

# 신약개발 글로벌 트렌드 분석 : Oncology

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## **I. Oncology market**

I-I. Global medicine market

I-II. Top 20 TA in global medicine market

I-III. Global Oncology market

I-V. Oncology market by cancer type

## **II. Oncology trends in 2021**

II-I. Novel Substances launched

II-II. Modality

## **III. Oncology deals in 2022**

III-I. Current global deals in first-half 2022

III-II. Antibody deals in 2022\_BsAb, ADC

# **I. Oncology Market**

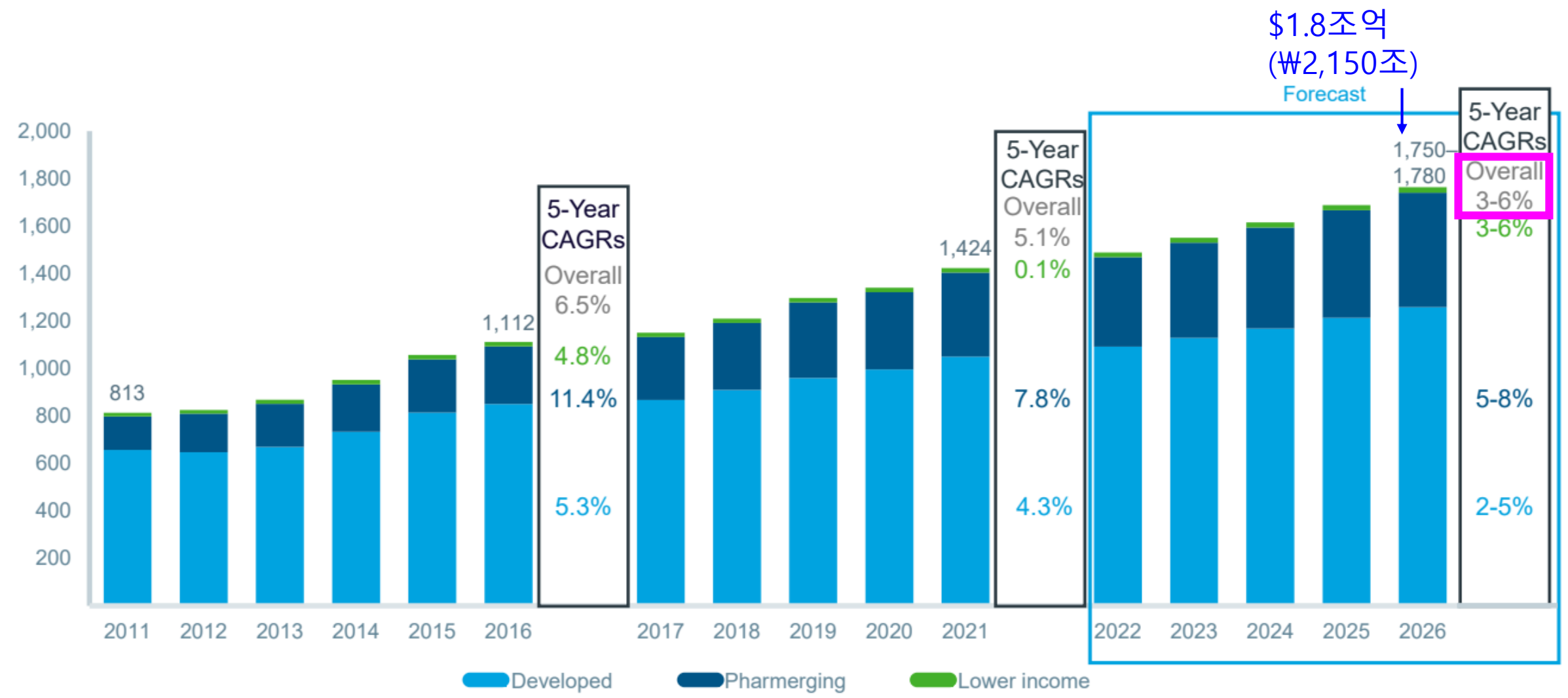
**I-I. Global medicine market**

**I-II. Top 20 TA in global medicine market**

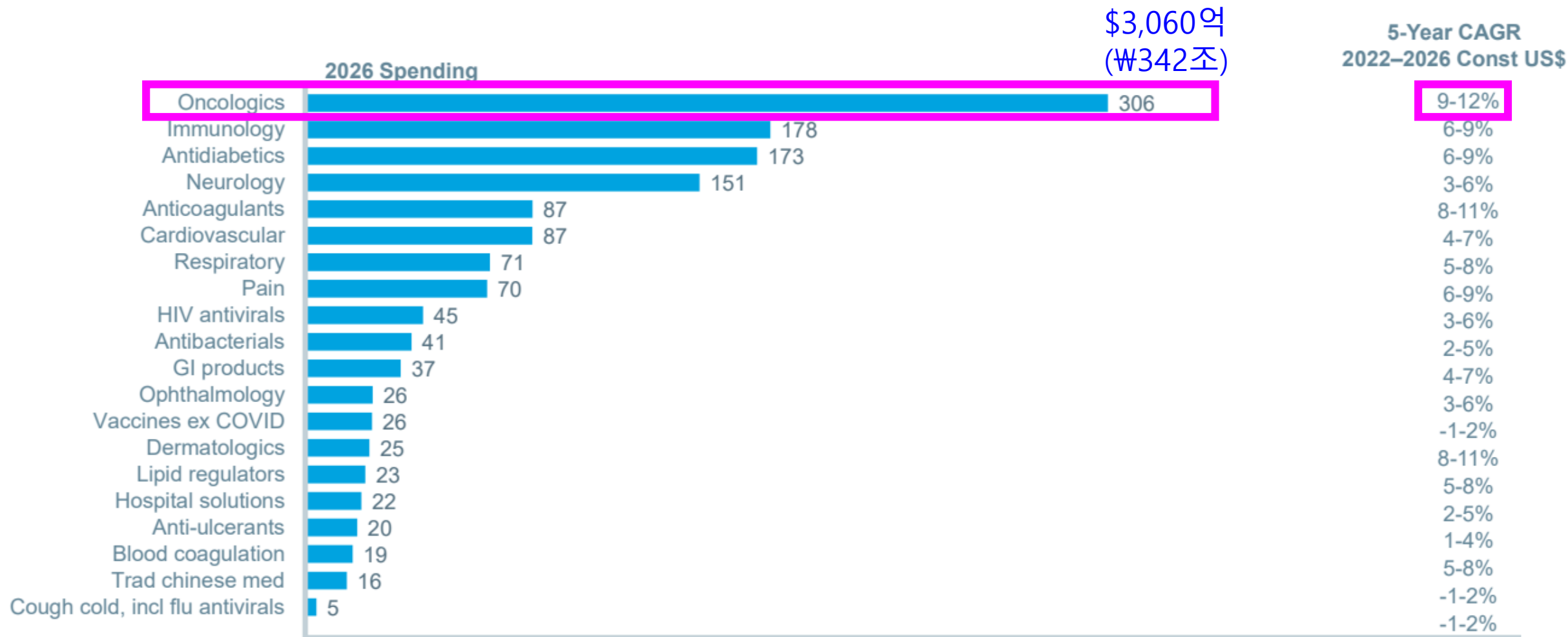
**I-III. Global Oncology market**

**I-V. Oncology market by cancer type**

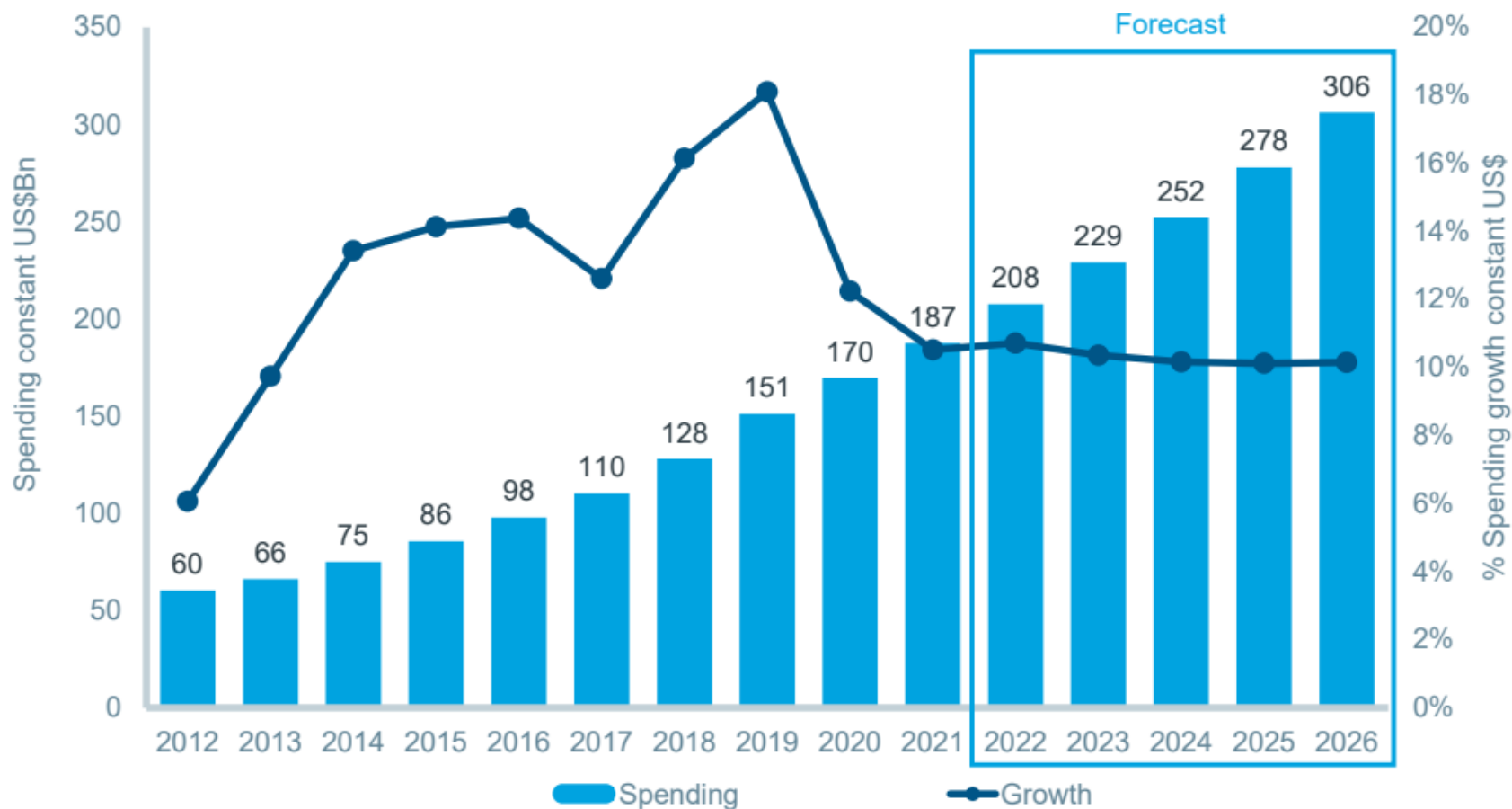
# I-I. Global medicine market



# I-II. Top 20 TA in global medicine market



# I-III. Global Oncology market



2022–2026 Key Metrics

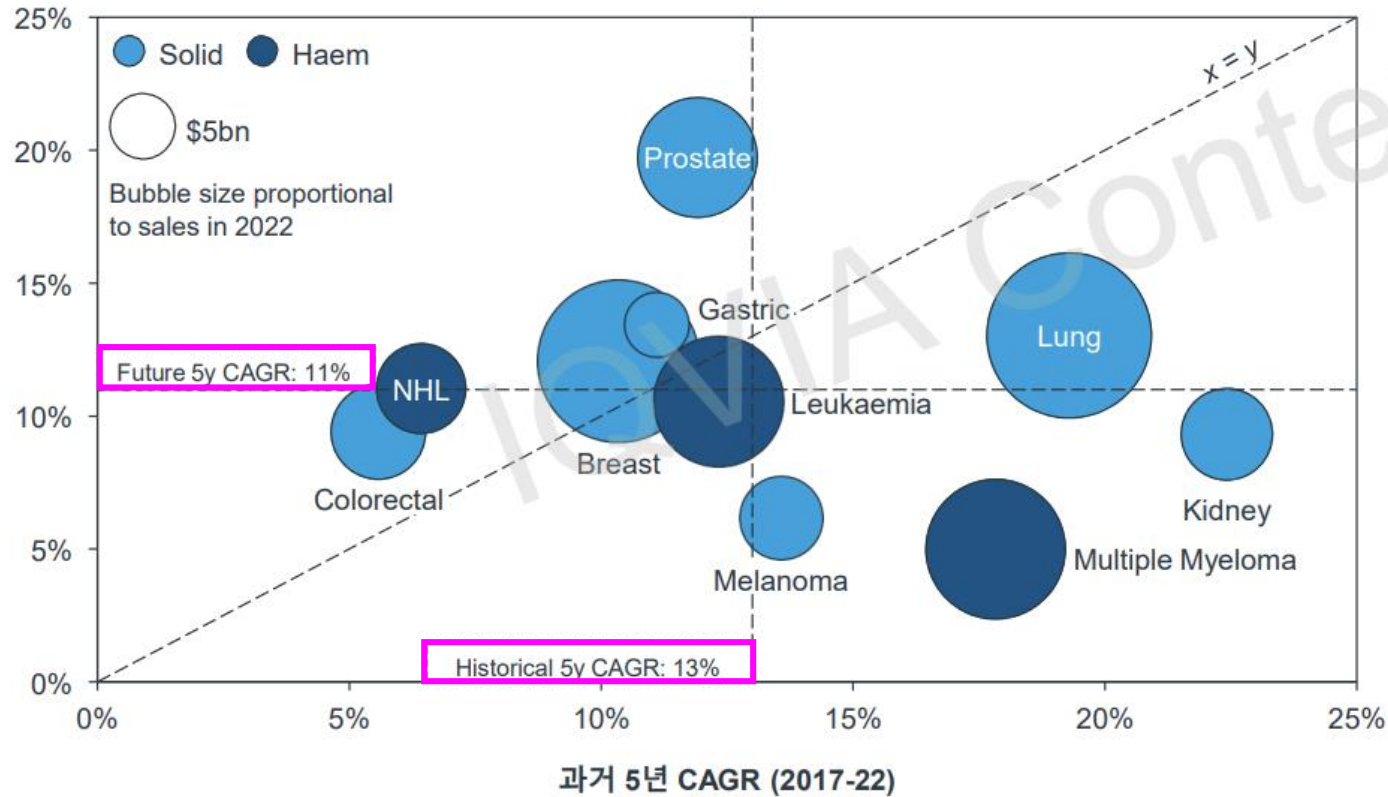
- +63% total spending growth (9–12% CAGR)
- +\$119Bn
- ~+100 new oncology drugs

\*Tot. global medicine (3–6% CAGR)

# I-IV. Oncology market by cancer type

상위 10개 암종의 성장 다이내믹스  
(Global, USD, 2017-27)

미래 5년 CAGR (2022-27)



상위 암종  
(Global, 2022)

암종	매출 (10억 달러)	점유율	CAGR (2017-22)
Lung	30	15%	19%
Breast	29	14%	10%
Prostate	22	8%	12%
Leukaemia	19	9%	12%
Multiple Myeloma	16	11%	18%
Colorectal	10	5%	6%
NHL	9	5%	6%
Kidney	9	5%	22%
Melanoma	8	4%	14%
Gastric	5	2%	11%

Note: NHL: Non-Hodgkin Lymphoma; USD in CER  
Source: IQVIA EMEA Thought Leadership, IQVIA Oncology Link May 2022



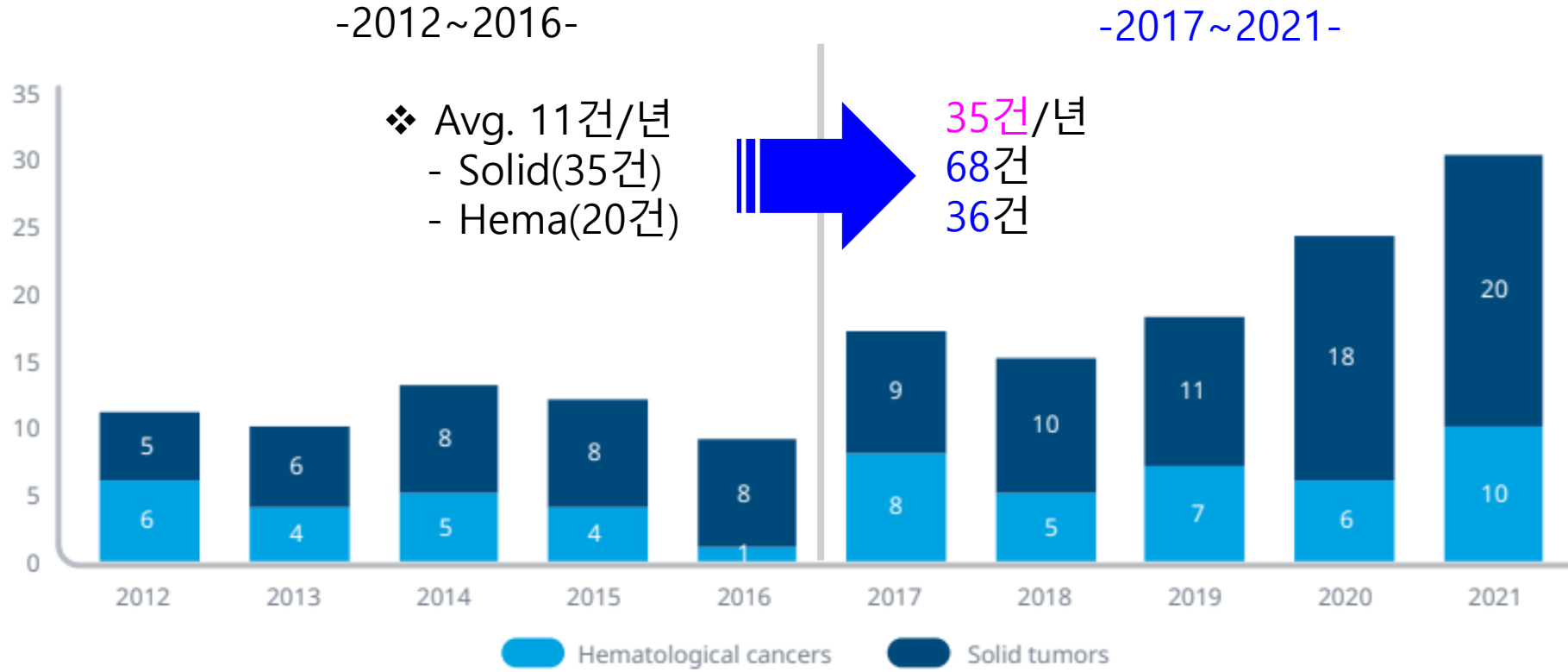
## II. Oncology trends in 2021

### I. Novel Substances launched

### II. Modality



# 1) Novel Substances launched in global



Source: IQVIA Institute, Apr 2022.

II. Oncology trends in 2021, Novel Substances launched

# 2) Novel Substances launched in the U.S(2021)

\*ATTRIBUTES KEY: 1 = Oral 2 = Recombinant 3 = Orphan 4 = First-in-class 5 = Accelerated approval  
 6 = RWE 7 = U.S. Patent to launch <5 years

THERAPY AREA	INDICATION	MOLECULE	BRAND	ATTRIBUTES*								
				1	2	3	4	5	6	7		
Oncology	Acute lymphoblastic leukemia (ALL) + Lymphoblastic lymphoma (LBL)	asparaginase erwinia chrysanthemi (recombinant)	Rylaze		●	●			●		●	
	Bone marrow suppression	trilaciclib	Cosela			●	●		●			
	Cervical cancer	tisotumab vedotin	Tivdak		●		●		●			
	Cholangiocarcinoma with fibroblast growth factor receptor 2 (FGFR2) mutation	infigratinib	Truseltiq	●		●			●			
	Chronic myelogenous leukemia	asciminib hydrochloride	Scemblix	●		●	●		●			
	Endometrial cancer	dostarlimab	Jemperli		●				●			
	HER2-positive + breast cancer	margetuximab	Marginza		●	●						
	Large b-cell lymphoma	lisocabtagene maraleucel loncastuximab tesirine	Breyanzi Zynlonta		●	●	●	●	●			
					●	●	●	●	●			
	Marginal zone lymphoma and follicular lymphoma	umbralisib	Ukoniq	●		●	●		●			
	Multiple myeloma	melphalan flufenamide idecabtagene vicleucel	Pepaxto Abecma			●	●	●	●			
					●	●	●	●	●	●	●	
	Neuroblastoma	naxitamab	Danyelza		●	●			●			
	Non-small cell lung cancer (NSCLC) with EGFR exon 20 insertion mutations	amivantamab mobocertinib	Rybrevant Exkivity		●	●		●	●	●		
					●		●	●	●			
	Non-small cell lung cancer (NSCLC) with KRAS G12C mutations	sotorasib	Lumakras	●		●	●		●	●	●	
	Non-small cell lung cancer (NSCLC) with MET exon 14 skipping alterations	tepotinib	Tepmetko	●		●						
	Prostate cancer	relugolix	Orgovyx	●								
	Renal cell carcinoma	tivozanib	Fotivda	●								
	Von hippel-lindau (VHL) disease with associated renal cell carcinoma (RCC), hemangioblastomas, or pancreatic neuroendocrine tumors (PNET)	Belzutifan	Welireg	●		●	●					
Diagnostics	Ovarian cancer imaging	pafolacianine			●	●						
	Prostate cancer imaging	piflufolastat F 18	Pylarify									
<b>Totals</b>				<b>9</b>	<b>9</b>	<b>16</b>	<b>13</b>	<b>14</b>	<b>3</b>	<b>3</b>		

- ❖ Novel substance
  - 1) Substances: 20건
    - ADC, mAb, BsAb, Cell/gene the.
  - 2) Diagnostics: 2건
    - Cancer imaging
- ❖ FIC: 13건
- ❖ ODD: 16건
- ❖ Accelerated approval: 14건(64%)
  - Significant clinical benefits & mechanisms

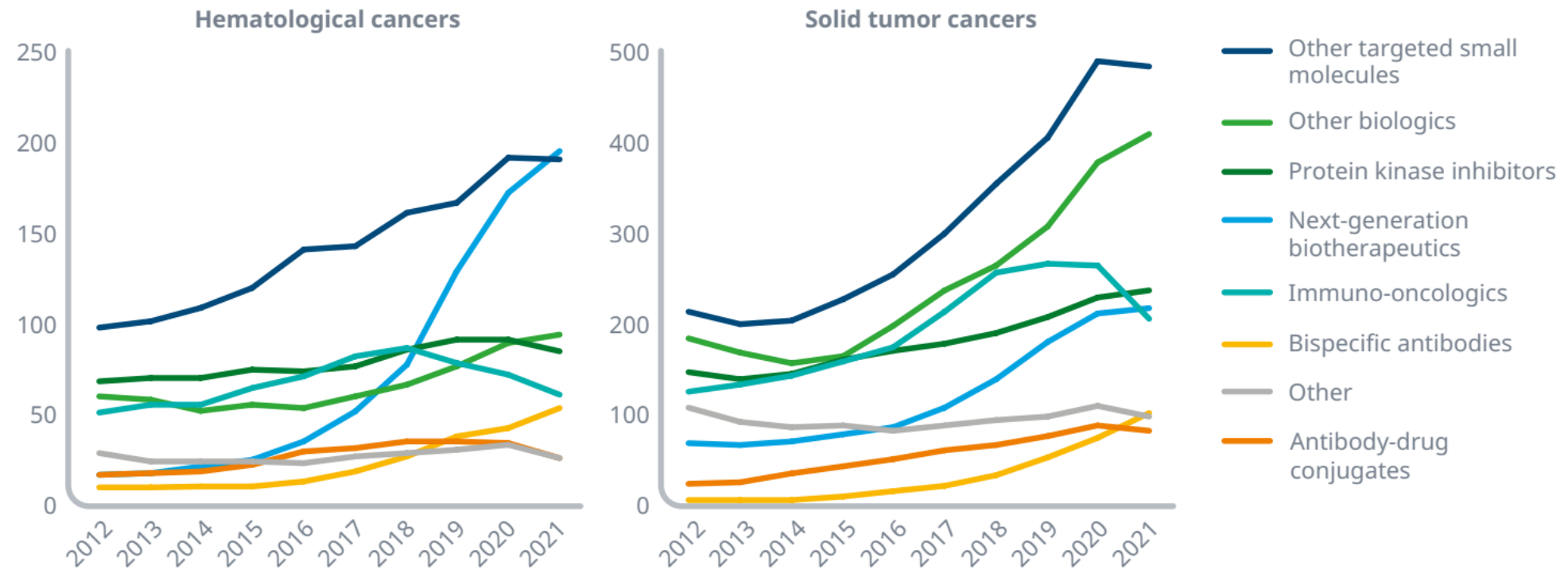
Source: IQVIA Institute, Apr 2022.

## II. Oncology Trends in 2021

- I. Novel Substances launched
- II. Modality

II. Oncology trends in 2021, Modality

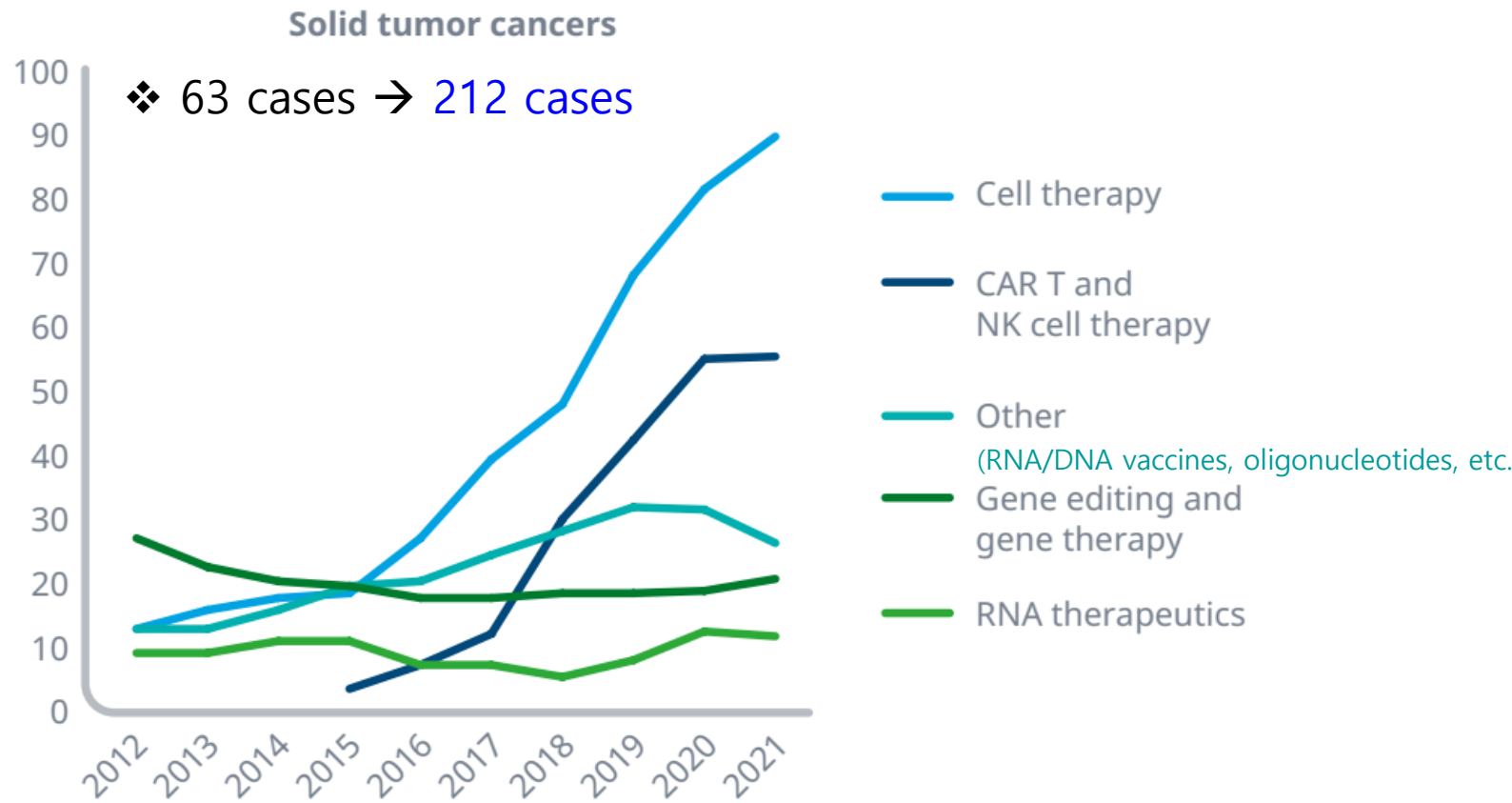
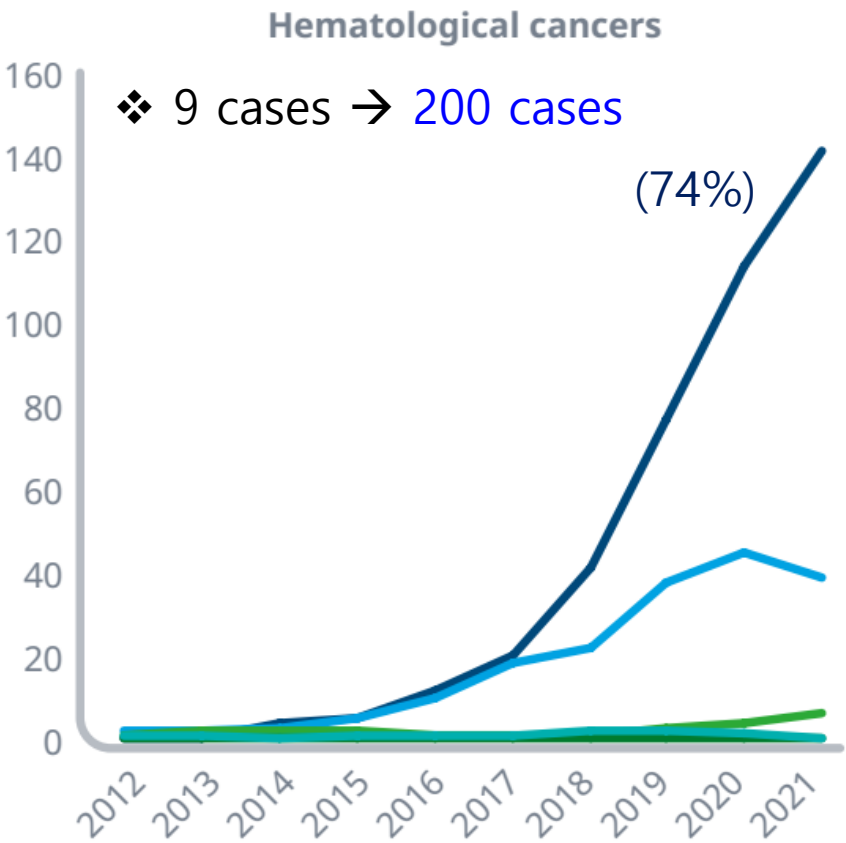
# 1) Oncology R&D pipeline Phase I to regulatory sub.



Source: IQVIA Pipeline Intelligence, Dec 2021; IQVIA Institute, Apr 2022.  
IQVIA Institute, The Global Use of Medicines, 2022

- ❖ Small molecules with **innovative target/MoA**
- ❖ Next-generation.(Cell/Gene) biotherapeutics
- ❖ **Immuno-oncologics**
- ❖ **BsAb**(Hema: 49, Solid: 97)
- ❖ **ADC** with significant clinical benefit

# 2) Cell/Gene therapy(Next-generation biotherapeutics)

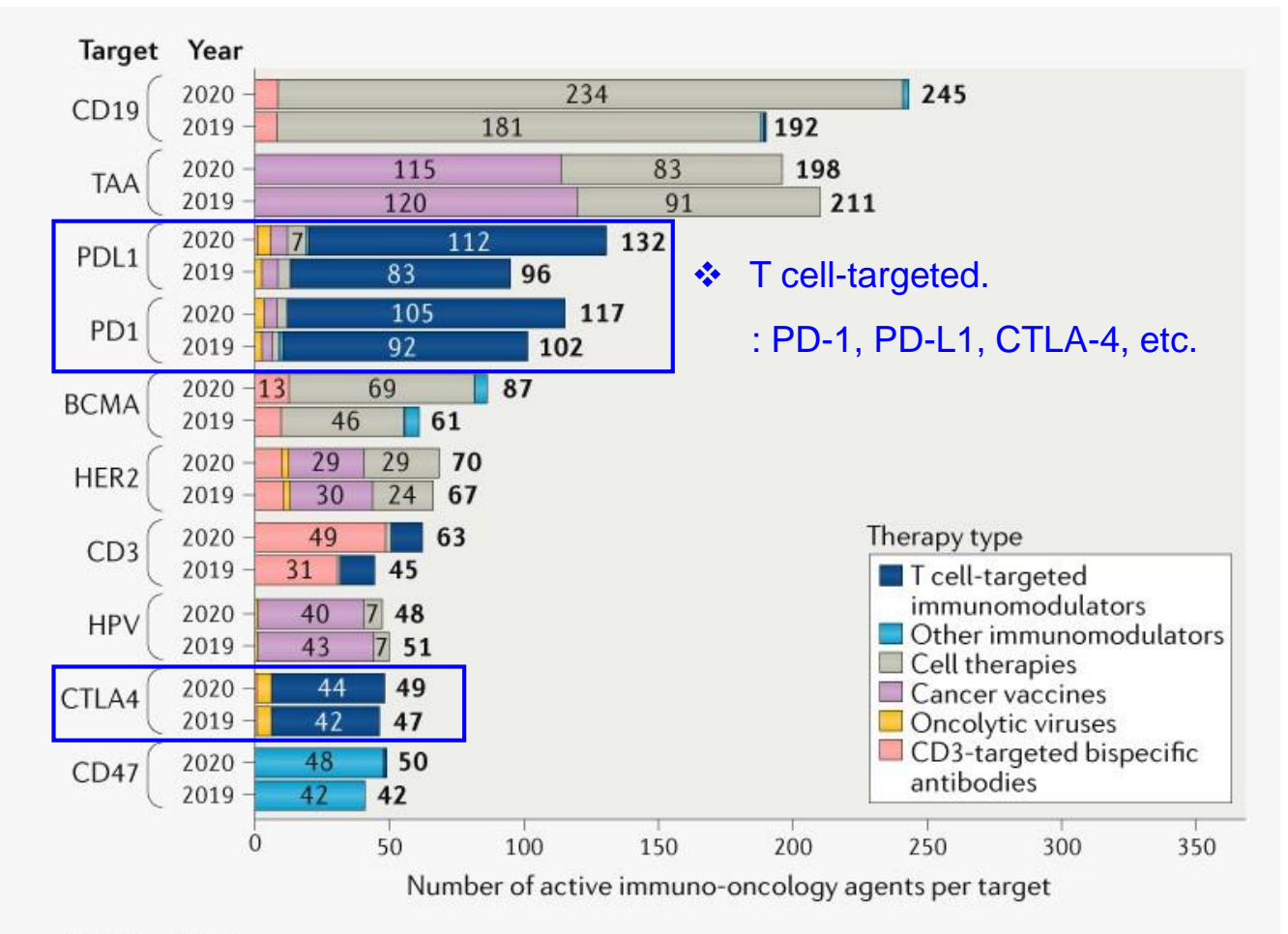
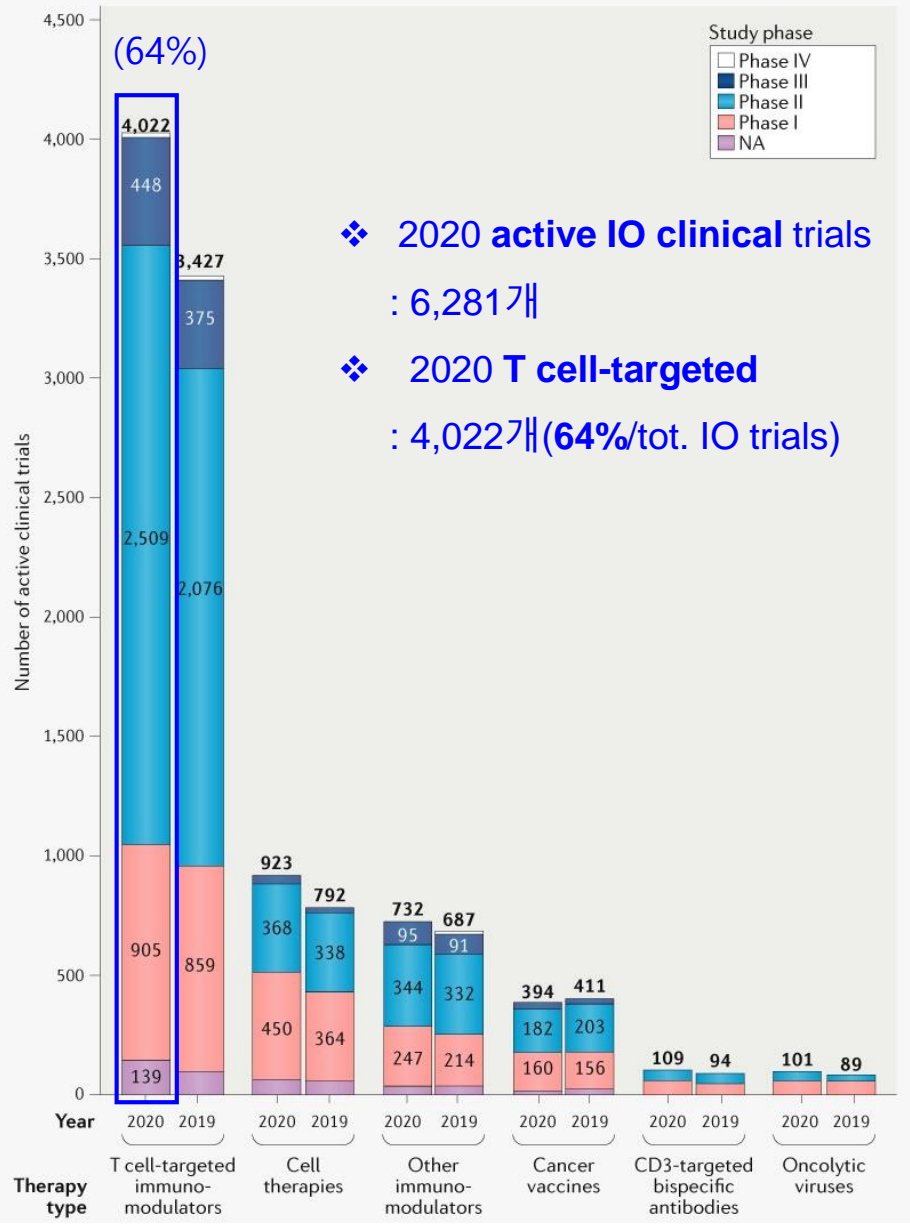


Source: IQVIA Pipeline Intelligence, Dec 2021; IQVIA Institute, Apr 2022.  
IQVIA Institute, The Global Use of Medicines, 2022

- ❖ Oncology(47%)/Next-generation therapy
- ❖ CAR-T/NK cell therapy in both Hema. & solid CA
- ❖ Gene therapy, RNA therapeutics

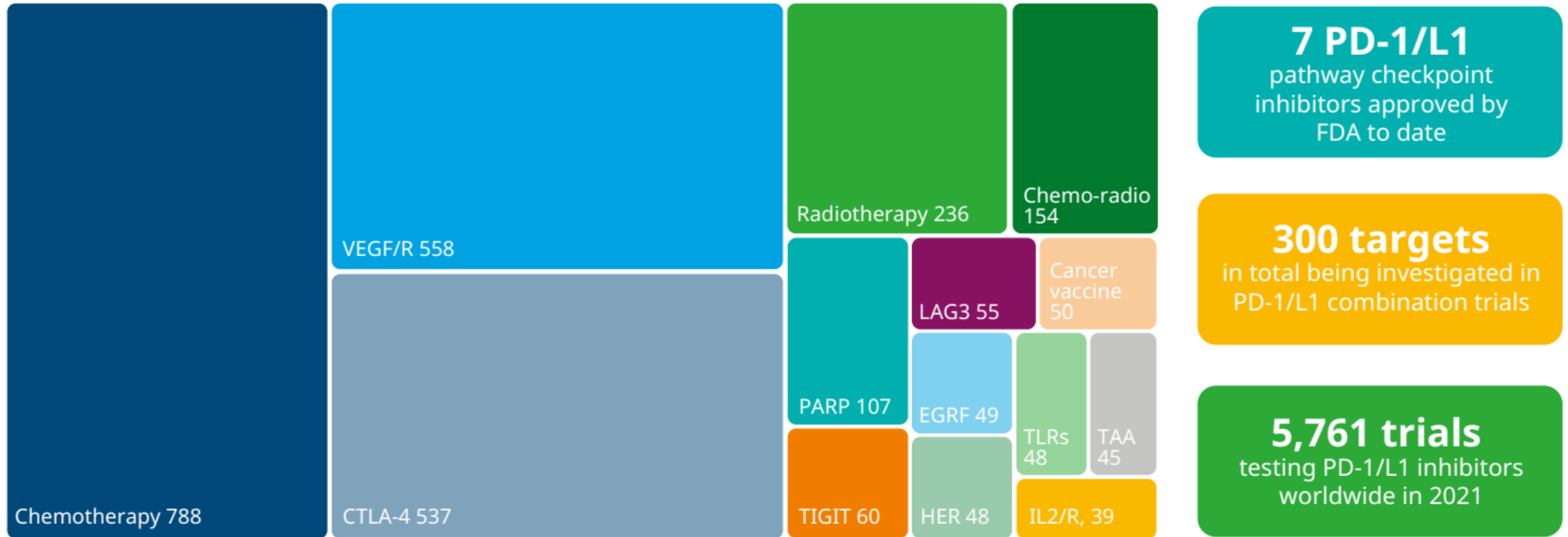
II. Oncology trends in 2021, Modality

# 3-1) Immuno-Oncologics



Nat Rev Drug Discov (2021)

## 3-2) Combination with $\alpha$ PD-1/ $\alpha$ PD-L1(2021)

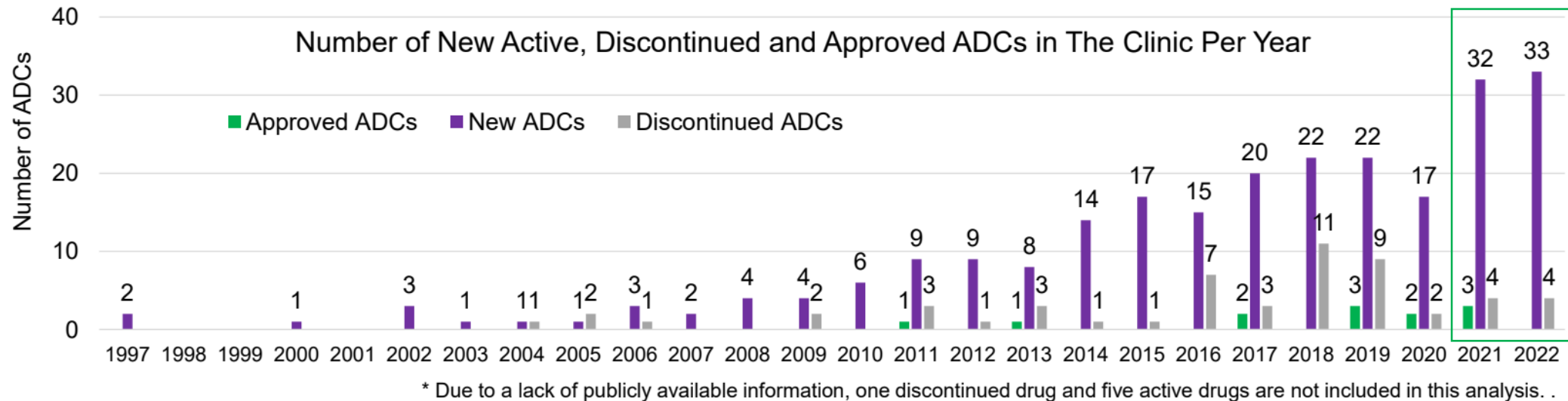


Source: Upadhaya S., Neftelinov S., Hodge J.,: Challenges and opportunities in the PD1/PDL1 inhibitor clinical trial landscape, Nature Reviews Drug Discovery, Feb 2022.

- ❖ 5,761 trials testing PD-1/PD-L1 inhibitors
- ❖ >80% of clinical trials with  $\alpha$ PD-1/ $\alpha$ PD-L1 inhibitor as a combination therapy(monotherapy trials ↓)
- ❖ 300 combi. Targets/pathways(Chemo: 14%/5,761 trials)

# 4) ADC(FIH clinical trials)

Retrieved from BEACON ADC Targeted Therapies, 2022



### [33 new ADCs initiated clinical trial, 2022]

- Disease: Solid CA(29), Blood CA(4)
- Antigen
  - CLDN18.2, TROP2, B7-H4, B7-H3, HER2, Nectin-4, etc.
- Payload
  - Tubulin<sub>1</sub>(7) > DNA damaging agent(5) > Topoisomerase<sub>1</sub> (4) > ISAC(3) > RNA pol.<sub>1</sub>(2), undisclosed(12)

\*Tubulin<sub>1</sub>: Eribulin(1), MMAE(6)

\*DNA damaging: Duocarmycin(1), PBD(2), Anthracycline(2)

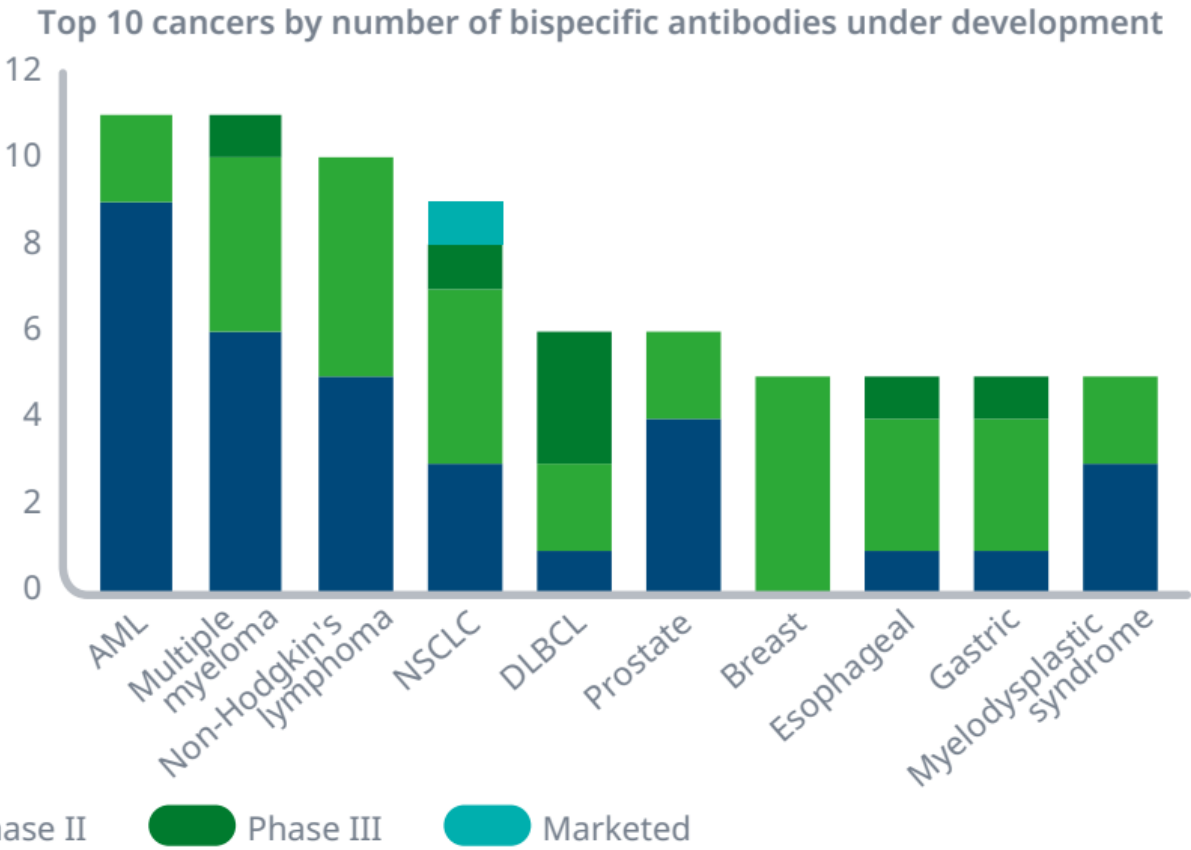
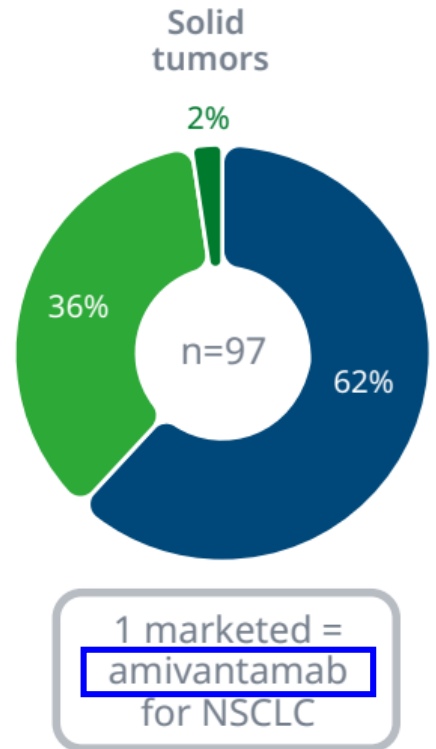
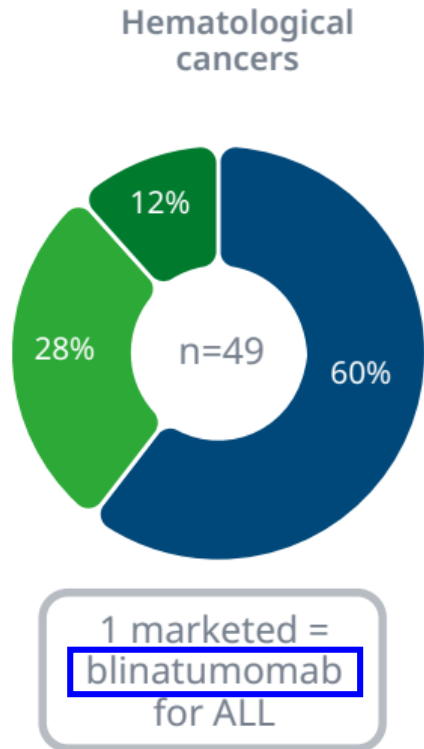
\*Topoisomerase<sub>1</sub>: Exatecan(2), Tubulysin(1), SN-38(1)

\*ISAC: TLR8(1), TLR9(1), STING(1)

\*RNA pol.<sub>1</sub>: Amanitin(2)



# 5) Bispecific Ab



❖ About 130 BsAbs (Hema: 30%, Solid: 60%, Both: 10%)

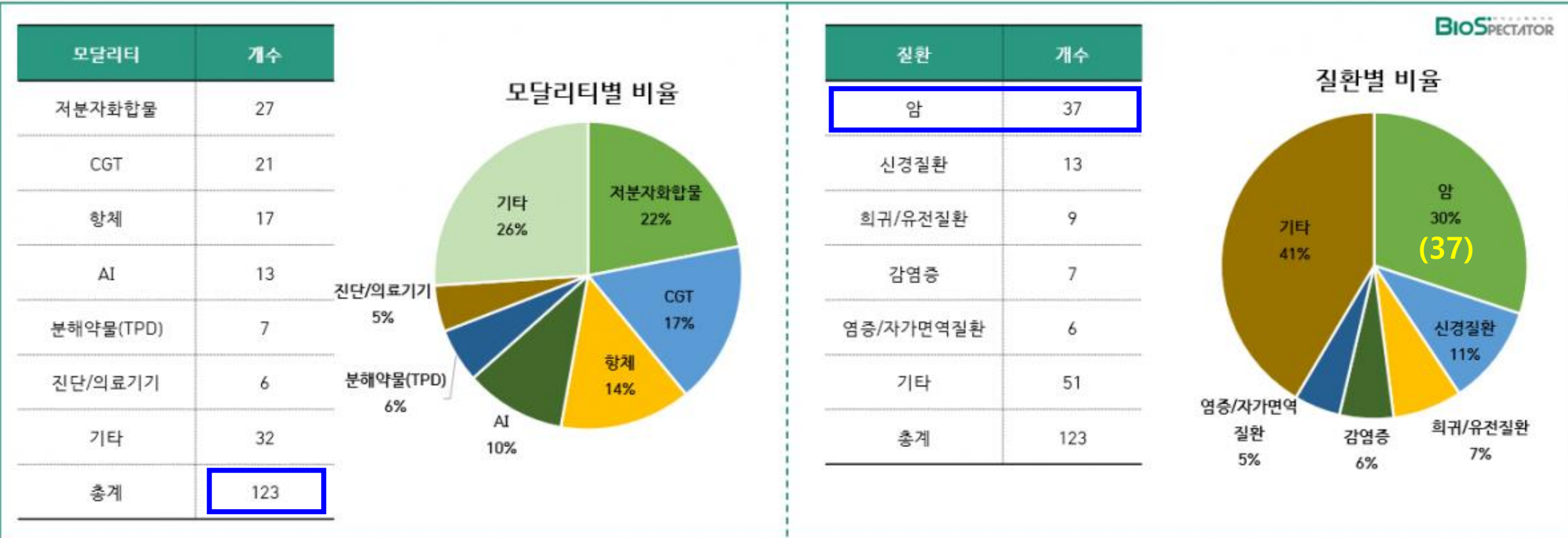
❖ Early trials (>60%), Phase III (Hema: 12%, Solid: 2%)

# **III. Oncology deals in 2022**

- I. Current global deals in first-half 2022**
- II. Antibody deals in 2022\_BsAb, ADC**

III. Oncology deals in 2022, Current global deals in first-half 2022

# 1) Current global deals in first-half 2022 (modality, TA)



바이오스펙테이터, "2022 상반기, 글로벌 123건으로 본 '8가지 시각'"

- ❖ Needs on new modality & technology (CGT > Ab-related. > AI > TPD ↑)
- ❖ Oncology ↑

### III. Oncology deals in 2022, Current global deals in first-half 2022

## 2) Top 5 partnership deals in first-half 2022

❖ Top 5 partnership deals, > 25억 달러

순위	날짜	구분	인수회사	피인수회사	총 규모	계약금	마일스톤	에셋	질환
1	0329	파트너십	사노피(Sanofi)	IGM 바이오사이언스 (IGM Biosciences)	60억+	1억5000만	-	IgM 항체(3개 타겟)	암, 자가면역/염증
2	0107	파트너십	사노피(Sanofi)	엑센티아(Exscientia)	53억	1억	52억	AI 기반 개인맞춤형 의료(personalised medicine) (저분자화합물)	암, 자가면역
3	0510	파트너십(연장)	BMS	에보텍(Evotec)	50억	2억	48억	TPD 개발(8년 연장)	-
4	0110	파트너십	BMS	센추리 테라퓨틱스 (Century Therapeutics)	31억5000만	1억+5000만 (지분투자)	30억	iPSC 기반 동종(allogenic) 세포치료제	암
5	0302	파트너십	사노피(Sanofi)	중국 아다진(Adagene)	25억	1750만	-	종양 주변에서만 항체가 활성화되는 세이프바디(SAFEbody) 기술 적용 항체	암

바이오스펙테이터, "2022 상반기, 글로벌딜 123건으로 본 "8가지 시각"

❖ Big pharm.' acquisition deals ↓ (18%, 23/123) \*2021: 30%(76/250), 2020: 23%(47/199)

❖ Top 5 partnership deals(Sanofi, BMS)

→ Next generation modalities(Antibody, TPD, Cell therapy, etc.)

→ Oncology, Immunology

### III. Oncology deals in 2022, Antibody deals in 2022\_BsAb, ADC

## 1) Antibody deals in first-half 2022\_BsAb, ADC

BsAb

날짜	구분	기업(인수)	기업(피인수)	총 규모(달러)	계약금(달러)	마일스톤(달러)	치료법(Modality) 및 타겟	적응증
0110	인수	다케다(Takeda)	어덱테이트 바이오테라퓨틱스 (Adaptate Biotherapeutics)	-	-	-	γδ T세포 이중항체	암
0111	파트너십	화이자(Pfizer)	드렌바이오(dren bio)	10억2500만	2500만	10억	ITAM 및 신생항원 타겟 이중항체	암
0112	파트너십	사노피(Sanofi)	에이비엘바이오(ABL Bio)	10억6000만	7500만	-	αSyn 타겟, BBB투과 이중항체	파킨슨병 등 퇴행성뇌질환
0201	파트너십	바이오젠(Biogen)	제넨텍(Genentech)	-	3000만(옵션료)	-	CD20xCD3 이중항체 '모수네투주맙(mosunetuzumab)'	비호지킨림프종 (NHL)
0407	파트너십	아스트라제네카(AstraZeneca)	중국 하버바이오메드 (Harbour BioMed)	3억5000만	2500만	3억2500만	CLDN18.2xCD3 '1+2' 이중항체	암
0502	파트너십	길리어드(Gilead Sciences)	드래곤플라이 테라퓨틱스 (Dragonfly Therapeutics)	-	3억	-	5T4 타겟 NK세포 인계이저(NK cell engager)	고형암
0623	인수	중국 시노 바이오팜 (Sino Biopharm)	에프스타 테라퓨틱스 (F-star Therapeutics)	1억6100만	-	-	'2+2(tetravalent)' 이중항체 플랫폼	암

ADC

날짜	구분	기업(인수)	기업(피인수)	총 규모(달러)	계약금(달러)	마일스톤(달러)	치료법(Modality) 및 타겟	적응증
0104	파트너십	젠맙(Genmab)	시나픽스(Synaffix)	4억1500만	450만	-	ADC 항체접합 기술 GlycoConnect™ 등 3개 기술	-
0203	파트너십	얀센(Janssen)	머사나 (Mersana therapeutics)	10억4000만+	4000만	10억+	ADC, 페이로드 DolaLock 및 Dolasynthen 플랫폼 활용	-
0215	파트너십	일라이 릴리(Eli Lilly)	이뮤노젠(ImmunoGen)	17억	1300만	-	캄토테신(Camptothecin) 페이로드 ADC	-
0316	파트너십	사노피(Sanofi)	씨젠(Seagen)	-	-	-	ADC, 최대 3개 타겟	암
0628	파트너십	아스텔라스(Astellas)	수트로(Sutro Biopharma)	13억5750만	9000만	타겟당 4억 2250만	iADC(immunostimulatory antibody-drug conjugate)	암

### III. Oncology deals in 2022, Antibody deals in 2022\_BsAb, ADC

## 2) ADC\_Enhertu, Trodelvy\_significant clinical benefits

Enhertu\_DESTINY-Breast04

유효성 평가지표	HR-양성 (n=494) <sup>i</sup>		전체 환자 (n=557)		HR-음성 (n=58) <sup>i</sup>	
	엔허투 (5.4 mg/kg) (n=331)	항암화학요법 (n=163)	엔허투 (5.4 mg/kg) (n=373)	항암화학요법 (n=184)	엔허투 (5.4 mg/kg) (n=40)	항암화학요법 (n=18)
<b>무진행생존기간(PFS)</b>						
무진행생존기간 중앙값 (months) <sup>ii</sup>	10.1 (9.5-11.5)	5.4 (4.4-7.1)	9.9 (9.0-11.3)	5.1 (4.2-6.8)	8.5 (4.3-11.7)	2.9 (1.4-5.1)
위험비 (95% CI)	0.51 (0.40-0.64)		0.50 (0.40-0.63)		0.46 (0.24-0.89)	
p-value	p<0.001		p<0.001			
<b>전체생존기간(OS)</b>						
전체생존기간 중앙값 (months)	23.9 (20.8-24.8)	17.5 (15.2-22.4)	23.4 (20.0-24.8)	16.8 (14.5-20.0)	18.2 (13.6-NE)	8.3 (5.6-20.6)
위험비 (95% CI)	HR 0.64 (0.48-0.86)		HR 0.64 (0.49-0.84)		HR 0.48 (0.24-0.95)	
p-value	p=0.003		p=0.001			
객관적 반응률 (Confirmed ORR) (%) (95% CI) <sup>iii,iii</sup>	52.6% (47.0-58.0)	16.3% (11.0-22.8)	52.3% (47.1-57.4)	16.3% (11.3-22.5)	50.0% (33.8-66.2)	16.7% (3.6-41.4)
완전반응(Complete Response, %)	3.6%	0.6%	3.5%	1.1%	2.5%	5.6%
부분 반응(Partial Response, %)	49.2%	15.7%	49.1%	15.2%	47.5%	11.1%
안정병변(Stable Disease, %)	35.1%	50.0%	34.6%	49.5%	30.0%	44.4%
질병진행(Progressive Disease, %) (95% CI)	7.8%	21.1%	8.3%	22.3%	12.5%	33.3%
반응기간 중앙값(Median DoR, months) <sup>ii</sup>	10.7	6.8	10.7	6.8	8.6	4.9
임상적 이득률(CBR, %) <sup>iii,iv</sup>	71.2%	34.3%	70.2%	33.7%	62.5%	27.8%
질병조절률(DCR, %) <sup>v</sup>	88.0%	66.3%	87.1%	65.8%	80.0%	61.1%

Trodelvy\_Tropics-02

An improving picture: Tropics-02 median overall survival (months)			
	Trodelvy	Control	Hazard ratio
Asco 2022 cutoff	13.9	12.3	0.84 (p=0.143)
Esmo 2022 cutoff	14.4	11.2	0.79 (p=0.02)

Note: median duration of follow-up was 10.5 months at Asco and 12.5 months at Esmo. Source: conference abstracts.

Tropics-02 post-hoc subgroup analysis						
	Her2 low		Her2 zero		All patients*	
	Trodelvy	Control	Trodelvy	Control	Trodelvy	Control
Median PFS (months)	6.4mth	4.2mth	5.0mth	3.4mth	5.5mth	4.0mth
Hazard ratio	0.58		0.72		0.66 (p=0.0003)	

\*Primary endpoint. Source: Esmo.

“팜뉴스”, <https://www.pharmnews.com/news/articleView.html?idxno=208435>

<https://www.evaluate.com/vantage/articles/events/conferences/esmo-2022-trodelvys-improving-trajectory-might-not-matter-much>

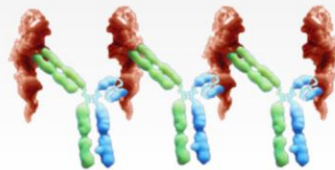
# 3) Current Antibody, ADC big deals in August 2022

## Zymeworks → Jazz Pharmaceuticals

### Zanidatamab's Unique Binding Geometry Promotes:

- Biparatopic – targets two distinct HER2 epitopes and results in HER2 binding across a range of expression levels (low to high)
- HER2-receptor cross-linking, clustering, internalization, and downregulation
  - Enhanced receptor clustering on cell surface (cluster internalization, receptor downregulation)
  - Inhibition of cellular proliferation
- Fc-mediated cytotoxicity: ADCC, ADCP, CDC

### Dual HER2-Binding of Zanidatamab Drives Unique MOA



The geometry of zanidatamab prevents it from binding to the same HER2 molecule

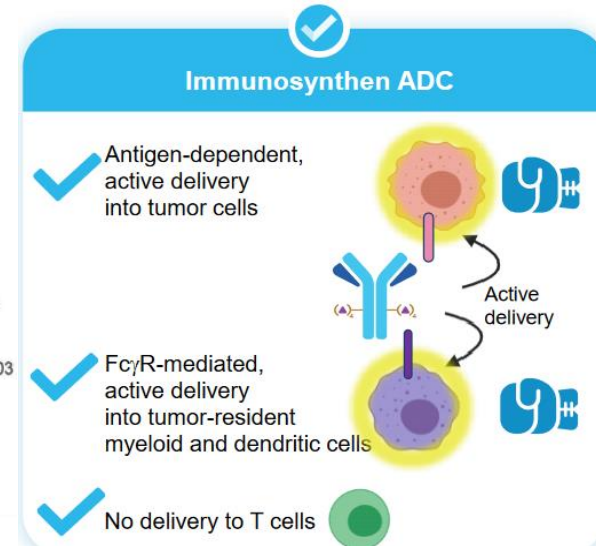
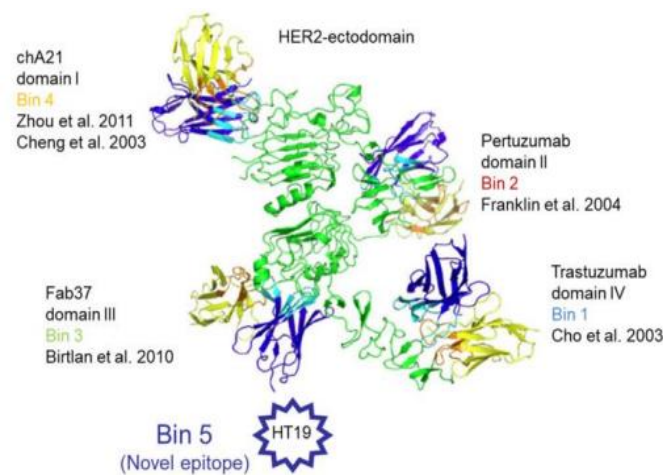
### 1. Deal

- Zymeworks → Jazz Pharmaceuticals (APAC 제외 전지역, 모든 적응증 개발/상업화 권리)
- Tot. 17억 6250만 달러 (Up. 5천만 달러 + Milestones)

### 2. ZW25(HER2 BsAb)

- 담도암 2상 mono. : ORR(40%)
- Jazz Pharmaceuticals → 1'st Antibody addition(FIC, late phase pipeline)

## Mersana → GSK



### 1. Deal

- Mersana → GSK(후보물질 공동개발, 상업화 독점 옵션)
- Tot. 13.6억 달러 (Up. 1억 달러 + Milestone)

### 2. XMT-2056(HER2 ISAC(STING))

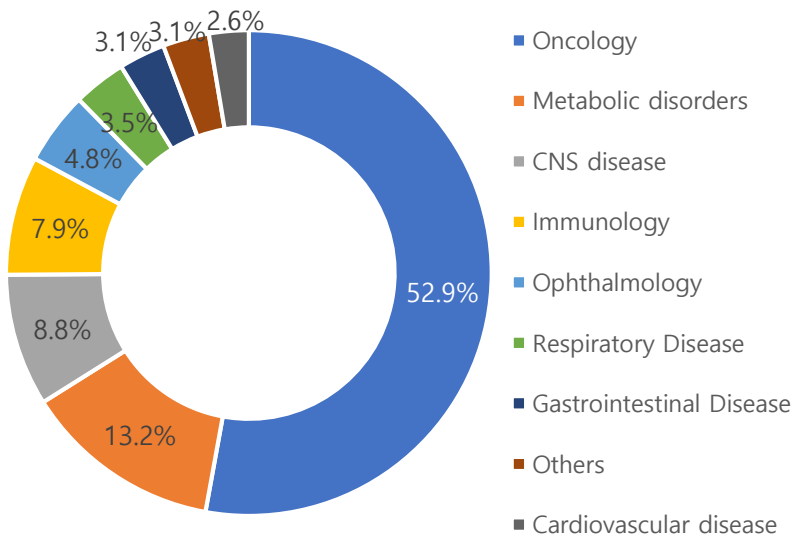
- Preclinical status (Mersana, 임상 1상 → 유방암, 위암, NSCLC)
- Novelty (신규 epitope, sting, 신규 MoA)
- Effective to HER2<sup>hi</sup>/HER2<sup>lo</sup>
- Combi. 가능(w 트라스트주맙, 퍼투주맙, αPD-1, 엔허투 ADC)
- ODD(위암, FDA)

# Summary

## < Global trends in Oncology >

- Oncology is a key driver in the global medicine market.
  - 5-year CAGR in 2026: 9-12%, \$300Bn
- Novel target & modality emerging
  - CGT, ADC, BsAb, small molecule with new target/MoA, etc.
- ADC growing with significant clinical benefit

### ❖ KDDF\_Disease area



### ❖ KDDF\_New target, New modality

	개수(건)	비율
New target	72	32%
New modality	35	15%
New target 또는 New modality	98	43%

### ❖ KDDF\_Modality in Oncology

