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Pharmaceuticals & Biotechnology

Source: Eikon Thomson Reuters

Market data	
EPIC/TKR	ABZA
Price (p)	40.0
12m High (p)	66.0
12m Low (p)	31.0
Shares (m)	137.8
Mkt Cap (£m)	55.1
EV (£m)	45.8
Free Float*	29%
Market	AIM

**As defined by AIM Rule 26*

Description

Abzena is a UK-based Life Sciences company engaged in the provision of services to enable the discovery and development of better bio-pharmaceuticals. Embedding its 'know-how' into customers' products is expected to generate a long-term royalty stream.

Company information

CEO	John Burt
CFO	Julian Smith
Chairman	Ken Cunningham
	+44 1223 903 498
	www.abzena.com

Key shareholders

Directors	2.1%
Invesco	26.4%
Woodford	23.0%
Imperial	19.8%
Ballie Gifford	3.3%

Diary

13 Dec 16	Hardman report
Jun-17	Finals
Sep-17	AGM

Analysts

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Abzena

ThioBridge® deal highlights undervaluation

Abzena is an integrated group offering a broad range of services and technologies to improve the chances of discovering and developing effective biopharmaceutical drugs. With strong footprints in both the US and UK, the company provides a fee-for-service offering with the additional opportunity to embed its technology – 'Abzena *Inside*' – into commercial products, on which it will derive a long-term royalty stream. Abzena has signed a licensing deal with a US biopharmaceutical company for the use of its ThioBridge technology. This deal has a potential value exceeding $300m and has significantly boosted market confidence in the company.

- **Strategy:** Abzena has a dual strategic objective of providing enabling technology on a fee-for-service basis and, where possible, to secure technology agreements from embedding its patented technology and 'know-how' into customers' final products to generate future licence revenues and, potentially, royalties.

- **ThioBridge:** Antibody Drug Conjugates (ADCs) link the tumour targeting properties of antibodies with a cytotoxic payload, but do have some drawbacks. Abzena has developed ThioBridge technology to produce more homogenous and stable ADCs thereby overcoming many of the inherent issues.

- **Licensing agreement:** Abzena has announced a new licensing deal with a San Diego-based biopharmaceutical company for the development of up to 10 ADCs targeted at various cancers. The deal is potentially worth up to $300m in access fees, and development and regulatory milestones. It also comprises a Service Agreement with Abzena's Chemistry division.

- **Risks:** There are inherent clinical trial and commercialisation risks in drug development. Any product emerging under the agreement would become part of the 'Abzena *Inside*' portfolio. However, in all probability, not all 10 of the potential ADCs under the agreement will reach commercialisation.

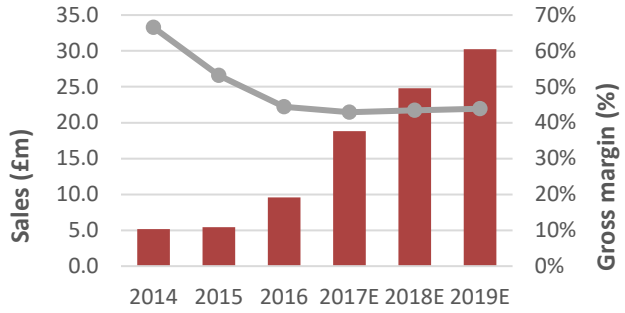
- **Investment summary:** The market reacted very positively to this news which was long overdue. The agreement represented further validation of Abzena's technology, increased market confidence that more deals will be done, and highlighted the undervaluation of the stock, with the fast-growing service business alone more than justifying the current market capitalisation.

Financial summary and valuation

Year end March (£m)	2014	2015	2016	2017E	2018E	2019E
Sales	5.18	5.41	9.57	18.84	24.80	30.26
R&D investment	-2.60	-2.99	-4.22	-4.26	-4.34	-4.47
Underlying EBIT	-1.14	-5.30	-8.21	-8.44	-7.06	-4.44
Reported EBIT	-1.56	-5.30	-10.90	-8.83	-7.49	-4.91
Underlying PBT	-1.11	-5.22	-7.96	-8.37	-7.07	-4.50
Statutory PBT	-1.53	-5.22	-10.66	-8.75	-7.50	-4.96
Underlying EPS (p)	-4.3	-6.6	-6.4	-5.5	-4.5	-2.6
Statutory EPS (p)	-7.5	-6.6	-8.9	-5.8	-4.8	-3.0
DPS (p)	0.0	0.0	0.0	0.0	0.0	0.0
Net (debt)/cash	2.8	15.8	13.7	2.7	-6.9	-14.6
Capital increase	10.7	19.0	20.0	0.0	0.0	0.0
EV/sales (x)	8.8	8.5	4.8	2.4	1.8	1.5

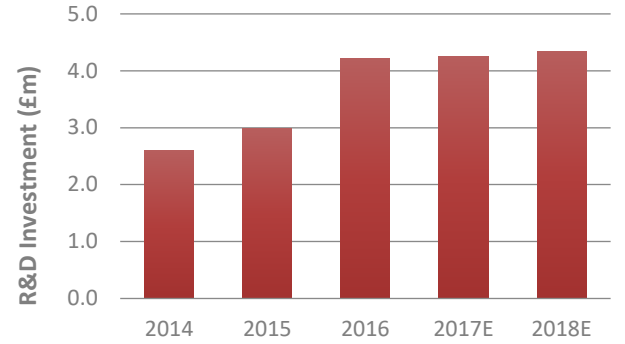
Source: Hardman & Co Life Sciences Research

Revenues & Gross margin



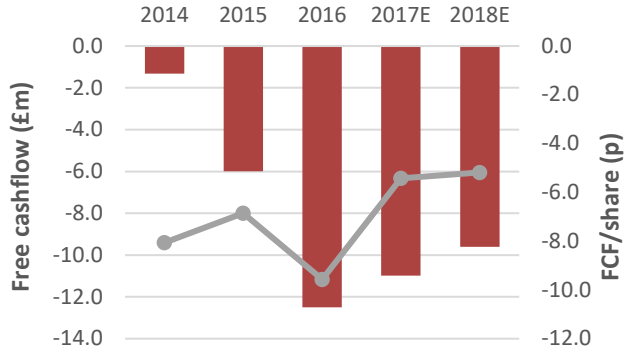
- Acquisitions have boosted reported sales growth to ca.100% in 2016 and 2017
- Underlying sales growth rates are closer to +25-30%
- Gross margins have been lowered by the acquisition of specialty manufacturing businesses
- Gross margins are forecast to reach a nadir in fiscal 2017 and to rise modestly thereafter

R&D spend



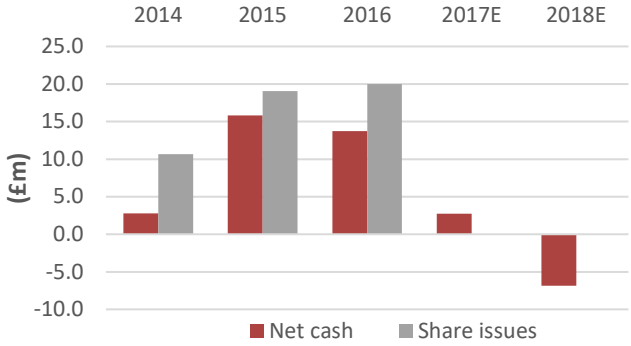
- Investment in R&D is ca.£4m per annum
- Focus is on service enhancement and technology development
- Abzena obtains tax credits on most of its UK R&D spend
- All clinical development costs of 'Abzena *Inside*' products are borne by customers

Free cashflow



- Trading profit is the key driver of cashflow
- Strong growth in the business requires a modest annual increase in working capital
- Some investment in capex will be required in the move to new labs and HQ in the UK and to support manufacturing in the US
- Forecasts do not allow for future licensing deals, the timing of which is difficult to predict

Net cash/capital increases



- At 30th September 2016, Abzena had net cash of £9.4m
- Based on current forecasts, Abzena has sufficient cash to deliver on strategy through to the early part of fiscal 2018
- No allowance is made for significant milestones from existing and new licensing agreements
- Current forecasts suggest that the royalties on 'Abzena *Inside*' products start in fiscal 2020

Source: Company data; Hardman & Co Life Sciences Research

ThioBridge update

Bioconjugation

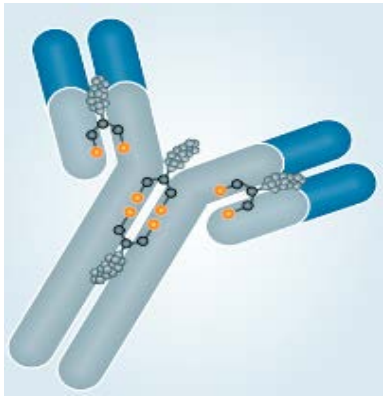
ADCs are considered to be one of the best ways of targeting cancer cells

An antibody drug conjugate (ADC) is a complex molecule that connects together a target-specific antibody with a toxic, and usually non-specific, drug. Although both the antibody and the cytotoxic drug could be used independently to treat the cancer, the combination allows the selective delivery of the toxic payload to a specific target, whilst minimising systemic side effects from exposure of healthy tissue to the drug. The two entities are coupled together by a stable linker system designed to securely bind the cytotoxic agent to the antibody, and then release the agent within the targeted cell. The inherent problems with current approaches to ADCs is the lack of homogeneity in the drug to antibody ratio, as well as instability of the linker.

Experience from several years of clinical development of early ADCs suggests that outcomes would be improved further if:

- ADCs were more homogenous
- The ADC had a more precise and controlled drug:antibody ratio
- The drug and antibody were coupled together using more stable linkers

ThioBridge



Source: Abzena

ThioBridge is Abzena's proprietary linker technology which is designed to produce more homogenous and stable ADCs. It tackles all the potential issues inherent to the existing ADC technology including heterogeneity, instability and tolerability. For this reason, Abzena is an attractive licensing partner for the many drug developers working in this field.

ThioBridge licence agreements

Existing ThioBridge deals

The flexibility of ThioBridge has been demonstrated with a range of antibodies being coupled to various cytotoxic payloads in a number of different configurations, which increases the range of options available to potential customers. The whole approach has been validated via a number of licensing deals signed in recent years, which are shown in the following table. Until recently, the largest deal was with Halozyme Therapeutics in January 2016 which was signed after extensive preliminary evaluation work and underpinned confidence in the Abzena's technology.

ThioBridge technology is versatile in linking antibodies with payloads…

…and increasingly attractive to drug development companies

ThioBridge licensing deals

Company	Deal date	Comments
Undisclosed	2014	Option to use ThioBridge technology for up to 10 ADCs (terms not disclosed)
Alpha Cancer Technology	May-2014	Use of ThioBridge using the alpha-fetoprotein (AFP) drug delivery system (ACT-903 in pre-clinical development))
Halozyme Therapeutics	Jan-2016	License fees and milestones up to $150m for the development of three designated targets
Undisclosed	Jan-2017	License fees and milestones up to $300m for up to 10 ADCs

Source: Hardman & Co Life Sciences Research

New licensing agreement

ThioBridge has attracted another significant partner…

Following an ongoing and extensive collaborative research programme with an undisclosed US biopharmaceutical company to evaluate ThioBridge, Abzena has concluded a licensing agreement for technology access with this San Diego-based company. This becomes Abzena's largest deal for the ThioBridge technology and further validates its potential applications in the field of cancer. The agreement covers the use of ThioBridge for the discovery and development of up to 10 ADCs across a wide range of undisclosed cancer indications.

Whilst full details of the terms remain confidential, the headlines are as follows:

… with an agreement for up to 10 ADCs that could exceed $300m

- Incorporation of the ThioBridge linker technology in up to 10 ADCs
- Licence fees and milestone payments up to $30m per ADC
- Total license fees and milestones could potentially exceed $300m
- Any successful, new ADC product would be included in, and expand, the 'Abzena *Inside*' portfolio
- Following drug approval, low single digit royalties would be paid on net sales
- The agreement also includes a "master services agreement" relating to Abzena's chemistry capability. Abzena will undertake the chemistry work for its partner under a fee-for-service arrangement

In reality, not all of the 10 targets will reach commercialisation

In order to achieve the maximum milestones under the agreement, the partners would need to obtain regulatory approval for all 10 ADC target products, which in reality, is unlikely to be the final outcome. However, this should not distract from the significance of the deal and the attractiveness of ThioBridge to the pharmaceutical industry.

The share price reaction was not justified by this deal alone…

…but reflected the enormous potential in Abzena and highlighted its undervaluation by the market

There was an immediate market reaction to this announcement news, with the Abzena share price rising about 65% on the day. On the face of it, this was an over-reaction to the news. However, this deal did highlight the under-valuation of the stock which was trading on an enterprise value below that which could be ascribed just to Abzena's service business. Further validation of the technology has highlighted its potential to other cancer development companies. Indeed, we believe that Abzena is having discussions with other possible partners for the evaluation of ThioBridge with their own proprietary products, suggesting that further deal announcements could be made in the near future. Therefore, this agreement has provided the market with confidence that ThioBridge on its own has the potential to generate a significant return for shareholders.

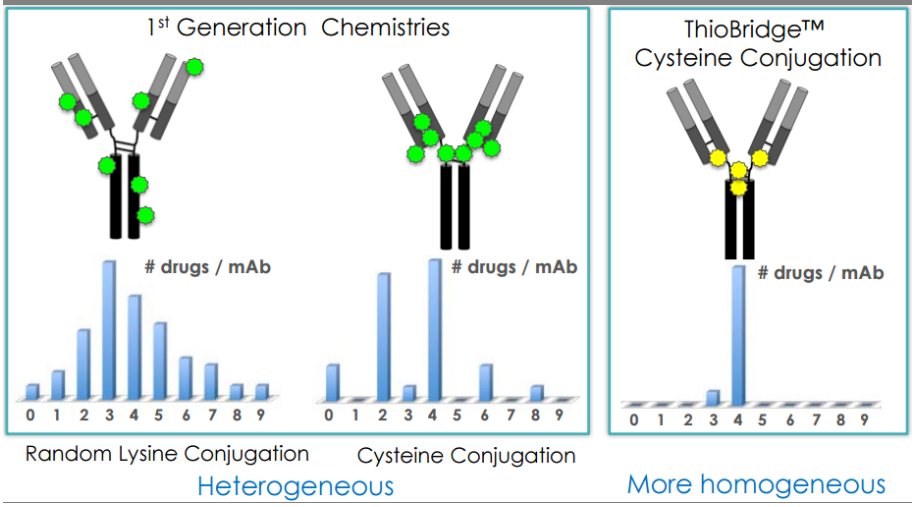
Halozyme Therapeutics update

Halozyme graphically presented the role it sees for ThioBridge technology

In January 2016, Abzena signed a licensing agreement with Halozyme Therapeutics to give Halozyme access to the ThioBridge technology for use in its ADC programme. Halozyme is pursuing an anti-EGFR (Epidermal growth factor receptor) therapeutic, even though these have been shown with certuximab (Erbitux, Lilly) to have certain limitations, notably dose-limiting skin rash and downstream mutations. Therefore, Halozyme is investigating the use of ADC technology to overcome these efficacy limitations when downstream mutations are present. Halozyme is specifically using ThioBridge as its leading next generation ADC technology to overcome these problems.

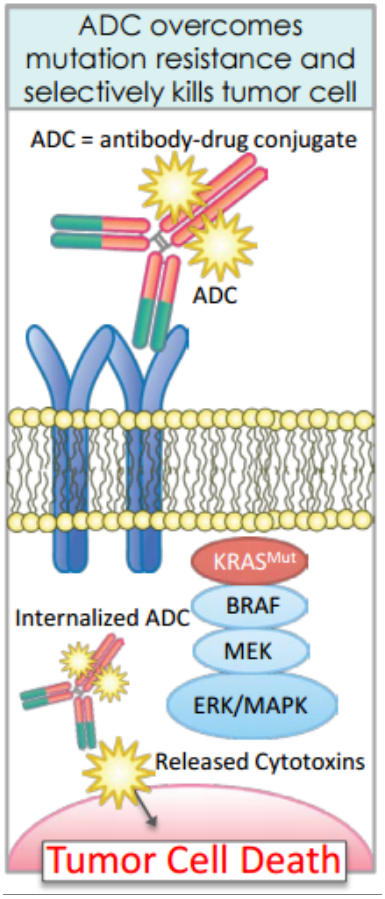
In a recent presentation, Halozyme presented a graphic indicating how it was positioning Abzena's ThioBridge technology as a 2nd generation ADC chemistry in its drug development programmes for anti-EGFR ADC. This implies that Halozyme has adopted the ThioBridge linker as the lead technology for its ADCs.

Halozyme – Next generation ADC technology



Source: Halozyme Therapeutics

Use of ADCs



Source: Halozyme Therapeutics

HTI-1511, Halozyme's ADC product, is using ThioBridge for its EGFR-positive tumours programme to overcome the two potential problems: mutations (including those with KRAS and BRAF) that can limit efficacy, and heterogeneity in an attempt to avoiding toxicity and improve tolerability.

As a reminder, Abzena has already received an initial license fee from Halozyme Therapeutics and has the potential to receive further milestones up to a total of $150m, across three targets, including EGFR. Low single digit royalties would be receivable on net sales of a commercialised drug.

Existing ADC deals

In the last five years, there has been considerable investment in ADC technology by a number of biopharmaceutical companies developing their own technology, as well as contract manufacturing organisations (CMOs). Manufacture of antibody-drug conjugates involves specialised technologies and know-how which has resulted in the outsourcing of more than 70% of all ADC production to the limited number of specialised CMOs that have the capability to manufacturing monoclonal antibodies, linkers and cytotoxic warheads. Moreover, there are even fewer CMOs with their own proprietary technologies, exemplified by Abzena's ThioBridge.

Therefore, to access ADC technology and know-how, companies have, and are continuing, to undertake collaborative deals and investments as detailed in the following non-exhaustive table.

M&A activity to gain access and ownership to relevant technologies is also quite common. For example, the purchase by Abbvie of Stemcentrix for $10.2bn to access Rova-T (rovalpituzumab tesirine) for small cell lung cancer.

ADC deals since 2013				
Company	**Partner**	**Date**	**Deal**	**Technology**
Abzena	Undisclosed	Jan-17	$300m	ThioBridge
Seattle Genetics	Pfizer	Jan-17	$200m	Proprietary linkers
Ambrx	MabSpace	Jan-17	Undisclosed	IMBT/EuCode
Nordic Nanovector	Heidelberg Pharma	Oct-16	Undisclosed	ARC
Nordic Nanovector	LegoChem	Oct-16	Undisclosed	ARC
ADC-therapeutics	Synaffix	Oct-16	Undisclosed	GlycoConnect, HydraSpace
Stemcentrx	AbbVie	Apr-16	$10.2bn	Acquisition/Rova-T
Abzena	Halozyme	Jan-16	$150m	ThioBridge
BioAtla	Pfizer	Dec-15	$1,000m	CAB-ADC
ImmunoGen	Takeda	Mar-15	$440m	TAP
Mersana	Takeda	Jan-15	$300m	Fleximer
Sutro BioPharma	Merck KGaA	Sept-14	$298m	–
Seattle Genetics	Genmab	Sep-14	$211m	HuMax-AXL-ADC
Mersana	Takeda	Apr-14	Undisclosed	Fleximer
Immunogen	Novartis	Nov-13	$200m	TAP
Spirogen	AstraZeneca	Oct-13	$440m	Acquisition
Immunogen	Eli Lilly	Aug-13	$200m	TAP
CytomX	Pfizer	Jun-13	$635m	Probody
ADC Therapeutics	GenMab	Jun-13	Undisclosed	Proprietary linkers
ADC-Therapeutics	VivaMab	Jun-13	Undisclosed	Proprietary linkers

Source: Hardman & Co Life Sciences Research

FDA approved ADC drugs

The lack of ADC drug approvals has in no way dimmed the clinical drug development work

Despite the first ADC being approved in 2000 (subsequently voluntary withdrawn in 2010 by Pfizer for lack of efficacy) and huge investments, only an additional two ADC-based drugs have received regulatory approval for commercialisation. Even with no new ADC-based drug approvals since 2013, research into novel ADCs has considerably increased, with nearly 150 open clinical trials (clinicaltrials.gov) currently exploring ADCs against cancer targets investigating a variety of cytotoxic drugs and technologies.

FDA approved ADC drugs				
Drug	**Combination**	**Target**	**Approved**	**Indication**
Mylotarg (Pfizer)	Gemtuzumab ozogamicin	CD33	2000*	Myeloid leukaemia
Adcetris (Takeda)	Brentuximab vedotin	CD30	2011	Hodgkin lymphoma; anaplastic large cell lymphoma
Kadcyla (Roche)	Trastuzumab emtansine	HER2	2013	HER2 +ve metastatic breast cancer

**Withdrawn from market in 2010, but in multiple Phase II/III studies for acute myeloid leukaemia*

Source: Hardman & Co Life Sciences Research

Biopharmaceutical market

ADCs currently represent a small part of the $180bn global biopharmaceutical market

The biopharmaceutical market is comprised a number of technologies including ADCs. In our initiation report on Abzena (*Servicing the revenue stream*; September 2016), we published that the global biopharmaceutical market was estimated to be worth $180bn in 2015, representing 23% of the entire pharmaceutical market. We are presently updating the statistics for 2016 and expect to see solid growth in sales of biopharmaceuticals relative to the overall global drug market.

Integrated services

ThioBridge is part of Abzena's Chemistry division that complements both Biology Research services and the Manufacturing business. It is comprised of a bioconjugation service which, amongst other things, couples drugs to antibodies, and provides chemistry services which undertake custom synthesis of complex molecules, including ADC linkers and payloads, from laboratory scale (mg) to clinical-scale (g) quantities of cytotoxic payloads and linker payloads.

- **Bioconjugation** – Antibody Drug Conjugates (ADC), ThioBridge, cytotoxic payloads, PEGylation
- **Chemistry** – Custom synthesis, small molecule manufacture, protein/NMR services, analytical services

This division has the capability of providing a host of chemical services mainly from its state-of-the-art laboratory centres based in Bristol, Pennsylvania and Cambridge, UK. However, a key area for Abzena is the conjugation and synthesis of Antibody Drug Conjugates, and aims to provide its customers with an integrated specialist contract research service from laboratory-scale right through to GMP manufacturing for Phase II clinical trials via its manufacturing division.

Integration of Chemistry with Manufacturing

Attribute	Comment
Scale up	Synthetic route design and optimisation Trouble-shooting Process optimisation World-wide sourcing for best quality and cost
Manufacturing	Non-GMP batches for toxicology studies In-house manufacturing up to 100g API (not ADC currently) Full batch records for regulatory submission Tech-transfer for multi-kg scale to GMP specification (not ADCs)

Source: Abzena

Antibody drug conjugates

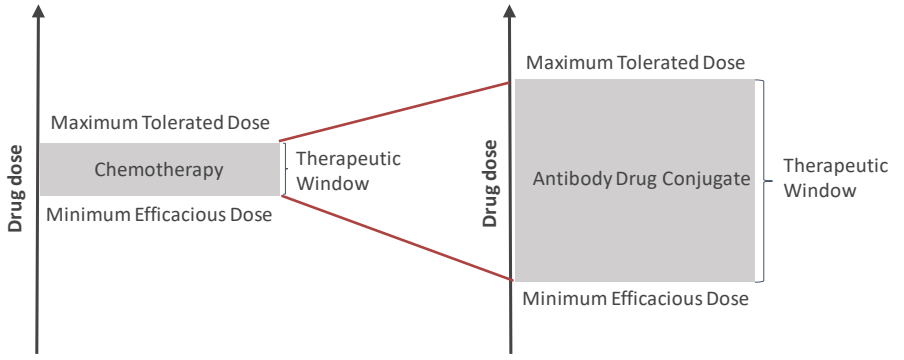
What are they?

Chemotherapy is an important component of most cancer treatment regimens and within this broad category cytotoxic drugs, which kill cells by preventing them from dividing, play a key role. However, by their very nature, they are limited by a narrow therapeutic window before serious toxic effects are seen and by their lack of specificity. Hence the concept of antibody-drug conjugates (ADC) arose, which combine the specific cancer killing ability of cytotoxic drugs with unique targeting capabilities of monoclonal antibodies (mAbs) for cancerous cells.

ADCs significantly improve the therapeutic window

By attaching biologically active chemotherapeutic drugs, radioactive isotopes, cytokines or cytotoxic compounds via chemical linkers to an antibody targeted to specific antigens, ADCs significantly improve the discrete sensitivity between healthy and diseased cells, greatly enhancing the therapeutic window.

ADC's therapeutic window



Source: Abzena; Hardman & Co Life Sciences Research

Lower dose to produce a response…

….and higher maximum dose before side effects appear

The toxic component of the ADC is hidden effectively while it is circulating in the blood system, only being released after the antibody has become bound to the target cancer cells, making it much safer than the naked drug itself. There are two consequences of this. First, because of the specific targeting and internalisation of ADCs, a lower dose is needed to start to produce a therapeutic effect. Secondly, a higher maximum dose is achievable before the onset of side effects

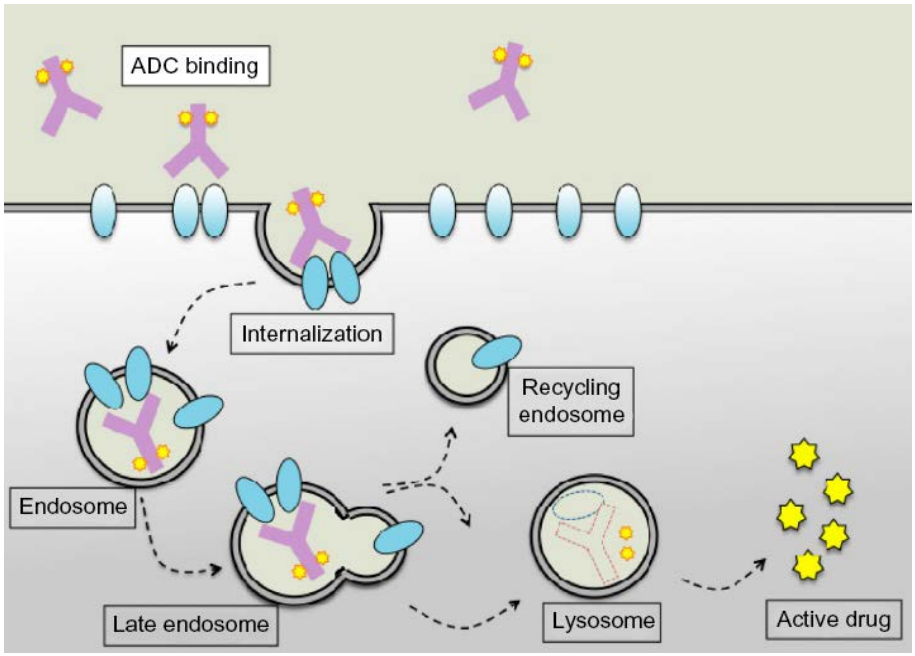
Mechanism of action

The mechanism of action of an ADC, from its pro-drug form to the point of release of the active target, is superbly demonstrated in the graphic[1] opposite.

- **Binding** – the ADC binds to a specific cancer antigen
- **Internalisation** – the ADC-antigen complex is absorbed into an endosome
- **Maturation** – from endosome to lysosomes associated with the acidification of the internal vesicle
- **Cleavage** – of the ADC linker releases the active cytotoxic drug
- **Cell death** – Action of the drug on its molecular target to ultimately generate cell arrest and/or cell death

[1] Scotti et al, Antibody Technology Journal, 2015:5 1–13

ADC – Mechanism of action



Source: Scotti et al[1]

Two drugs using ADC technology are currently on the market…

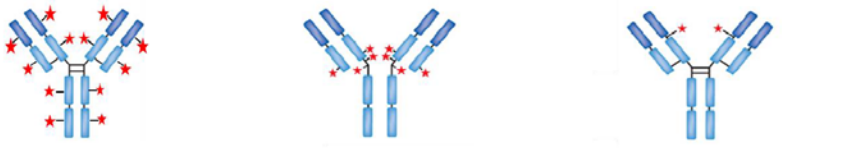
…with many more in clinical trials

At present, only two ADC-based drugs are available commercially but, as mentioned earlier, interest in this field is very strong, with about 50 molecules in clinical development with a variety of cytotoxic drugs for multiple indications – leading to >190 active clinical trials globally. Of these, approximately 25% are in Phase II or Phase III trials and there is an a rapidly expanding pre-clinical pipeline.

Although the theory surrounding ADCs is compelling, there are some inherent potential problems – heterogeneity and stability.

- **Heterogeneity** – The Drug to Antibody Ratio (DAR) is an important factor to consider in ADC. It is essential to have a reliable technique that will accurately introduce a known number of drug molecules within the protein in a reproducible manner for dosing purposes
- **Stability** – In physiological media. Several methods exist using readily accessible lysine and cysteine residues which generated the first generation of ADC products

ADC – Payload attachment options



Lysine chemistry
- Low efficiency
- Non-specific
- High heterogeneity

Cysteine chemistry
- Semi-specific
- Bond breaking
- High heterogeneity
- Maleimide instability

Cysteine chemistry
- Re-engineering approach
- Site-specific
- Reduced heterogeneity
- Maleimide instability

Source: Abzena

Despite the availability of these methods, results from the first generation of ADCs indicated that there was a need to address these issues, and Abzena is providing the technology to tackle them with ThioBridge.

ThioBridge™

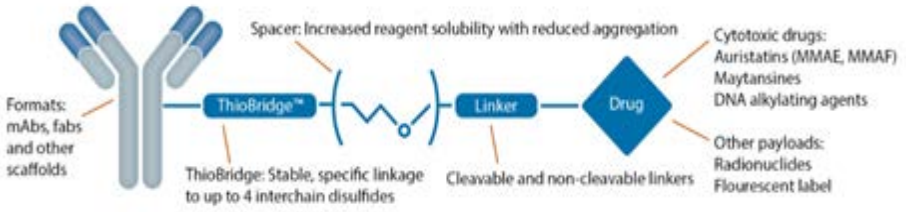
ThioBridge is one of the few technologies available that addresses the issues

ThioBridge is a site-specific conjugation technology applied to ADCs. By targeting the disulphide bonds in an antibody, Abzena is tackling all the potential issues inherent to existing ADC technology – including heterogeneity, instability and tolerability – which is one of the reasons that it is an attractive licensing partner to drug developers working in this field.

Heterogeneity

Given that there are four solvent-accessible inter-chain disulphides bonds within antibodies, there are four potential sites for the attachment of ThioBridge, which limits the DAR number to 4 (only one disulphide bond is accessible on each fragment antigen-binding (Fab)). It should be noted also that the technology has the potential to be used for a range of different payload classes that partners may be evaluating in order to select the ideal payload for their particular product.

ThioBridge™ conjugation technology

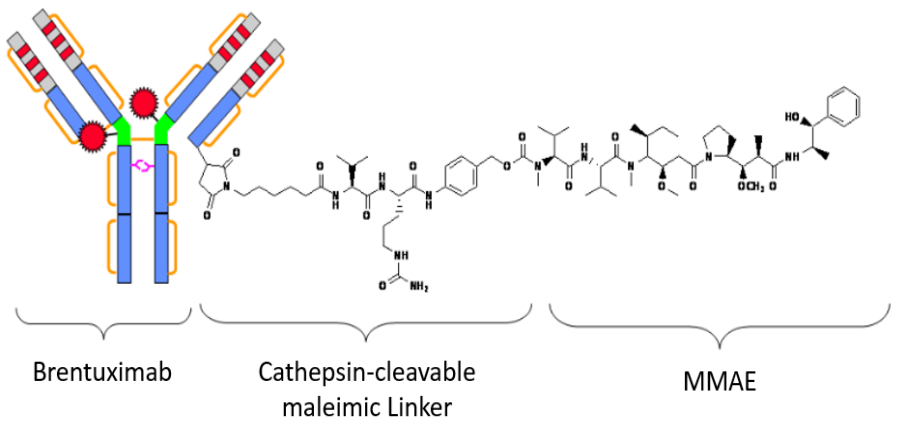


Source: Abzena

Case study: ThioBridge version of Adcetris

Adcetris is an ADC comprised of an antibody (bretuximab) targeting the CD30 antigen plus the anti-mitotic agent monomethyl auristatin E (MMAE) using a maleimic-type linker. It has been marketed since 2011 for Hodgkin lymphoma and systemic anaplastic large cell lymphoma by Seattle Genetics and Takeda.

Structure of Adcetris

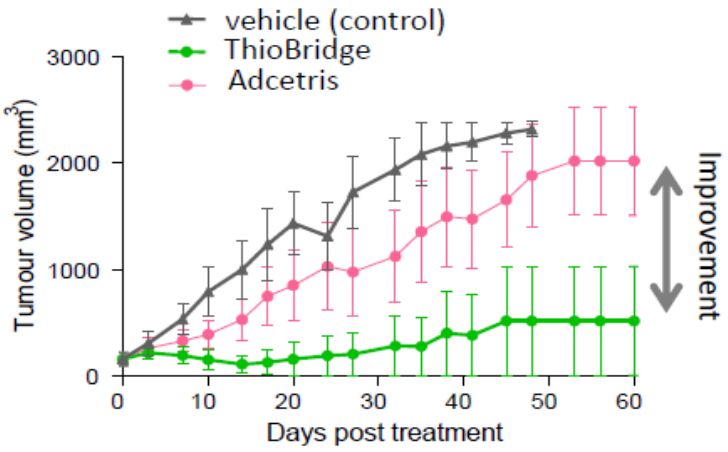


Source: adapted from www.newdrugapprovals.org

Between zero to eight units of MMAE are attached to the antibody, hence the heterogeneity issue as illustrated in the Halozyme 1st generation cysteine chemistry (see graphic on page 5). The linker is cleaved by Cathepsin, an enzyme present in the lysosome after internalisation of the ADC in the cell.

The experiment below shows results from an *in-vivo* assay assessing the efficacy of marketed Adcetris using the maleimic-type linker compared to the equivalent of Adcetris using ThioBridge. There is a clear reduction in tumour volume using ThioBridge.

Adcetris vs Adcetris-ThioBridge version



Source: Abzena

Some efficacy was observed with Adcetris in this tumour model. But an impressive response was observed with the ThioBridge equivalent of Adcetris, where tumour remission was achieved. Although there might be a number of explanations, it is thought that stability of the linker was the key factor. Maleimide linkers are known for the ability to be labile in physiologic conditions, as described previously, limiting the level of ADC reaching the cancer cells, and diminishing their anti-tumour effect.

Conclusion

Versatility = interest…

…interest leads to evaluation studies…

evaluation studies conclude with deals…

…licensing deals boost market confidence

The growing interest and investment in next generation ADCs suggests that Abzena is well positioned to have its ThioBridge technology more widely used. ThioBridge was developed to produce more homogenous and stable ADCs in an attempt to improve clinical outcomes. The versatility and reproducibility of ThioBridge has been demonstrated in several evaluation studies by potential partners coupling a number of specific antibodies with a range of cytotoxic payloads, allowing them to select the optimal candidate to take through clinical development. Therefore, ThioBridge is increasingly attractive to drug development companies in the field of oncology.

The latest agreement for ThioBridge technology after extensive evaluation work provides further validation for the technology and has boosted market confidence that Abzena offers significant returns for investors.

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