# *Transforming Oncology Care*
# Through Medically Integrated Collaboration

## 2025 NCODA INTERNATIONAL SPRING FORUM

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# Antibody-Drug Conjugates and Bispecifics: A Guide for Oncology Pharmacy Technicians

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# DISCLOSURES

The following relevant financial relationships from the past 24 months have been identified and disclosed for the following faculty and planners of this CE activity:

- C. Brooke Adams, PharmD, BCOP
  - Advisory board member for Johnson and Johnson and Genmab
  - Consultant for Bristol-Myers Squibb
  - Speaker for Pfizer

No relevant financial relationships from the past 24 months have been identified for the following planners of this CE activity:

- Tahsin Imam, PharmD
- Daisy Doan, PharmD
- Taryn Newsome, CPhT

# OBJECTIVES

1. Review the mechanisms of action and federal drug administration (FDA) approvals for antibody-drug conjugates (ADCs) and bispecifics used in hematology/oncology.

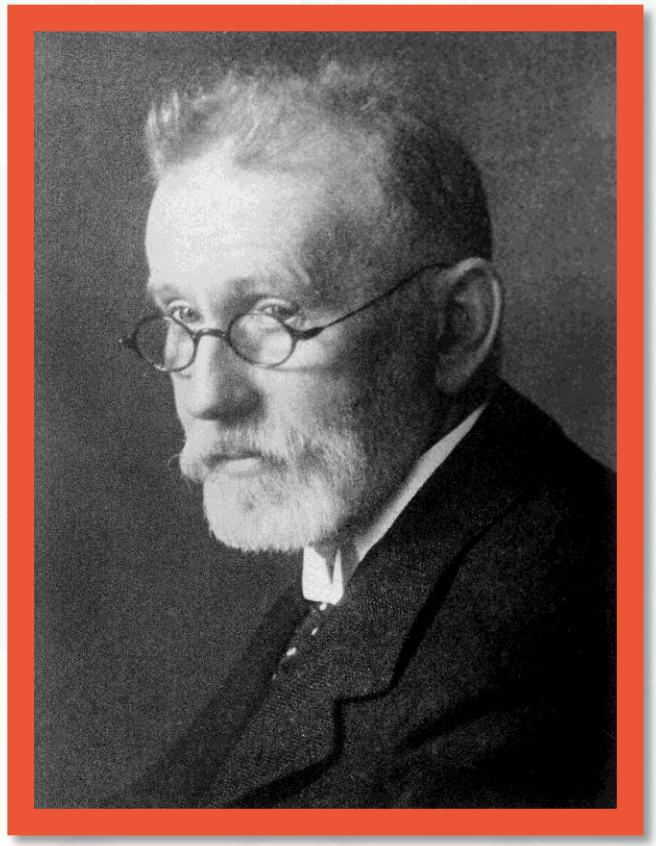
2. Discuss common adverse events and management strategies for ADCs and bispecifics.

3. Identify emerging ADCs and bi-specifics in the pipeline.

4. Summarize strategies to increase patients' access to ADCs and bispecifics.

# Introduction to ADCs

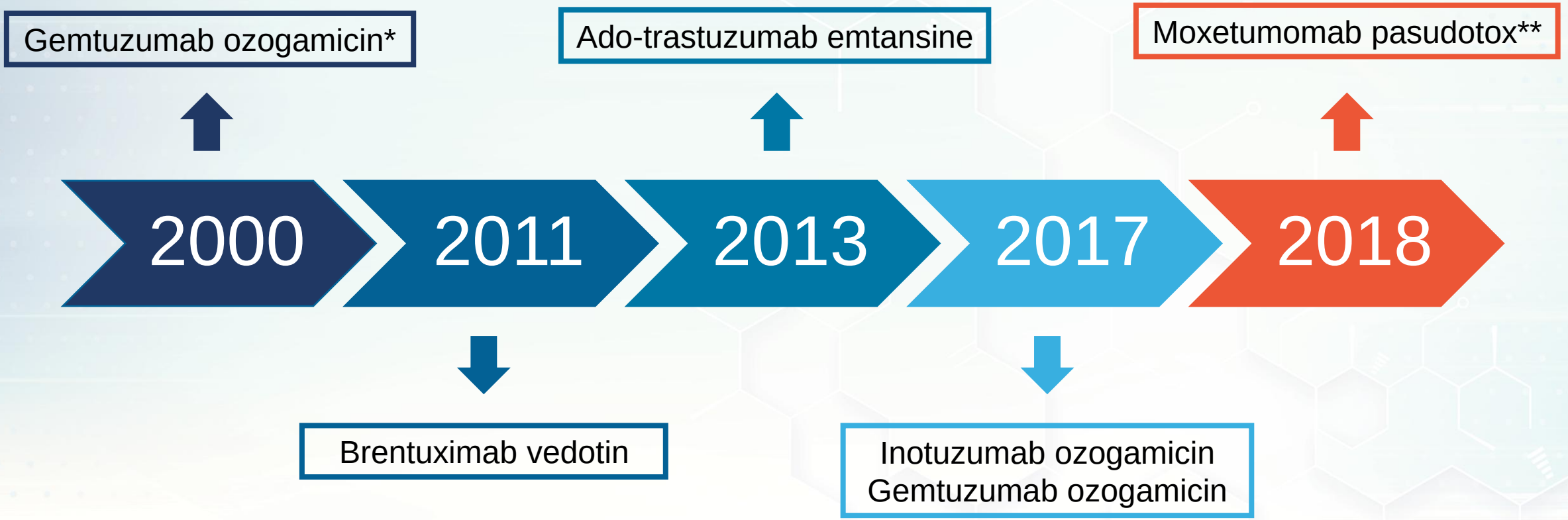
- ADC research has been conducted for more than a century.
- Paul Ehrlich first introduced the concept of the "magic bullet" in 1913.
- In 1997, the first monoclonal antibody, rituximab was FDA approved.
- In 2000, the first ADC came to market.



Dr. Paul Ehrlich

Strebhardt K, et al. Nat Rev Cancer 2008 (8): 473-480.

# ADCs FDA Approvals




*Removed from the market in 2010; **Removed from the market in 2023

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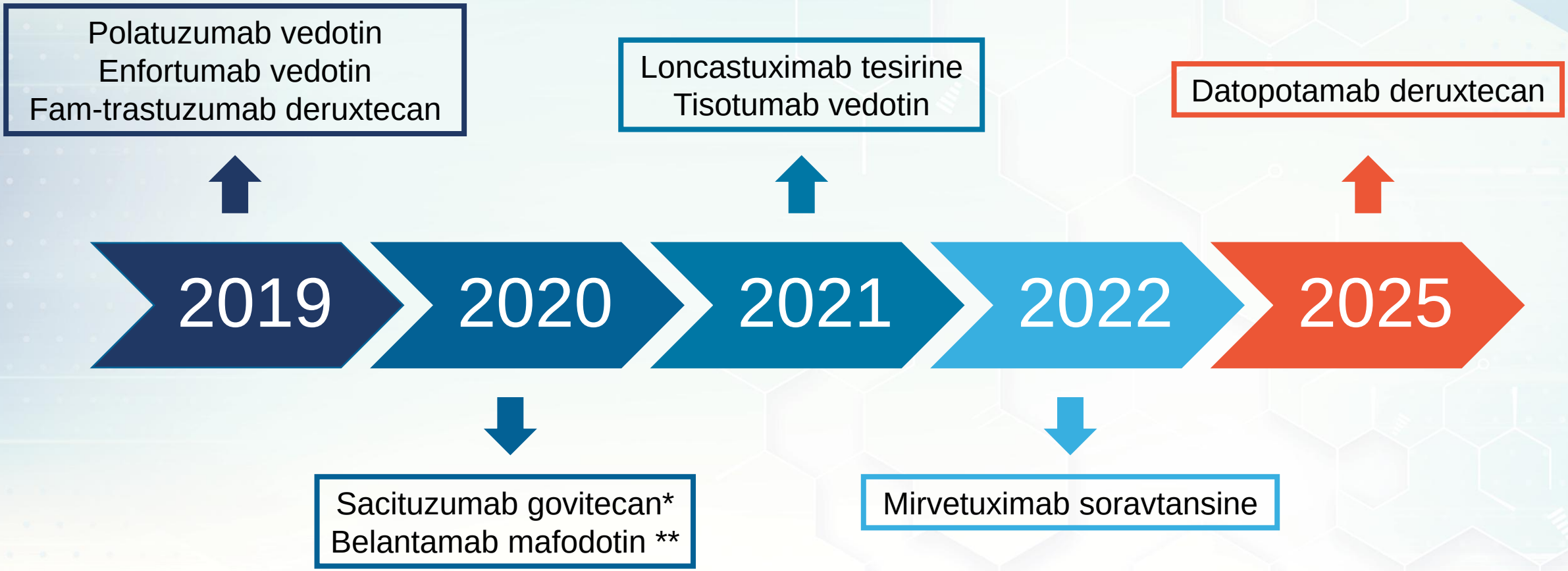
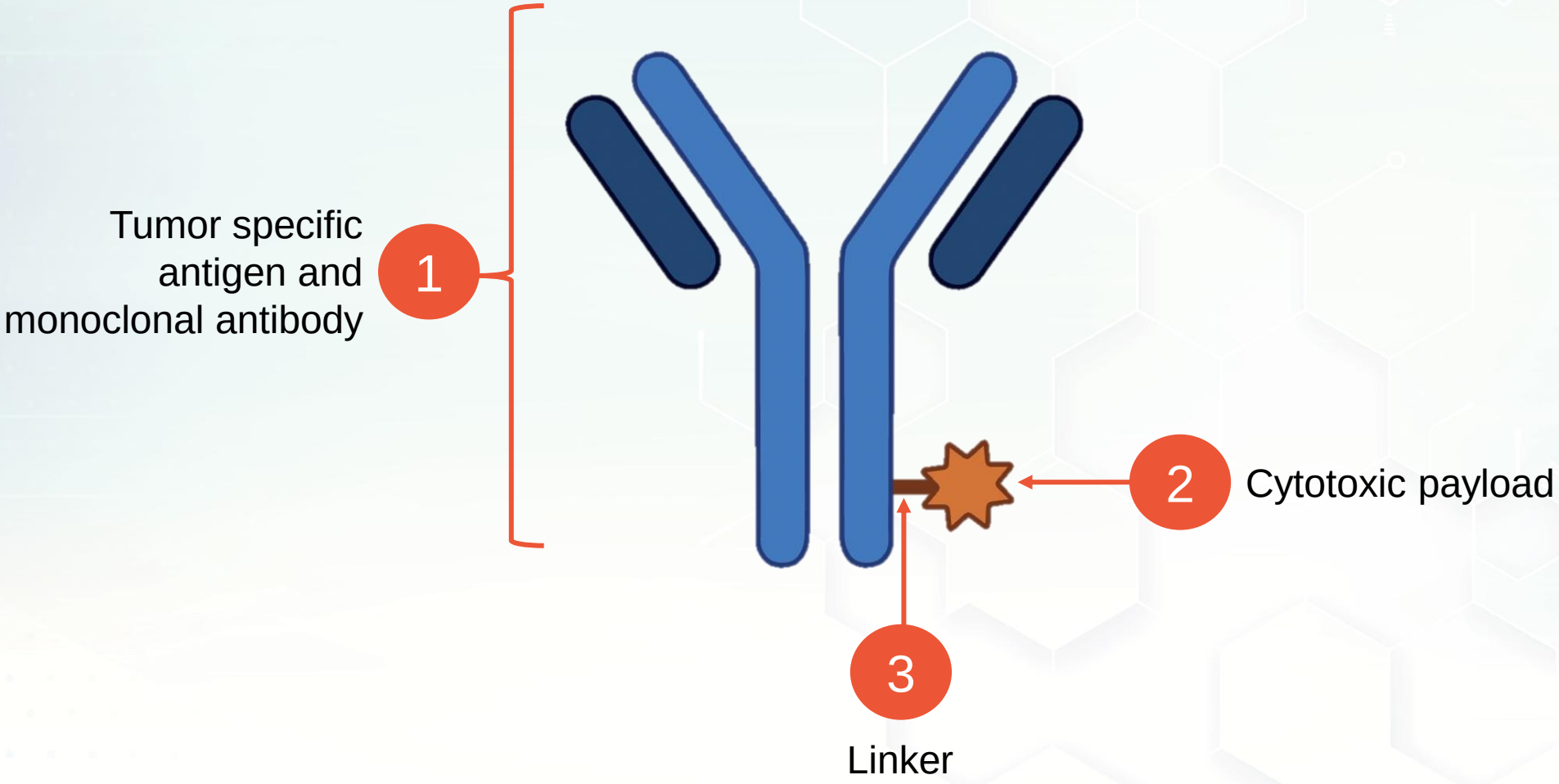
# ADCs FDA Approvals Continued



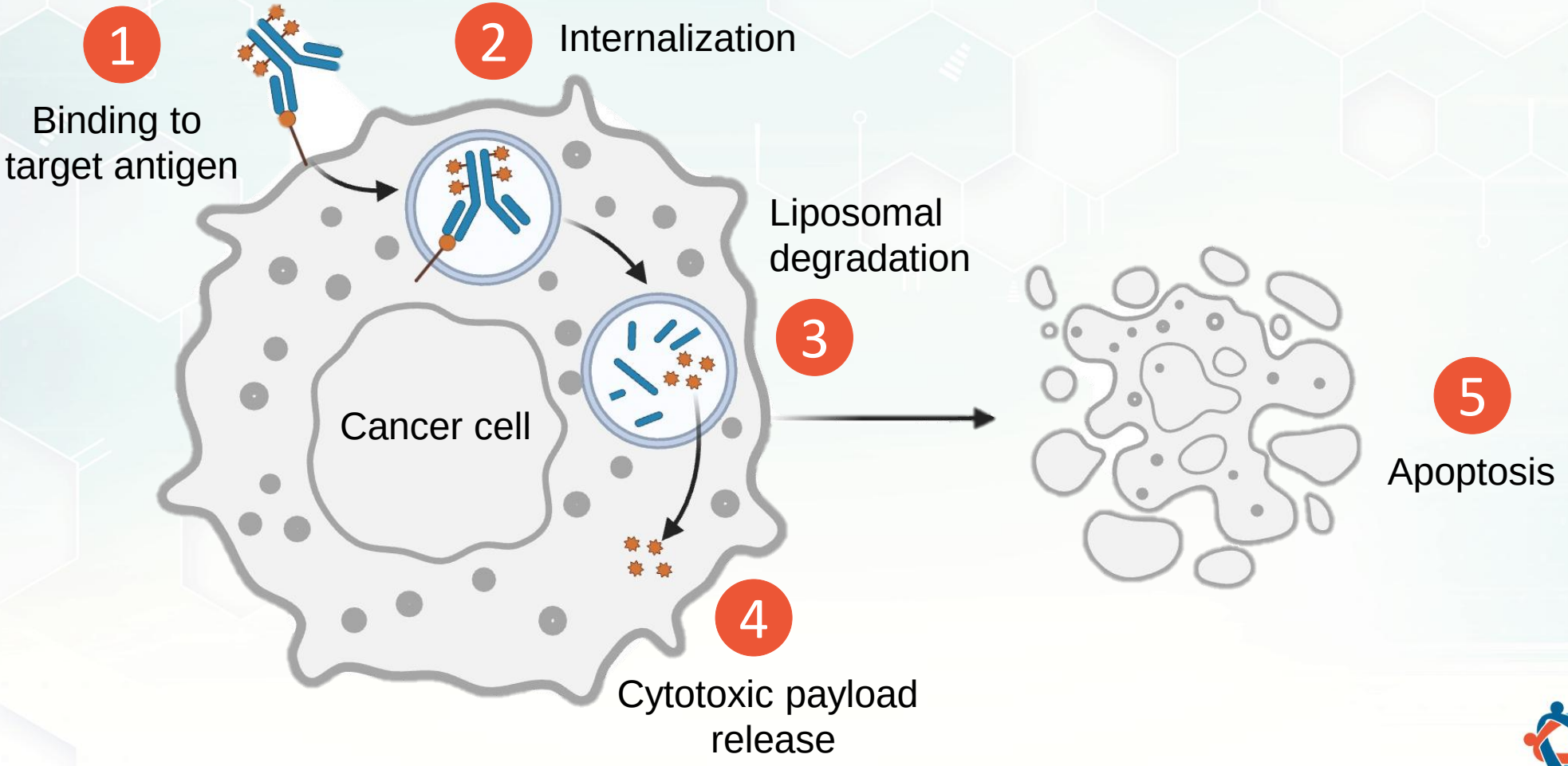

* Removed from the market in 2024; **Removed from the market in 2022

# The Design of ADCs




Chau CH, et al. The Lancet. 2019; 394 (10200): 793-804. Made in ©BioRender - biorender.com

# ADCs Mechanism of Action




Chau CH, et al. The Lancet. 2019; 394 (10200): 793-804. Made in ©BioRender - biorender.com.

# Cytotoxic Payloads


Conilh L, et la. J Hematol Oncol. 2023; 16 (3):1-28.

# Toxicity Mechanisms

## On-target toxicity

- ADC binding to the targeted cell surface protein on healthy cells

## Off-target toxicity

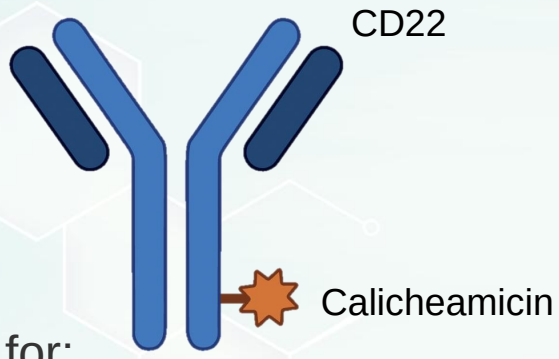
- Payload distribution to non-targeted healthy cells

Nguyen TD, Bordeau BM, Balthasar JP. Cancers (Basel). 2023 Jan 24;15(3):713.

# ADCs in Acute Leukemias

## B-cell Acute Lymphoblastic Leukemia (ALL)

### Inotuzumab ozogamicin

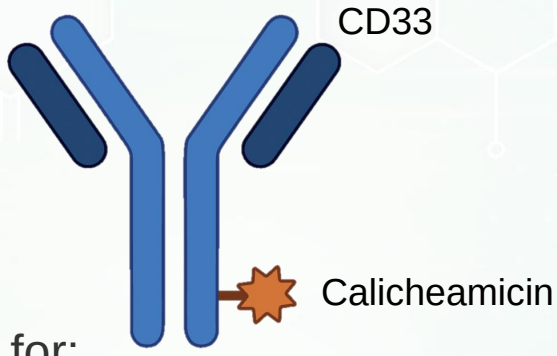



FDA approved for:

- Relapsed or refractory B-cell ALL in adults (2017) and patients ≥ 1 year of age (2024)

## Acute Myeloid Leukemia (AML)

### Gemtuzumab ozogamicin




FDA approved for:

- Relapsed or refractory AML in patents 2 years and older (2017)
- Newly-diagnosed CD33-positive AML in combination with chemotherapy in adults (2017) and patients 1 month and older (2020)

Key adverse events: myelosuppression 49-64% (calicheamicin), infusion related reactions 2% (calicheamicin), and hepatotoxicity including veno-occlusive disease 5-14% (calicheamicin)

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Besponsa. Prescribing Information. Pfizer; March 2024; Mylotarg. Prescribing Information. Pfizer; August 2021

# ADCs in Breast Cancer

## Metastatic Breast Cancer

### Ado-trastuzumab emtansine

FDA approved for human epidermal growth factor receptor 2 (HER2)-positive, metastatic breast cancer patients who previously received trastuzumab and a taxane, separately or in combination and have received prior therapy for metastatic disease or progressed within 6 months of completing adjuvant therapy (2013).

### Fam-trastuzumab deruxtecan

FDA approved for HER2-positive, metastatic or unresectable breast cancer, who have received a prior chemotherapy in the metastatic setting; or developed disease recurrence during or within 6 months of completing adjuvant chemotherapy (2019).

### Datopotamab deruxtecan

FDA approved for adult patients with unresectable or metastatic hormone receptor (HR)-positive, HER2-negative breast cancer who have received prior endocrine-based therapy and chemotherapy for unresectable or metastatic disease (2025).

Kadcyla. Prescribing Information. Genentech; February 2022; Enhertu. Prescribing Information. Daiichi-Sankya and AztraZeneca; January 2025; Datroway. Prescribing Information. AztraZeneca. January 2025.

# ADCs in Breast Cancer

## Early Breast Cancer

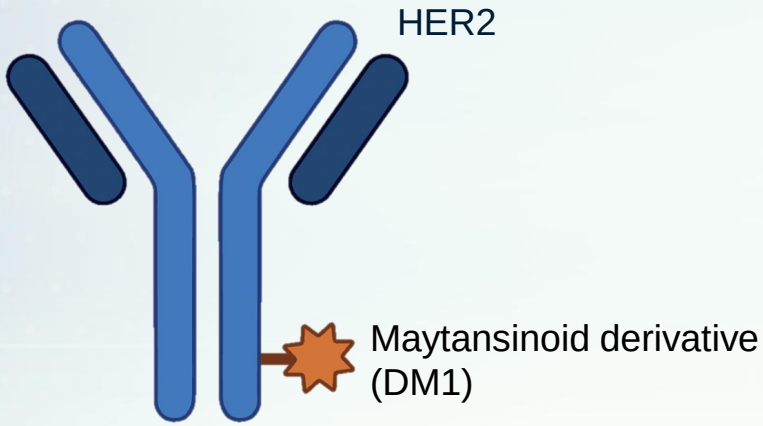
## Ado-trastuzumab emtansine

FDA approved for the adjuvant treatment of patients with HER2-positive early breast cancer who have residual invasive disease after neoadjuvant taxane and trastuzumab-based treatment (2019).

Kadcyla. Prescribing Information. Genentech; February 2022

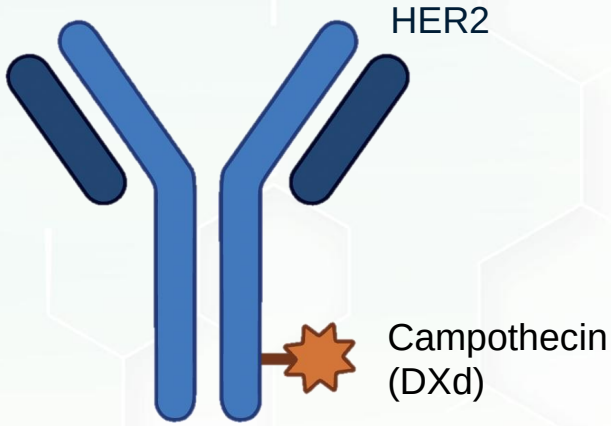
# ADCs in Breast Cancer

## Ado-trastuzumab emtansine



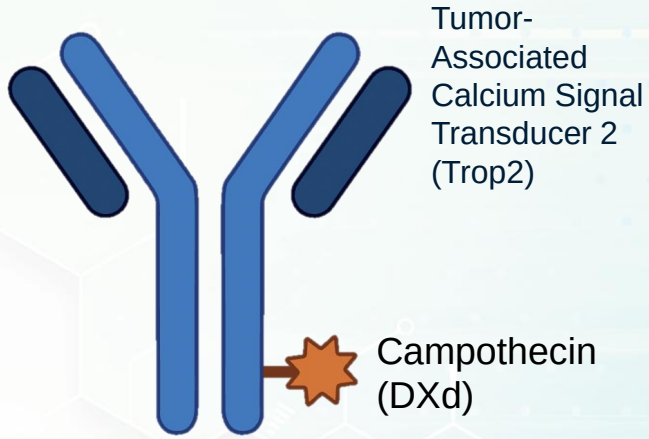

Key adverse events: peripheral neuropathy 32% (DM1), myelosuppression 31% (DM1), cardiotoxicity 22% (HER2), and pneumonitis 1.1% (HER2)

## Fam-trastuzumab deruxtecan




Key adverse events: moderate-high emetogenicity (DXd), myelosuppression 72% (DXd) cardiotoxicity 8% (HER2), and pneumonitis 12% (HER2)

## Datopotamab deruxtecan




Key adverse events: moderate emetogenicity (DXd), myelosuppression 41% (DXd), ocular toxicity 51% (trop2), skin toxicity 19% (trop2), and stomatitis 59% (trop2)

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Kadcyla. Prescribing Information. Genentech; February 2022; Enhertu. Prescribing Information. Daiichi-Sankya and AztraZeneca; January 2025; Datroway. Prescribing Information. AztraZeneca. January 2025.

# ADCs in Lymphoma

## Large B-cell Lymphoma (LBCL)

### Loncastuximab tesirine

FDA approved for adult patients with relapsed or refractory (R/R) LBCL after 2 prior lines of systemic therapy (2021).

### Brentuximab vedotin

FDA approved for adults under brentuximab vedotin in combination with lenalidomide and rituximab for R/R LBCL after 2 prior lines of systemic therapy and ineligible for an autologous stem cell transplant or chimeric antigen receptor T-cell therapy (2025).

### Polatuzumab vedotin

FDA approved for adult patients in combination with rituximab, cyclophosphamide, doxorubicin, prednisone (R-CHP) for newly diagnosed LBCL (2023) and adult patients with R/R LBCL in combination with bendamustine, rituximab (BR) that have failed 2 prior line of systemic therapy (2019).

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Polivy. Prescribing Information. Genentech; April 2023; Zynlonta. Prescribing Information. ADC Therapeutics. October 2022; Adcetris. Prescribing Information. Seagen Inc., a subsidiary of Pfizer; February 2025.

# ADCs in Lymphoma

## Classical Hodgkin Lymphoma (cHL)

### Brentuximab vedotin

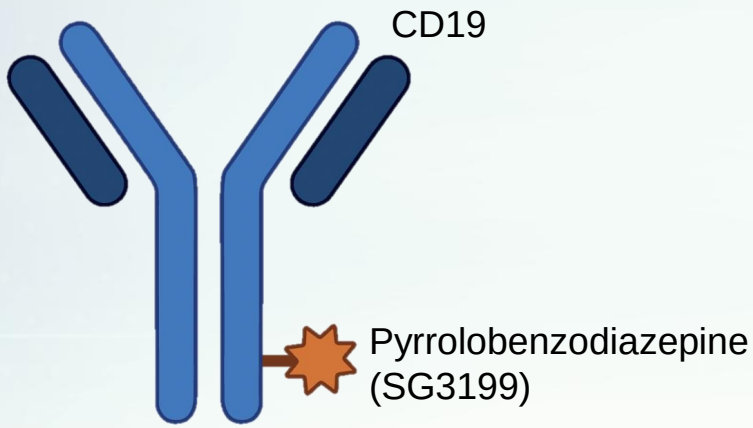
FDA approved for:

- Newly diagnosed cHL adult patients with stage III or IV disease in combination with doxorubicin, vinblastine, and dacarbazine (2018).
- Newly diagnosed high risk cHL pediatric patients 2 years and older in combination with doxorubicin, vincristine, etoposide, prednisone, and cyclophosphamide (2022).
- Maintenance after auto-HCT for high-risk adult patients (2015).
- Adult patients with R/R cHL after failure of auto-HCT or at least two prior multi-agent chemotherapy regimens in patients who are not auto-HCT candidates (2011).

Adcetris. Prescribing Information. Seagen Inc., a subsidiary of Pfizer; February 2025.

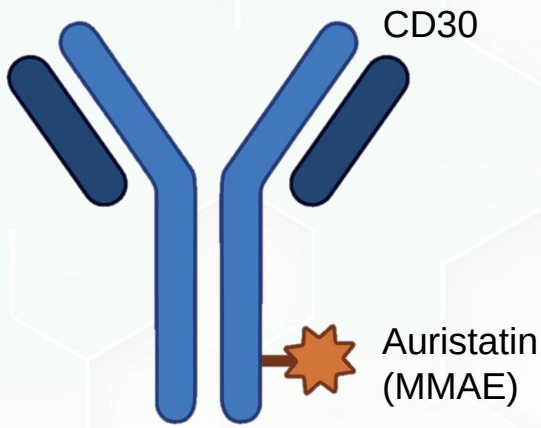
# ADCs in Lymphoma Continued

## Loncastuximab tesirine

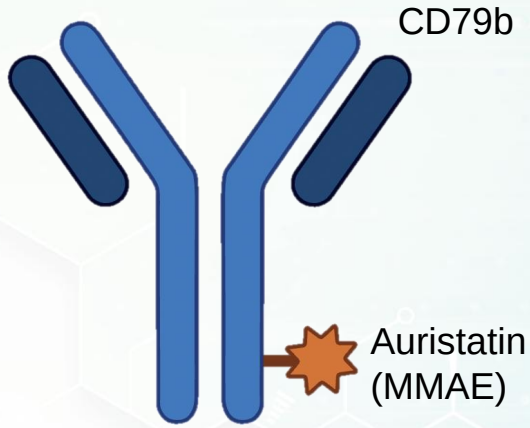



Key adverse events: fluid retention 20% (SG3199), skin and nail reactions 30% (SG3199)

## Brentuximab vedotin




## Polatuzumab vedotin




Key adverse events: peripheral neuropathy 20-30% (MMAE), myelosuppression 37-46% (MMAE)

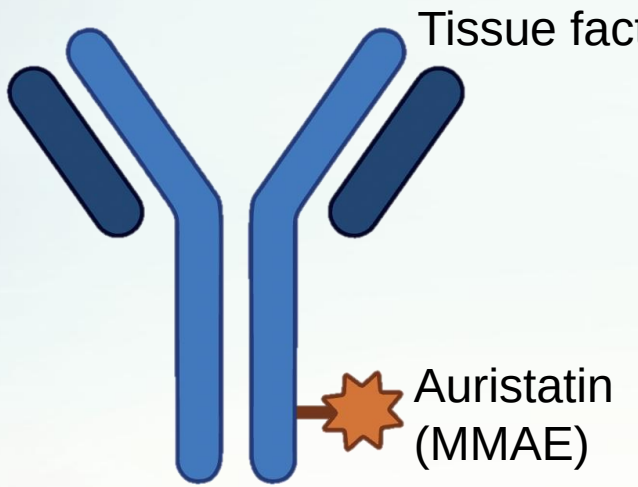


Polivy. Prescribing Information. Genentech; April 2023; Zynlonta. Prescribing Information. ADC Therapeutics. October 2022; Adcetris. Prescribing Information. Seagen Inc., a subsidiary of Pfizer; February 2025.

# ADC in Cervical Cancer

## Tisotumab vedotin

FDA approved for recurrent or metastatic cervical cancer with disease progression on or after chemotherapy (2021).




Key adverse events:

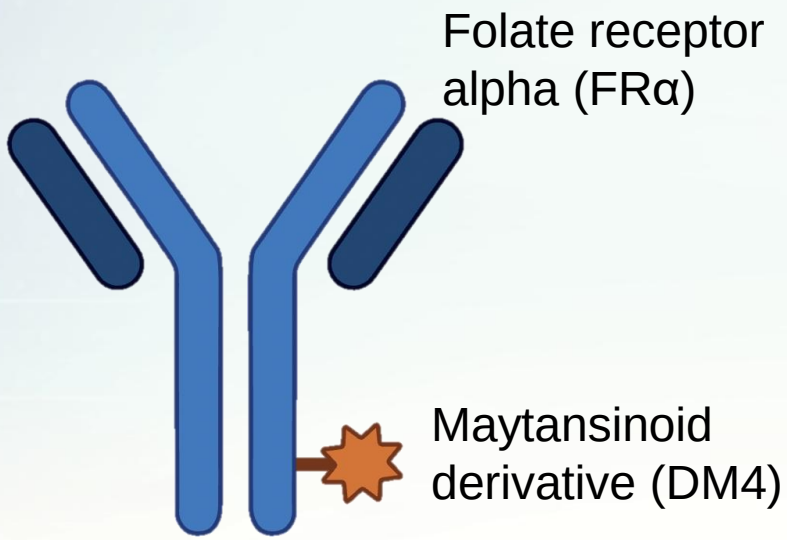
- Peripheral neuropathy 39% (MMAE)
- Myelosuppression 16% (MMAE)
- Ocular toxicity including dry eye, keratitis, blurry vision, and excessive lacrimation 55% (TF)
- Cutaneous reactions including skin rashes, Stevens-Johnson syndrome and toxic epidermal necrolysis 17% (TF)

Tivdak. Prescribing Information. Pfizer and Genmab; April 2024

# ADC in Ovarian Cancer

## Mirvetuximab soravtansine

FDA approved for adult patients with FRα positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have received 1-3 systemic treatment regimens (2024).




Key adverse events:

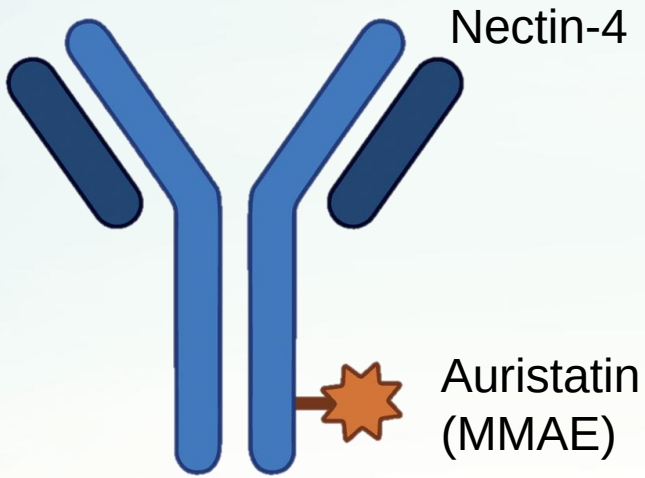
- Moderate emetogenicity (DM4)
- Peripheral neuropathy 36% (DM4)
- Myelosuppression 22% (DM4)
- Ocular toxicity including dry eye, keratitis, blurry vision, and excessive lacrimation 59% (FRα)

Elahere. Prescribing Information. AbbVie; October 2024

# ADC in Bladder Cancer

## Enfortumab vedotin

FDA approved in combination with pembrolizumab for patients with locally advanced or metastatic urothelial cancer who are ineligible for cisplatin-containing chemotherapy (2019).




Key adverse events:

- Peripheral neuropathy 50% (MMAE)
- Myelosuppression (MMAE)
- Ocular toxicity including dry eye, keratitis, blurry vision, and excessive lacrimation 24% (nectin-4)
- Cutaneous reactions including skin rashes, Stevens-Johnson syndrome and toxic epidermal necrolysis 54% (nectin-4)
- Dysgeusia 26% (nectin-4)



Padcev. Prescribing Information. Astellas and Pfizer; August 2024

# QUESTION 1

Which of the following would be an **on-target** toxicity of an ADC?

a) MMAE causing peripheral neuropathy

b) Binding to HER2 on the heart leading to heart failure

c) DM4 causing nausea and vomiting

d) SG3119 causing fluid retention

# Strategies to Prevent Toxicity

## Ocular toxicity

- Baseline ophthalmologic exam then as needed/recommended
- Lubricant eye drops QID
- Corticosteroid and vasoconstrictor eye drops prior to infusion
- Cooling eye pads
- Avoid contact lenses
- Dose reduce or hold therapy based on severity

## Dermatologic toxicity

- Early intervention with topical or systemic corticosteroids.
- Dose reduce or hold therapy based on severity

## Peripheral neuropathy

- Monitoring prior to each dose
- Dose reduce and hold therapy based on severity

## Cardiotoxicity

- Baseline echocardiogram (ECHO) then as needed

## Veno-occlusive disease

- Ursodiol prophylaxis
- Liver function monitoring

## Infusion-related reactions

- Pre-medications 30-60 minutes prior to the infusion

Nguyen TD, Bordeau BM, Balthasar JP. Cancers (Basel). 2023 Jan 24;15(3):713.

# ADCs in the Pipeline

| ADC | Target | Payload | Most advance clinical phase | Disease |
|---|---|---|---|---|
| Telisotuzumab adizutecan | c-MET | adizutecan | II | Metastatic colorectal cancer |
| ARX517 | PSMA | amberstatin-269 | II | Metastatic prostate cancer |
| CMG901 | Claudin 18.2 | MMAE | II | Metastatic gastroesophageal and biliary cancers |
| AZD8205 | B7-H4 | TOP1i | II | Advanced breast biliary, ovarian, endometrial, and squamous non-small cell lung cancers |
| CX-2051 | EpCAM | CAMP59 | I | Advanced solid tumors |
| IBI3009 | DLL3 | TOP1i | I | Metastatic SCLC |

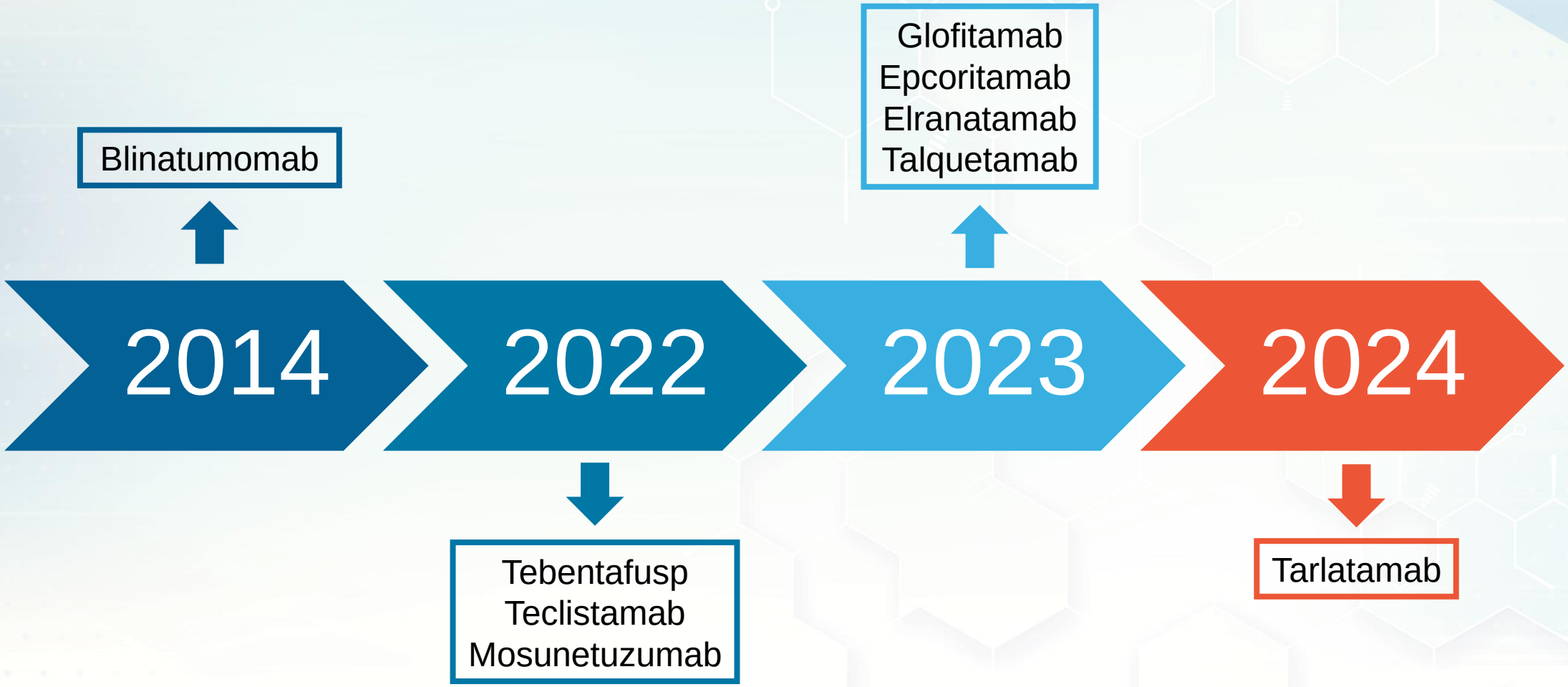
MET, mesenchymal-epithelial transition factor receptor; PSMA, prostate-specific membrane antigen; EpCAM, epithelial cell adhesion molecule; DLL3, delta-like Ligand 3; TOP1i, Top1 inhibitor 1

# Introduction to Bi-specifics

| Bi-specific antibodies (BsAbs) | Bi-specific T-cell Engagers (BTCEs) |
| --- | --- |
| • Antibody that binds to two different targets | • Binds to surface tumor antigen on malignant cell and CD3 on T-cell |

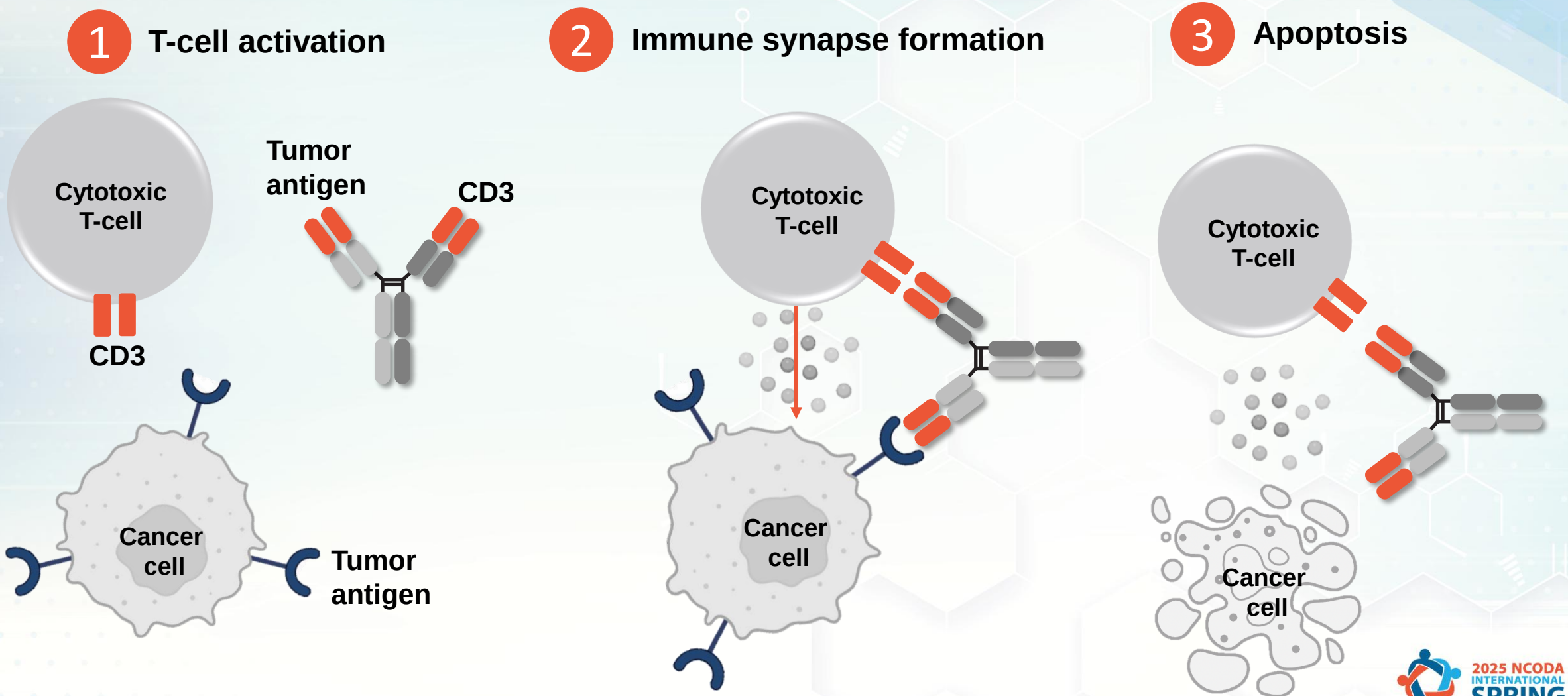
Spiess C et al. Mol Immunol. 2015;67(2 Pt A):95-106

# BTCE FDA Approvals




Herrera M, et al. *Trends in Cancer.* 2024;10(10):893-919.

# BTCE Mechanism of action

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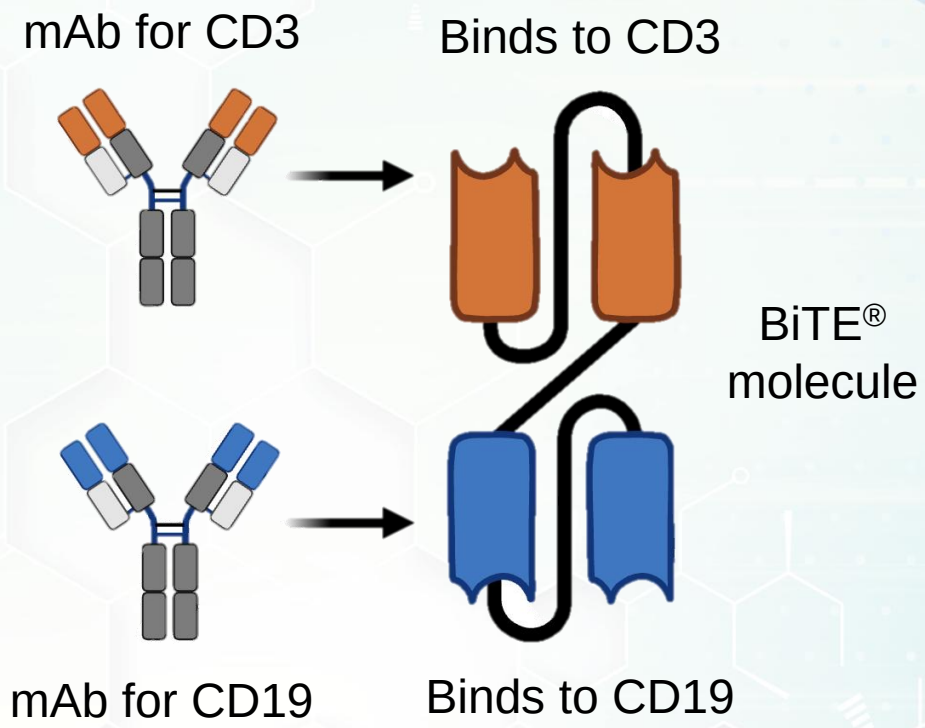
# BTCE in B-cell Acute Lymphoblastic Leukemia

## Blinatumomab

FDA approved for those ≥ 1 month with:

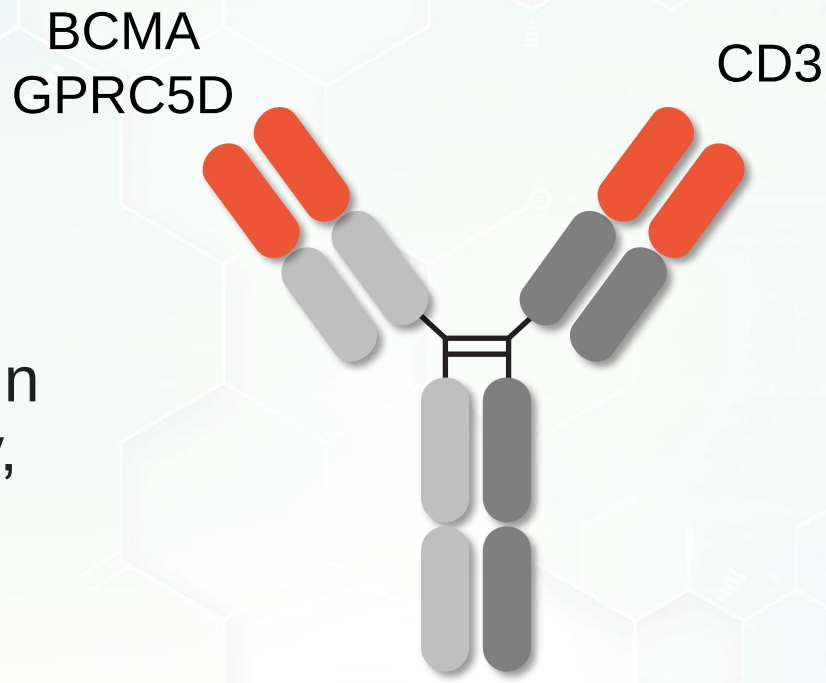
- Relapsed or refractory CD19-positive B-cell ALL (2014)
- CD19-positive B-cell acute lymphoblastic leukemia (ALL) in first or second complete remission with minimal residual disease (MRD) greater than or equal to 0.1% (2018)
- CD19-positive Philadelphia chromosome-negative B-cell ALL in the consolidation phase of multiphase chemotherapy (2024)




Blincyto. Prescribing Information. Amgen; December 2024. Made in ©BioRender - biorender.com

# BTCE in Multiple Myeloma (MM)

- Teclistamab, Elranatamab — BCMA
- Talquetamab — GPRC5D




FDA approved for relapsed or refractory MM in adults who have received ≥4 lines of therapy, including a proteasome inhibitor, an immunomodulatory drug, and an anti-CD38 monoclonal antibody (teclistamab: 2023; elranatamab and talquetamab: 2024).

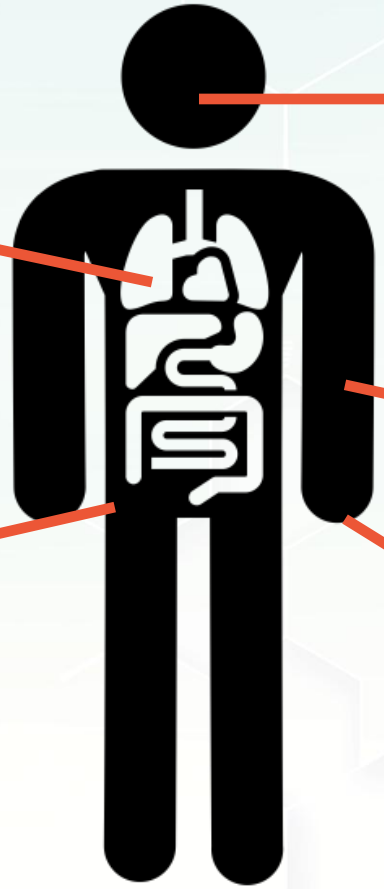
BCMA: B-cell maturation antigen; GPRC5D: G protein - coupled receptor, class C, group 5, member D

Tecvayli. Package Insert. Janssen. November 2024; Talvey. Package Insert. Janssen. August 2023; Elrexfio. Package Insert. Pfizer. August 2023.

# GPRC5D Expression

Variable expression in the **lungs**

**Plasma cells**



Hard **keratinized** tissue of the tongue and **plasma cells** in the salivary glands and tonsils

**Keratin**-expressing hair follicles

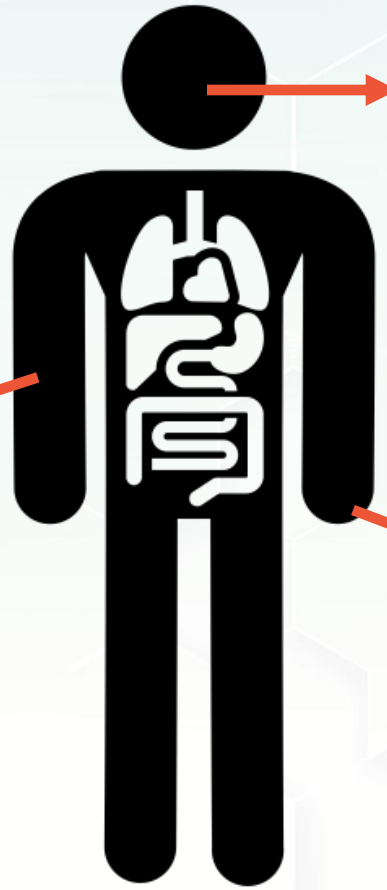
**Keratogenous** zone of the nail

Smith EL, et al. Sci Transl Med. 2019;11(485):eaau7746.

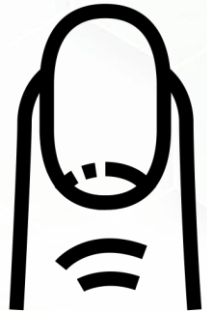
# Side Effects of Interest

**Skin Toxicity: Rash (38%)**
Median time to onset: 21 days (5-250)
61.8% of events resolved
Median event duration: 17 days (2-350)

**Skin Toxicity: Non-rash (30%)**
Median time to onset: 24 days (3-384)
46% of events resolved
Median event duration: 39 days (1-218)



**Oral Toxicity: Dysgeusia (49%)**
Median time to onset: 13.5 days (1-350)
Median event duration: 47.5 days (4-382)



**Nail Toxicity (50%)**
Median time to onset: 50.5 days (6-316)
Median event duration: 74 days (15-247)

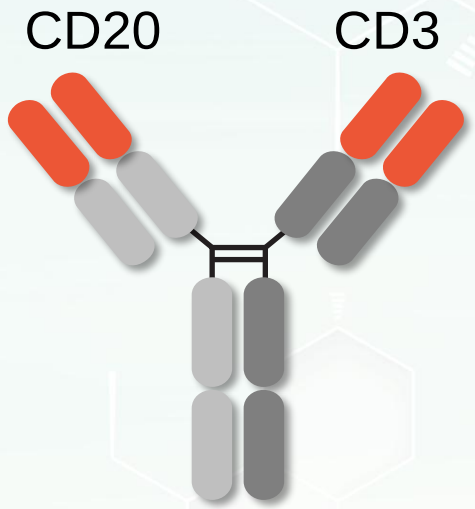
Char A, et al. N Engl J Med. 2022;387(24):2232-2244.

# BTCE in Lymphoma

**Large B-cell Lymphoma**

Glofitamab (2023)

Epcoritamab (2023)




**Follicular Lymphoma**

Mosunetuzumab (2022)

Epcoritamab (2024)

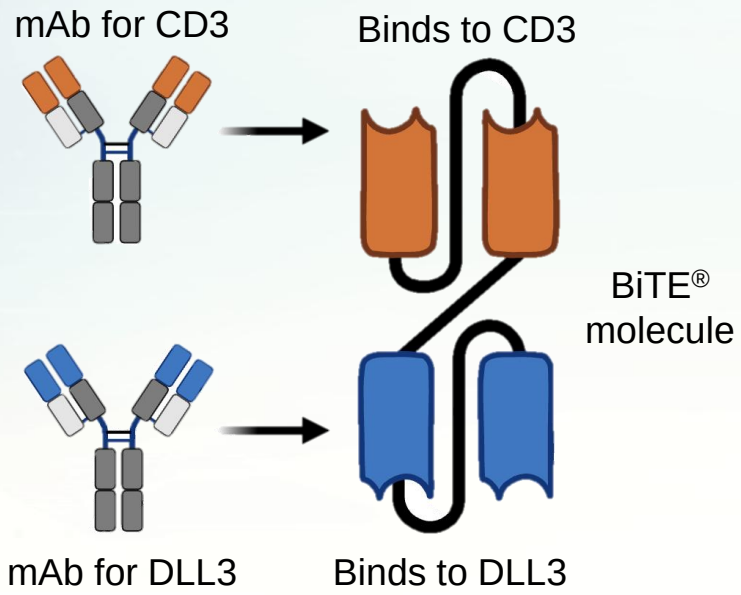
FDA approved for released or refractory disease after 2 or more lines of systemic therapy.

Columvi. Package Insert. Genentech. June 2023; Epkinly. Package Insert. Genmab. August 2024; Lunsumio. Package Insert. Genentech. November 2024.

# BTCEs in Solid Tumors

## Tarlatamab

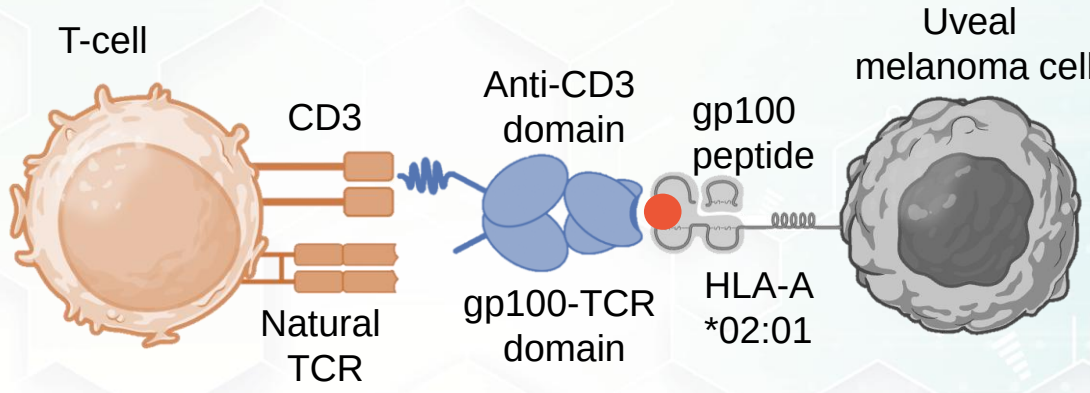
FDA approved for extensive stage -SCLC with disease progression on or after platinum-based chemotherapy (2024).




## Tebentafusp

FDA approved for HLA-A*02:01-positive adult patients with unresectable or metastatic uveal melanoma (2022).

Key adverse events: hair discoloration 20% (gp100), and rash 83% (gp100)




mAb, monoclonal antibody; gp100, glycoprotein 100; TCR, t-cell receptor; HLA, human leukocyte antigen

Imdelltra. Prescribing Information. Amgen; May 2024; Kimmtrack. Prescribing Information. Immunocore. November 2022; Made in ©BioRender - biorender.com

# Key BTCE Adverse Events

Cytokine release syndrome (CRS)

Neurotoxicity including immune-effector cell neurotoxicity syndrome (ICANS)

Strategies to prevent CRS and ICANS:

- Step-up dosing
  - Hospitalization commonly required based on dose and product
  - Outpatient dosing with close monitoring may be considered
- Pre-medications
  - Commonly dexamethasone, acetaminophen, and diphenhydramine

van de Donk NWCJ, Zweegman S. Lancet. 2023;402(10396):142-158.

# CRS Clinical Presentation

**Brain:** headache, confusion, hallucinations, delirium, aphasia, paresis, seizures, ataxia dysphagia

**Blood and vasculature:** cytopenias, coagulopathy, disseminated intravascular coagulation (DIC), capillary leak, fever

**Heart:** Tachycardia, hypotension, troponin elevation, arrhythmia, QT prolongation, stress cardiomyopathy, acute heart failure

**Liver:** Hepatomegaly, elevated liver enzymes, hypofibrinogeniemia, liver failure

**Colon:** diarrhea

**Lungs:** tachypnea, hypoxia, pulmonary edema, respiratory failure

**Spleen:** splenomegaly

**Stomach:** nausea and vomiting

**Kidneys:** acute kidney injury, renal failure

**Joints, muscles, and skin:** myalgia, arthralgia, rigor, rash, and edema

Shimabukuro-Vornhagen A, et al. J Immunother Cancer. 2018;6(1):56.

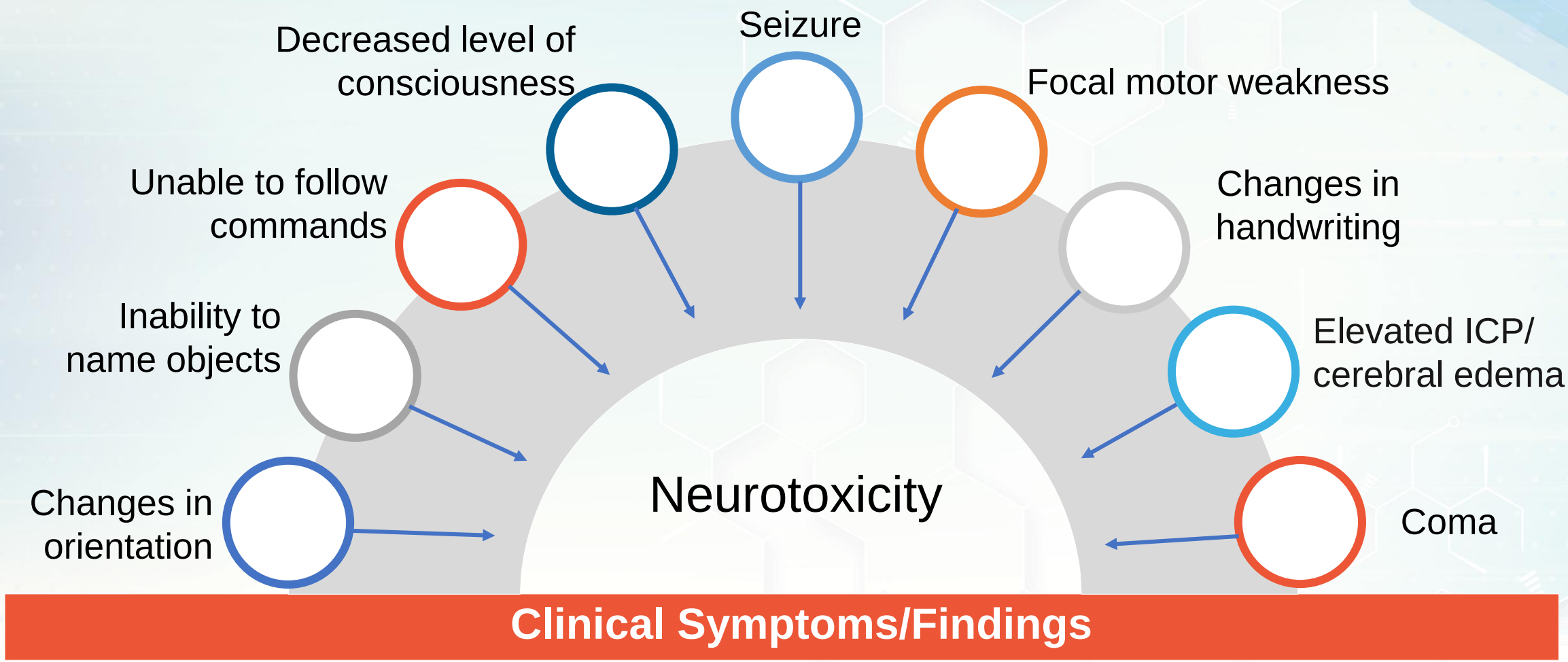
# ASTCT Consensus CRS Grading

| CRS Parameter | Grade 1 | Grade 2 | Grade 3 | Grade 4 |
|---|---|---|---|---|
| Fever | Temperature ≥38°C | | | |
| | WITH | | | |
| Hypotension | None | Not requiring vasopressors | Requiring a vasopressor with or without vasopressin | Requiring multiple vasopressors (excluding vasopressin) |
| | AND/OR | | | |
| Hypoxemia | None | Requiring low-flow nasal cannula or blow-by (6L/minute or less) | Requiring high-flow nasal cannula, facemask, nonrebreather mask, or Venturi mask (> 6L/minute) | Requiring positive pressure (CPAP, BiPAP, intubation and mechanical ventilation) |

CPAP, continuous positive airway pressure; BiPAP, bilevel positive airway pressure

Lee DW, et al. *Biol Blood and Marrow Transplantation* 2019;25(4):625-638.

# Neurotoxicity Clinical Presentation




ICP, intracranial pressure

Lee DW. *Biol Blood Marrow Transplant*. 2019;25:625-638

# ASTCT ICE Scoring Tool

The ICE score (10-point scale) can measure subtle changes in cognition by evaluating orientation, attention, writing, and language.

| Assess | Orientation | Naming | Following commands | Writing | Attention |
|---|---|---|---|---|---|
| **Task** | Oriented to year, month, city, hospital | Name 3 objects (eg, point to clock, pen, button) | Eg, “show me 2 fingers” or “close your eyes and stick out your tongue” | Ability to write a standard sentence | Count backward from 100 by 10 |
| **Points assigned** | 4 | 3 | 1 | 1 | 1 |

| Grade 1 | Grade 2 | Grade 3 | Grade 4 |
|---|---|---|---|
| 7-9 | 3-6 | 0-2 | 0 (unarousable) |

2025 NCODA INTERNATIONAL SPRING FORUM

Lee DW, et al. *Biol Blood and Marrow Transplantation* 2019;25(4):625-638.

# ASTCT Consensus ICANS Grading (Adults)

| Neurotoxicity Domain | Grade 1 | Grade 2 | Grade 3 | Grade 4 |
|---|---|---|---|---|
| ICE Score | 7-9 | 3-6 | 0-2 | 0 (unarousable) |
| Level of consciousness | Awakens spontaneously | Awakens to voice | Awakens only to tactile stimulus | Unarousable or requires vigorous or repetitive tactile stimuli to arouse. Stupor or coma. |
| Seizure | N/A | N/A | Any clinical seizure focal or generalized that resolves rapidly or nonconvulsive seizures on electroencephalogram that resolve with intervention. | Life-threatening prolonged seizure (>5 min); or repetitive clinical or electrical seizures without return to baseline in between. |
| Motor Findings | N/A | N/A | N/A | Deep focal motor weakness such as hemiparesis or paraparesis. |
| Elevated Intracranial pressure/cerebral edema | N/A | N/A | Focal/local edema on neuroimaging | Diffuse cerebral edema on neuroimaging; decerebrate or decorticate posturing; or cranial nerve VI palsy; or papilledema; or Cushing's triad. |

Lee DW, et al. *Biol Blood and Marrow Transplantation* 2019;25(4):625-638.

# Risk Evaluation and Mitigation Strategies (REMS) Certification

## REMS requirements for Prescribers

### Online training and enrollment

- Review the following materials:
  - Prescribing Information
  - Prescriber Training Program
  - Adverse Reaction Management Guide
- Successfully complete the Knowledge Assessment, and submit it to REMS
- Complete the Prescriber Enrollment Form, and submit it to REMS

### Patient counseling

Before treatment initiation (first step-up dose), counsel patients and/or their caregivers .Complete and provide patients or their caregivers with the Patient Wallet Card.

## REMS requirements for Pharmacies and Healthcare Settings

### Designation

Designate an **Authorized Representative** for the Pharmacy and Healthcare Setting.

### Online training and enrollment

**Authorized Representative** must review the Pharmacy and Healthcare Setting Training Program.

**Authorized Representative** must complete the Pharmacy and Healthcare Setting Enrollment Form and submit it to REMS.

### Staff training

Train all relevant staff involved in dispensing on the REMS requirements using the Pharmacy and Healthcare Setting Training Program.

Required for teclistamab, elranatamab, and talquetamab

# QUESTION 2

Which of the following is a common adverse event seen with **ALL** bi-specific T-cell engagers?

a) Hair loss

b) Weight loss

c) Taste changes

d) Cytokine release syndrome

# Institutional Considerations

- **Infrastructure & resources**
  - What is needed to implement a new therapy like BTCEs
  - Who are the key players involved in multidisciplinary team
  - What resources should be created and available to staff
  - What type of infrastructure and workflows are needed to provide these therapies

- **Formulary decisions**
  - How do you handle having multiple BCTEs with different indications
  - How do you prepare staff for the differences between products

- **Financial impact and considerations**
  - Site of care considerations
  - Chair time

# BCTEs in the Pipeline

| Bi-specific | Target | Most advance clinical phase | Disease |
|---|---|---|---|
| Catumaxomab | EpCAM x CD3 | III | Gastric, ovarian, bladder, malignant ascites, fallopian tube neoplasms, peritoneal neoplasms |
| Brenetafusp | PRAME x CD3 | III | Ovarian, uterine, melanoma, NSCLC, SCLC, breast |
| BNT-142 | Claudin-6 x CD3 | II | Ovarian, NSCLC, testicular |
| Cibisatamab | CEA x CD3 | II | NSCLC |
| CX-904 | EGFR x CD3 | I | Advanced solid tumors |
| EMB-07 | ROR1 x CD3 | I | Advanced solid tumors or relapsed/refractory lymphoma |

PRAME, Preferentially Expressed Antigen in Melanoma; CEA, carcinoembryonic antigen; EGFR, Epidermal Growth Factor Receptor; ROR1, receptor tyrosine kinase-like orphan receptor 1; NSCLC, non small cell lung cancer

# QUESTION 3

Which of the following therapies may pose an access issue in a rural community setting?

a) Tarlatamab

b) Brentuximab vedotin

c) Polatuzumab vedotin

d) Loncastuximab tesirine

# SUMMARY

- ADCs and BTCEs have changed the treatment paradigm for a number of hematological and solid tumor malignancies.
- BTCEs offer several advantages including decreased risk of adverse events, increased access, and improved patient convenience.
- BTCEs are not without unique challenges including logistical complexities especially in the community.
- ADCs and BTCEs are here to stay with hundreds in the pipeline.
- Pharmacy technicians play a critical role in the successful implementation of these therapies.

QUESTION & ANSWER

# Antibody-Drug Conjugates and Bi-specifics: A Guide for Oncology Pharmacy Technicians

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CE CODES

# Antibody-Drug Conjugates and Bi-specifics: A Guide for Oncology Pharmacy Technicians