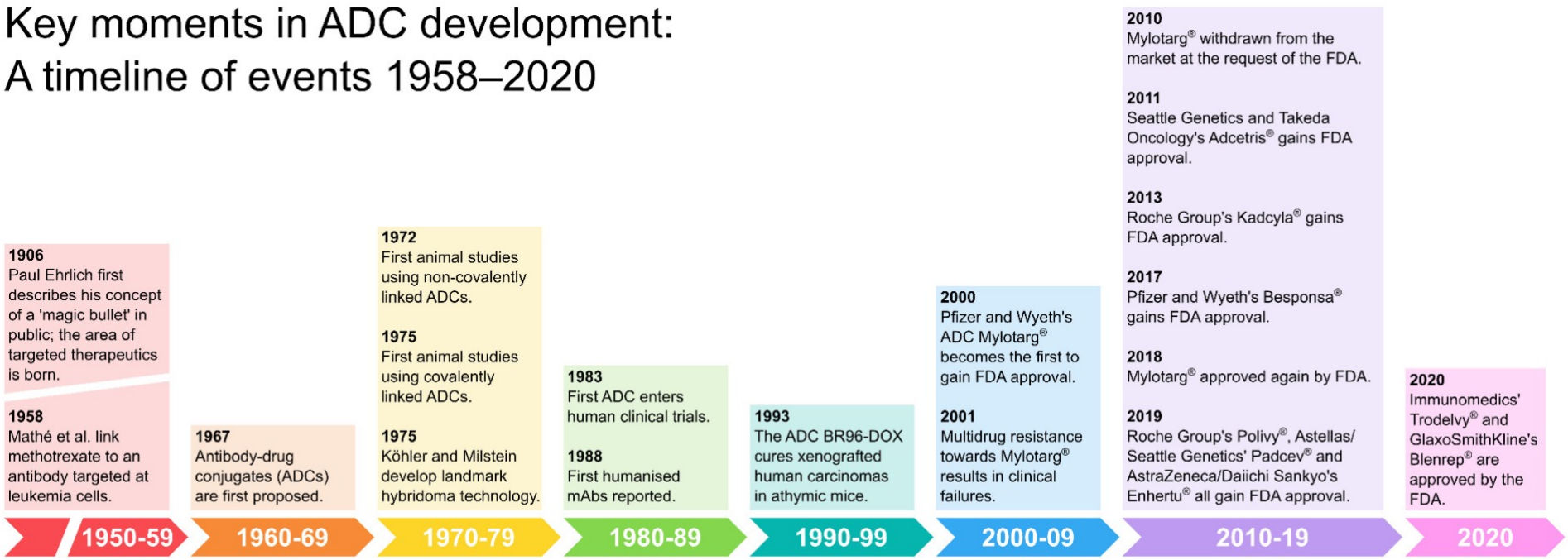
Antibody-based approaches have the potential to save millions of lives, but currently can only be utilised to their full potential in specific cancer types

Limitations of existing antibody-based, anti-cancer therapeutic approaches:

- Commonly target **single** tumour-associated antigens
- **Absence of truly cancer-specific targets**, meaning targets are often **also expressed on vital healthy cells**
- Causes **significant toxicities**, including **patient deaths**
- Limiting the safe dose that can be given and the effectiveness of the treatment

ANTIBODY-DRUG CONJUGATES

- ADCs as a sub-group of biologic therapeutics gaining momentum
- Complex modality with increased understanding of challenges & opportunities
- Starting to realise on P Ehrlich's 'magic bullet' concept?!
- However, all approved ADCs to date are monospecific.



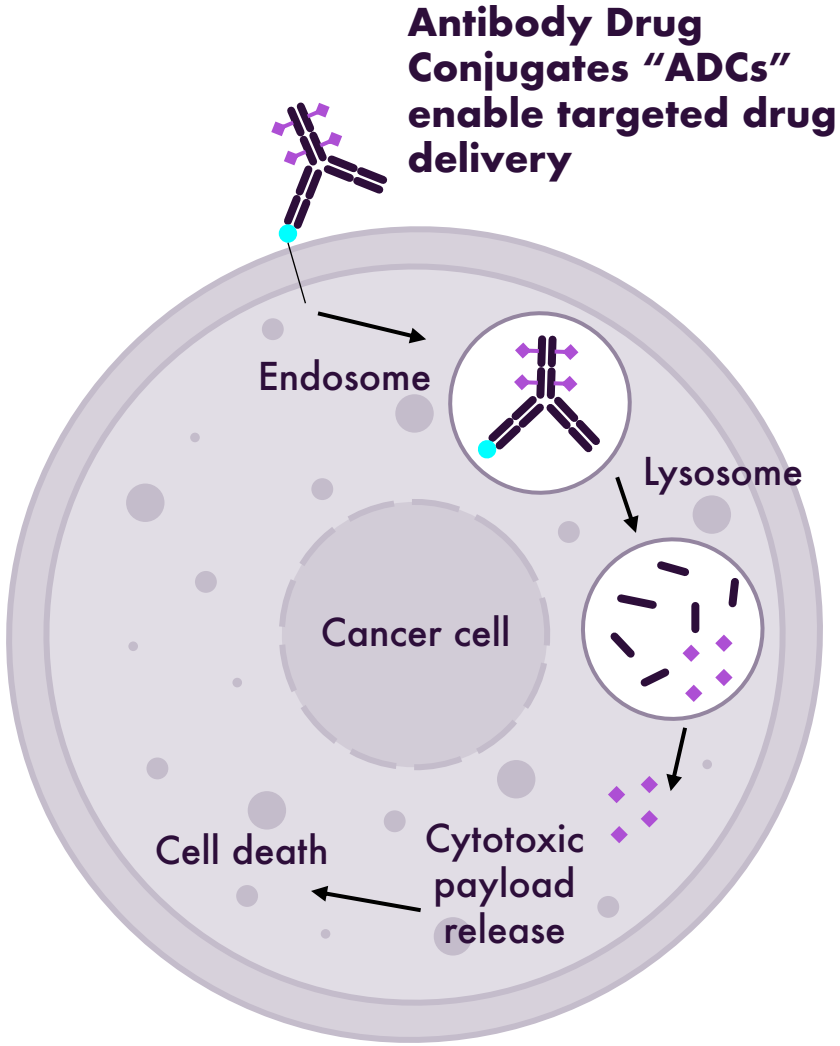
Baah *et al.*, *Molecules* 2021

DELIVERING A DIFFERENTIATED APPROACH WITHIN THE RAPIDLY EXPANDING ADC MARKET

$4.3bn	2020 ADC MARKET SIZE[1]
$23.9bn	2028 ADC MARKET SIZE (Forecast)[1]
>23%	CAGR*
12	ADCs approved

ADC MoA considered the **most validated antibody-based therapeutic concept,** with 12 approved drugs on the market

We apply the **Bi-Cygni® approach** to the established ADC MoA to build a differentiated pipeline of **next-generation ADCs with superior efficacy and cancer selectivity**

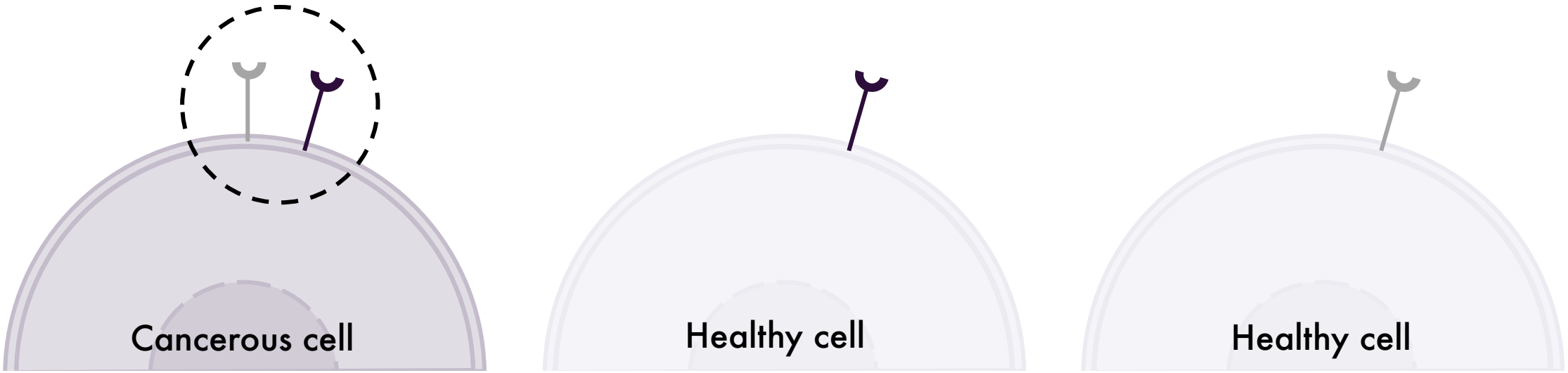


1. Grand View Research In, 2021; * Compound annual growth rate

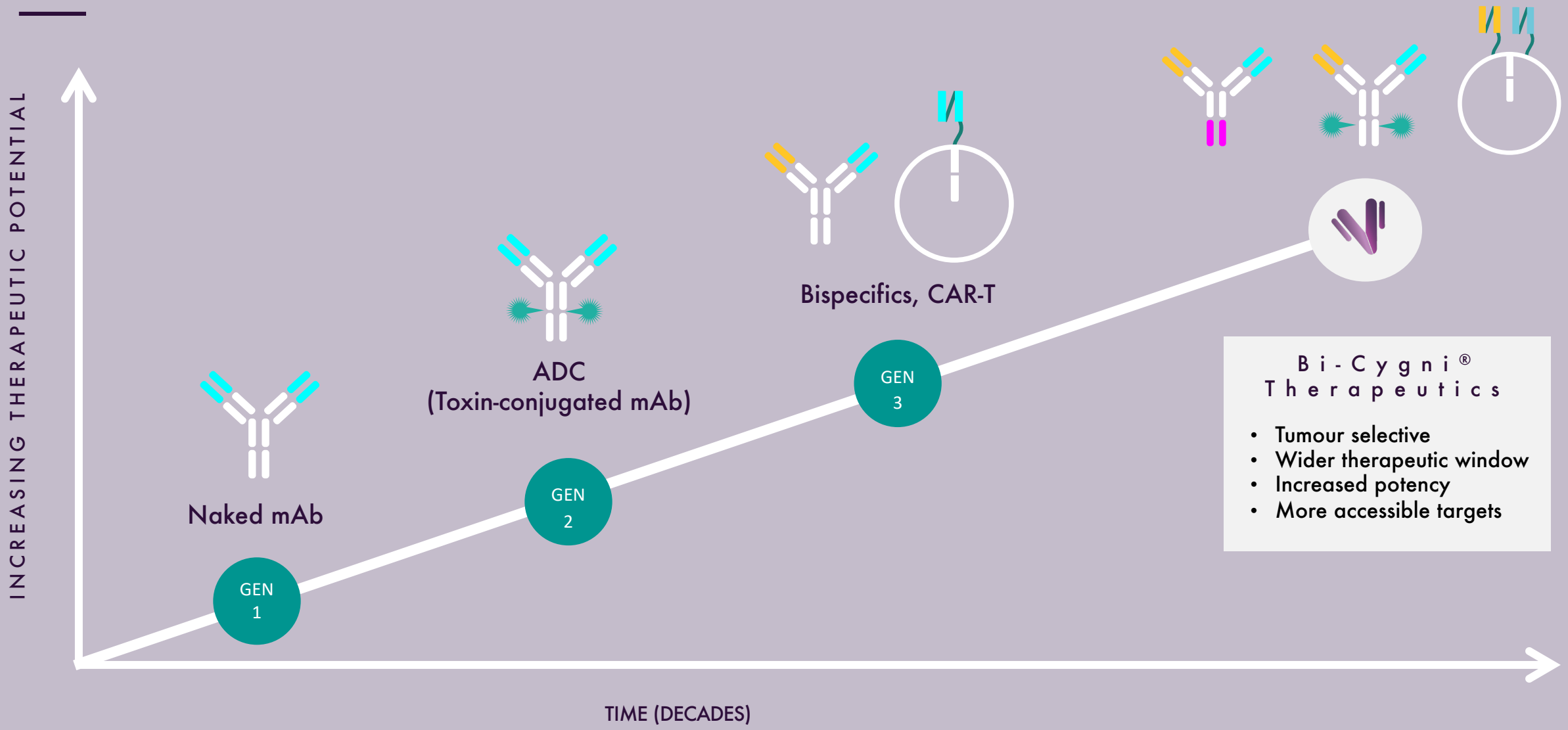
SOLUTION: TARGET CANCER-SPECIFIC "TWIN ANTIGENS"

Cancer-specific "twin antigen" fingerprints clearly differentiate cancerous vs healthy cells

'A Holy Grail' in Oncology



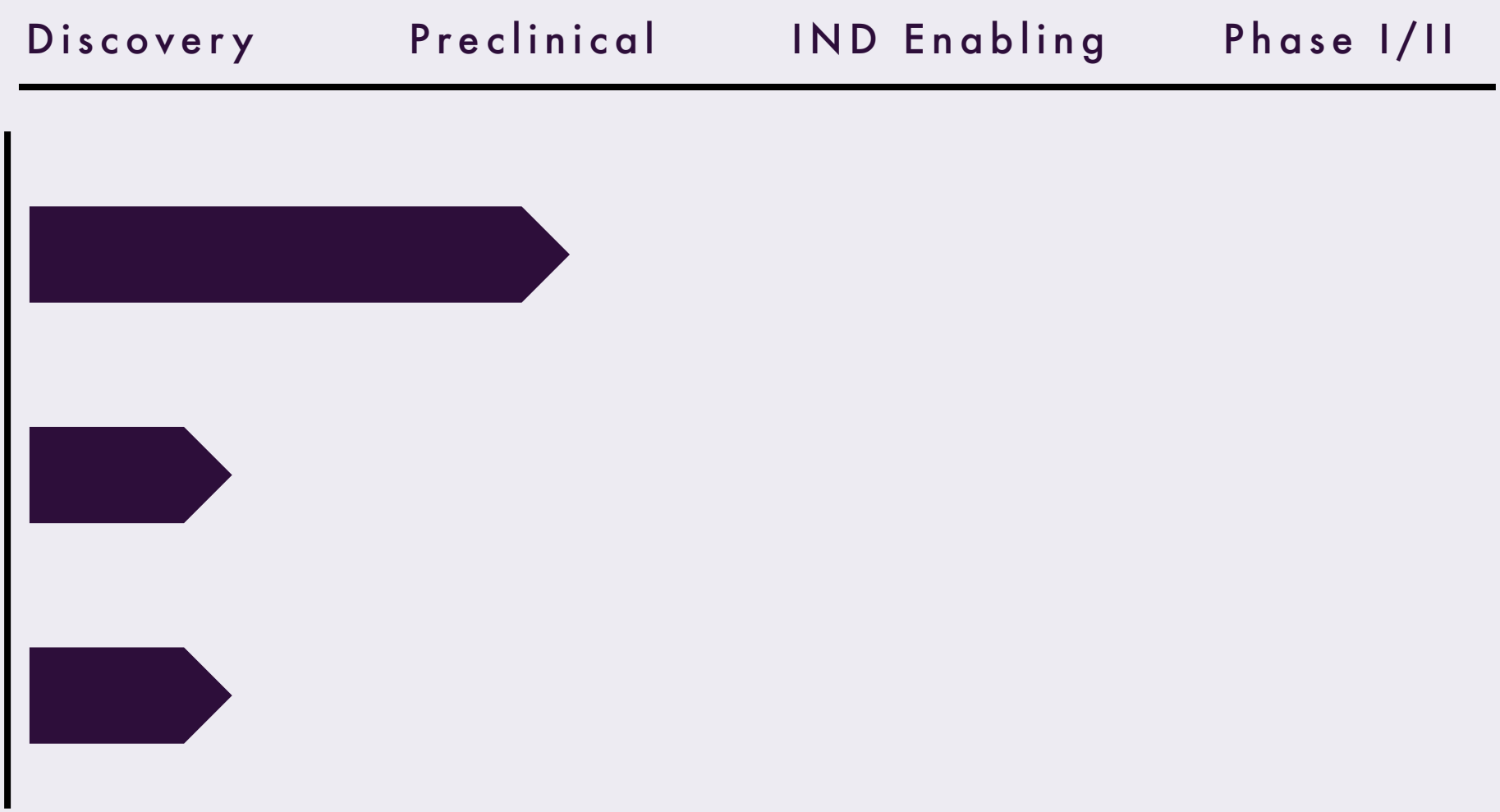
THE NEXT PHASE OF TARGETED CANCER THERAPY



Bi-Cygni® Therapeutics

- Tumour selective
- Wider therapeutic window
- Increased potency
- More accessible targets

BROAD PIPELINE ESTABLISHED



BVX001
Bi-Cygni® ADC
Targets: CD7 x CD33
Indications: AML, other haem cancers

BVX002
Bi-Cygni® ADC
Targets: undisclosed
Indications: various haem cancers

BVX003
Bi-Cygni® ADC
Targets: undisclosed
Indications: various haem cancers & solid tumours

THE PROPOSITION – BVX001 IN ACUTE MYELOID LEUKAEMIA

- Acute Myeloid Leukaemia (AML) is a haematological malignancy representing >90% of adult acute leukaemia cases
- Age is a major risk factor with many older patients not eligible to receive highly toxic chemotherapeutic combinations. Mortality rate amongst AML patients remains high: 5-year survival at 15%, dropping to 12% in patients >65year old.
- All currently available AML therapies offer only limited improvements in efficacy whilst carrying significant treatment-related toxicities, some life-threatening.
- CD33 is expressed on the majority of AML cells but CD7, a lymphocytic cell marker, is aberrantly expressed on a chemotherapy-resistant, poor prognosis subtype of AML. Approximately 25-30% of AML cases show this target co-expression.
- The lead program, BVX001 has the potential to address a key unmet need in AML with a truly novel immunotherapeutic approach suitable for both younger and older patients.
- Clearly, a disease with unmet clinical need for a better treatment option to serve many patients.

AML – ONE OF THE FASTEST GROWING ONCOLOGY INDICATIONS

$1.46bn — 2019 AML MARKET SIZE[1]

$3.56bn — 2027 AML MARKET SIZE (Forecast)[1]

13% — CAGR

Initial Route to Market

- Frontline therapy in CD7+CD33+ underserved elderly patient population
- Monotherapy in CD7+CD33+ relapsed/refractory AML

Addressable Market*

- Forecasted as >$1bn/yr (2027)[1]
- Representing av.30% of total AML patient pool

Competitors Validate Forecast

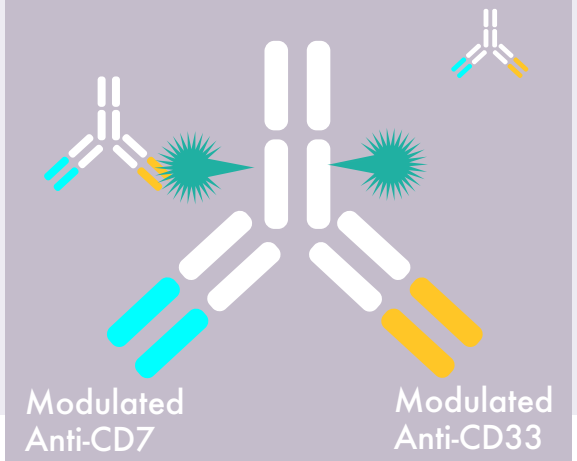
- Agios recently parted with oncology arm to Servier for $2bn + royalties, led by Agios' two AML drugs Tibsovo and Idhifa (IDH1/2 inhibitors, targeting just 20-25% of AML together)

1. Reports and Data, Globe Newswire 2020

BVX001 – FIRST IN CLASS CD7+CD33+ BI-CYGNI® ADC

Bi-Cygni® therapeutics require dual binding for activity, ensuring they are rapidly released from healthy cells while exhibiting maximum selectivity and enhanced potency for the targeted cancer cells.

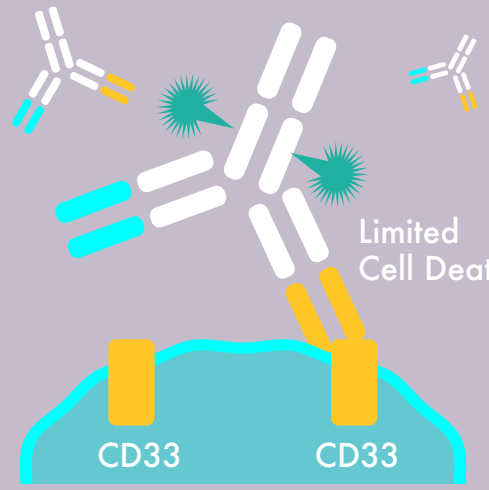
Bi-Cygni® ADC



Lead Molecule in Orphan Indication

- CD7+CD33+ represents poor-prognosis AML subpopulation
- Currently no therapeutics targeting CD7+ CD33+ AML subgroup

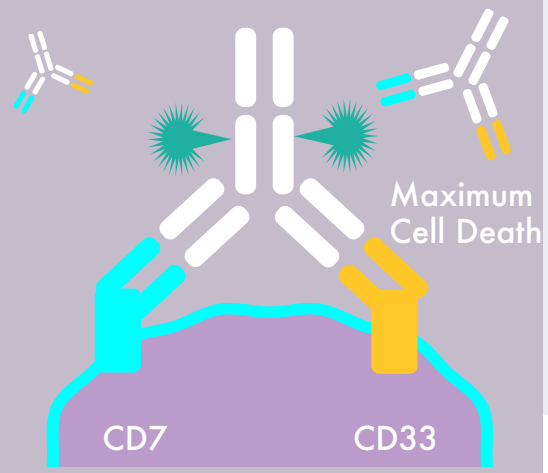
Healthy Cell



Targeting a well-defined patient subgroup

- CD7+CD33+AML represents ca.20-30% of total AML patient pool (ca. 16,000 pts/yr)
- Pfizer's newly approved ADC Besponsa targets ca.15,000 pts/yr

Cancer Cell

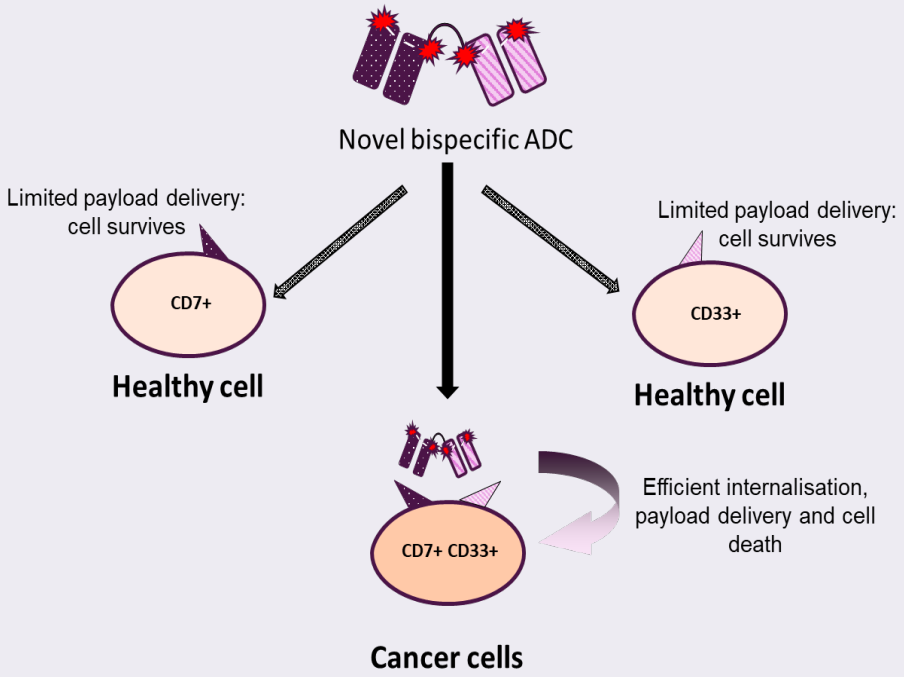


Obligate Target Binding resulting in maximum Cell Death

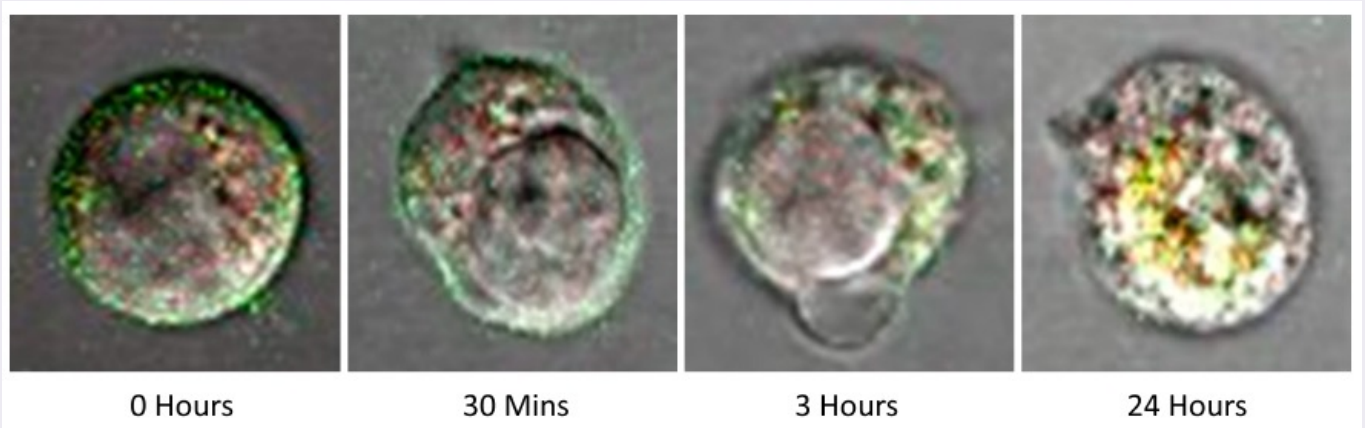
- Optimally tuned target affinities ensure ADC/target complex formation & internalization predominantly on malignant cells

BVX001 SHOWS EFFICIENT BINDING, INTERNALISATION & LYSOSOMAL CO-LOCALISATION IN TARGET CELLS

PoC format is a chemically linked bi-Fab conjugated to MMAF – DAR4

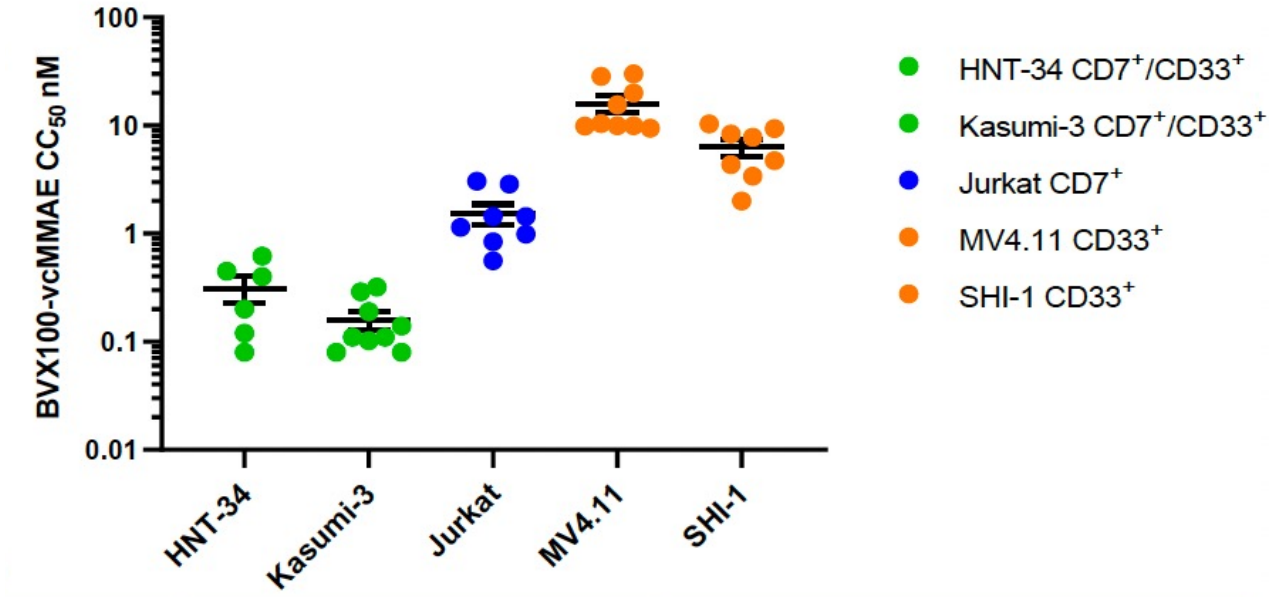


Fluorophore labelled bi-Fab internalizes specifically & rapidly in dual-target expressing cell lines



SIGNIFICANT TARGET CELL SELECTIVITY FOR BVX001 BI-FAB

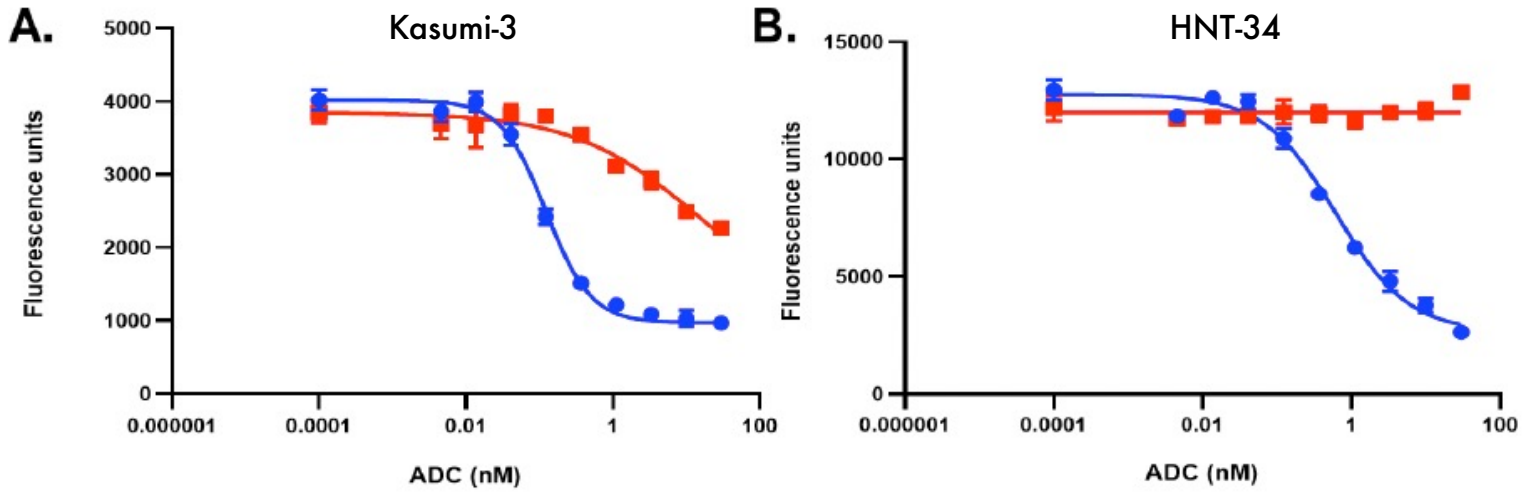
- Cell Lines from different haematological malignancies used for cytotoxicity & selectively *in vitro* assays.
- Bi-Fabs show significant cell kill selectivity of dual-target expressing cells
- Avidity and individual Fab target affinity believed to drive selectivity.
- *In vitro* selectivity could be indicative of desirable toxicity profile *in vivo* for Bi-Fab.



Significant & selective cell cytotoxicity of BVX001 Bi-Fab on dual-antigen expression AML cell lines

SUPERIOR CELL CYTOTOXICITY IN HARD-TO-TREAT LEUKEMIA CELL LINES

- Affinity-tuned Bi-Fab Lead shows superior cytotoxicity of AML cell lines w/c to bivalent CD33-monospecific Gemtuzumab-mcMMAF.
- Similar cytotoxicity profile for Bi-Fab Lead on cells with 10-fold difference in CD33+ SABC*
- Broad target cell selectivity



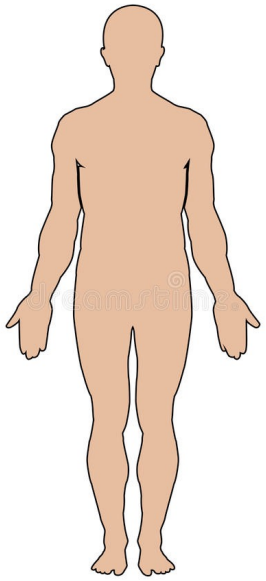
Cell Line	SABC	
	CD7	CD33
Kasumi-3	19,500	99,000
HNT-34	22,000	11,000

Gemtuzumab-mcMMAF

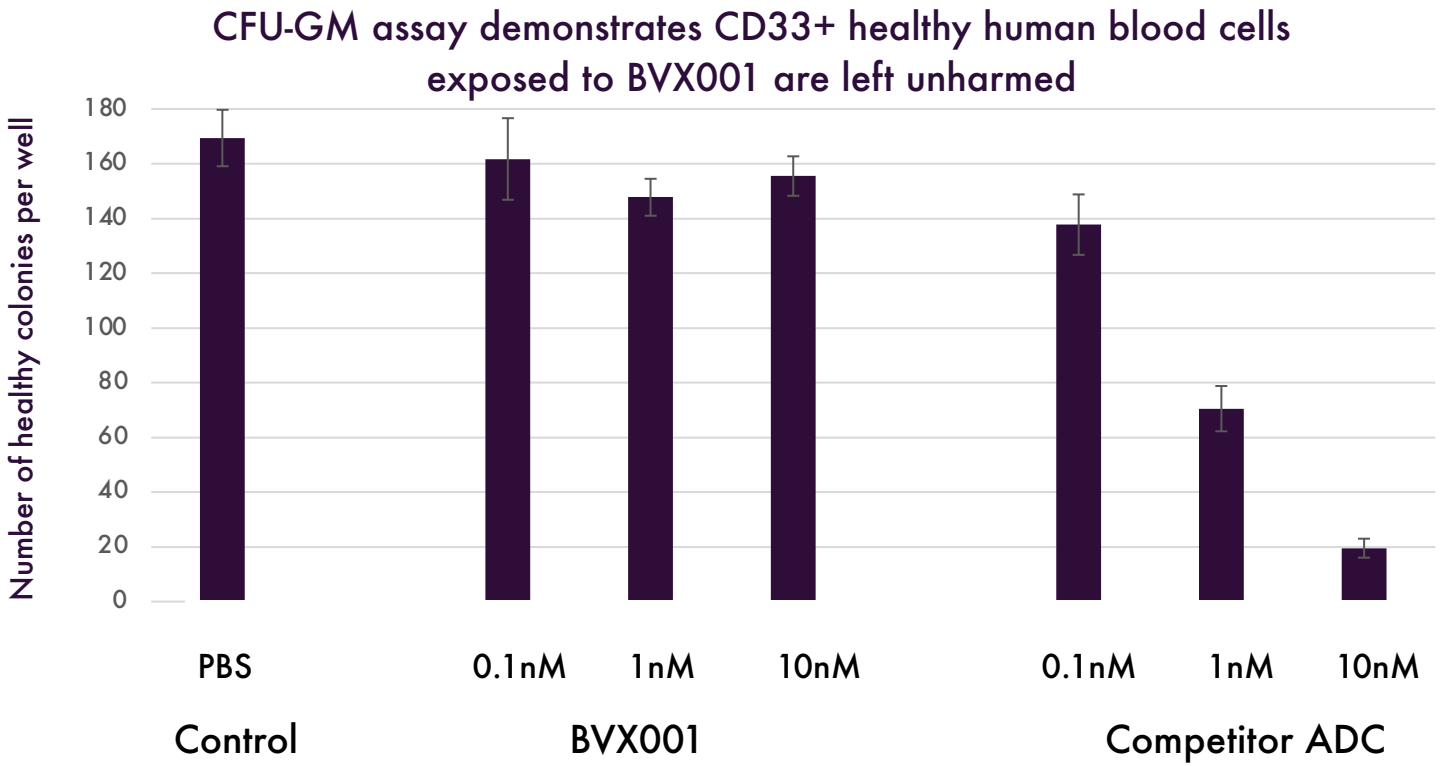
BVX001 lead Bi-Fab-mcMMAF

* Specific Antibody Binding Capacity

BVX001 HAS MINIMAL EFFECT ON HEALTHY CELLS



Healthy blood stem cells taken from human donors



- Life-threatening bone marrow suppression is a major clinical concern reported with competitor therapies due to the expression of the targeted antigens being present on both healthy blood progenitor cells and cancer cells
- Cellular data from human donors demonstrate that a competitor ADC kills >85% of CD33+ healthy cells
- In contrast, increasing concentrations of BVX001 have little effect on the CD33+ healthy blood cells

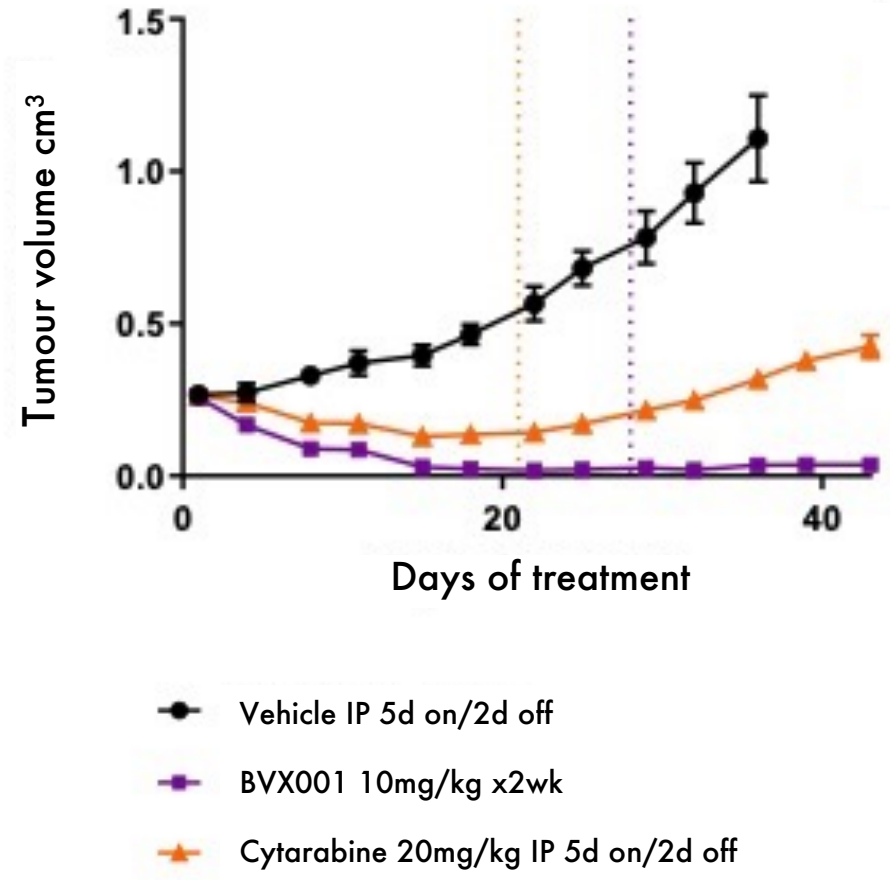
BVX001 INDUCES SUBSTANTIAL TUMOUR REGRESSIONS

- Xenograft model using CD7+CD33+ HNT-34 cells
- Model selected due to inherent resistance to CD33-based competitor ADCs, resulting from low CD33 expression
- Cytarabine (currently used in standard of care for AML) dosed at the MTD in a prior tolerability study
- BVX001 dosed based on PK/PD data as MTD not reached
  - Well tolerated with comparable body weight change across test articles
- Mice dosed for 28 days, with 10 mice per group

3/10 animals tumour free

4/10 animals tumours too small to measure

AACR American Association for Cancer Research



Bethell, R. et al, 2020. Bispecific Antibody Drug Conjugates Targeting CD7 and CD33 for the Treatment of Acute Myeloid Leukaemia, AACR poster #2887.

SIGNIFICANT BENEFITS OFFERED BY BI-CYGNI ® THERAPEUTICS

1. Significantly Reduced Toxicity Enables Higher Dosing and Greater Efficacy
2. Reduced Toxicity Expands Options for Combinatorial Therapies
3. Superior Potency Achieved Through Targeting Dual Antigens
4. Effective Across Both High and Low Expressing Tumours
5. Expands the Universe of Potential Drug Targets
6. Highly Adaptable Across Solid/Liquid Cancers, Not Reliant on Tumour Microenvironment

SUMMARY / VISION

- New Drug development company pioneering the development of the **next wave of precision medicines**, unlocking the full potential of next generation biologics.
- **Clinically-led concept** offers clear differentiation & USP of approach.
- Developing **Diverse proprietary pipeline** in heam and solid tumor.
- **Bi-Cygni® therapeutics** are uniquely designed to exhibit superior cancer cell selectivity, enabling higher dosing resulting in greater efficacy - even in the most vulnerable patient cohorts.
- BVX001 Lead Bi-Fab has shown significant target cell selectivity in *in vitro* & *in vivo* using otherwise treatment-resistant* AML cell lines.
- Currently moving BVX001 PoC molecule into therapeutic format & pre-clinical development.

* Gemtuzumab-conjugate

THANK YOU!

Q&A

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