

2022 글로벌 제약·바이오 기술거래 및 M&A 동향 : Oncology

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Contents

I. Biopharma Dealmaking in 2022

- I-I. Overall current deals
- I-II. Top 10 M&As
- I-III. Top 10 Partnerships

II. Oncology Trends in 2022

- II-I. Oncology spending(2026)
- II-II. 2021 R&D_CGT, IO, ADC, BsAb
- II-III. 2023 R&D_Valuable R&D projects

III. ADC in Oncology

- III-I. Top 8 Partnerships of 2022, Mersana Therapeutics
- III-II. FDA approval
- III-III. R&D(2022), Clinical trials
- III-IV. Enhertu, Trodelvy
- III-V. Ongoing clinical trials

IV. Learning & Key Takeaways

I. Biopharma Dealmaking in 2022

I-I. Overall current deals

I-II. Top 10 M&As

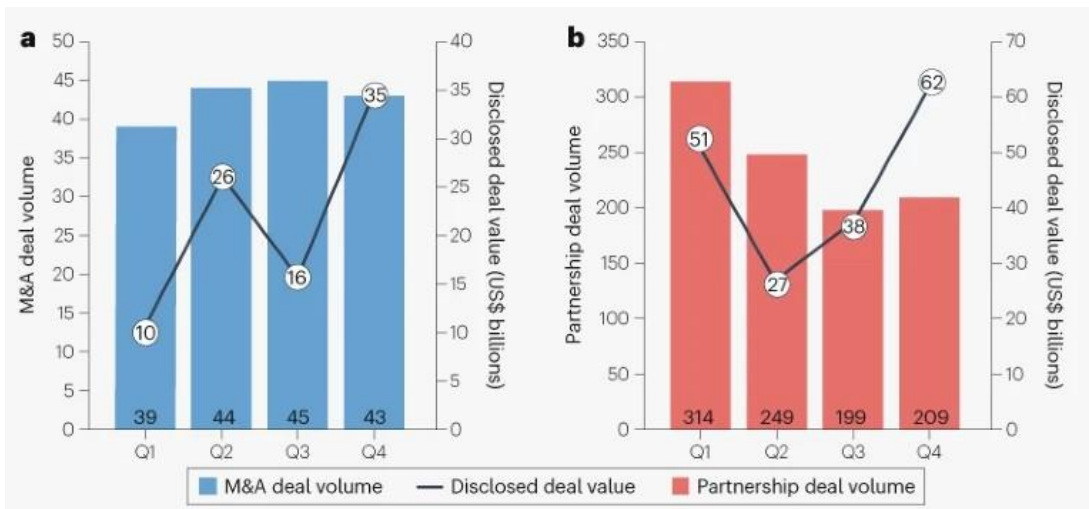
I-III. Top 10 Partnership

I-I. Overall current deals

Retrieved from Nat Rev Drug Disc(2023)
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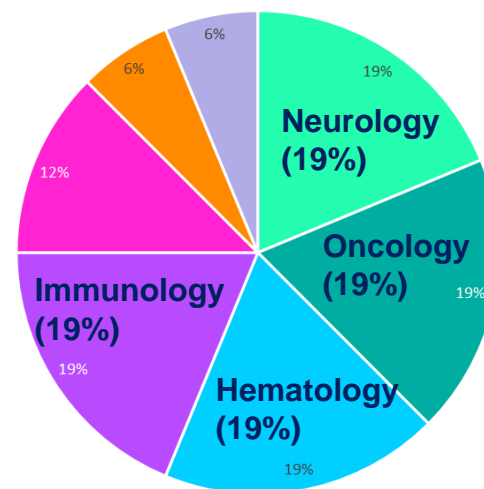
❖ Dealmaking

- M&As -

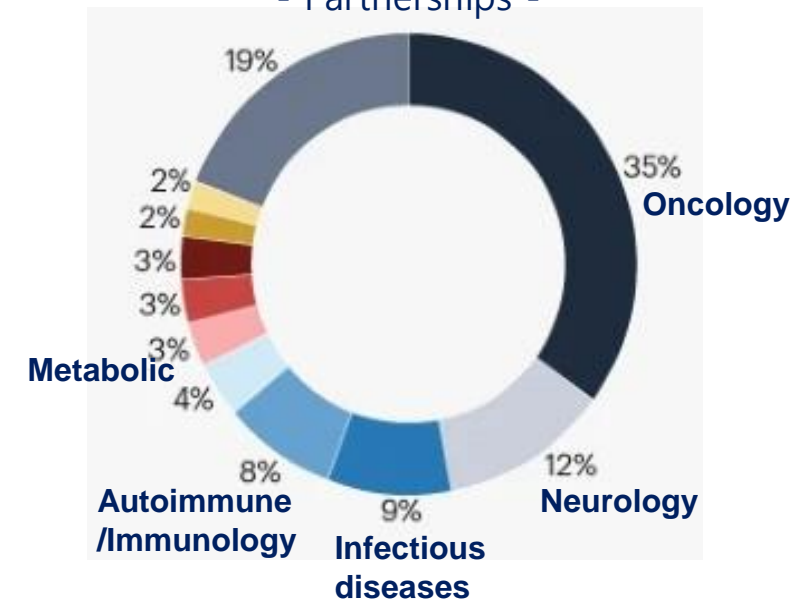


❖ Breakdown by TA

- M&As -



- Partnerships -



Deals in 2021, 2022				
	Deal Volume		Deal Value(disclosed tot.)	
	2021	2022	2021	2022
M&A	196	171(↓)	\$153Bn	\$87Bn(↓)
Partnership	1,200	971(↓)	\$178Bn	\$179Bn

Partnerships by TA in 2021, 2022					
		TA		Ratio	
		2021	2022	2021	2022
Partnership /TA	1 st	Oncology	Oncology	34%	35%
	2 nd	Infectious.	Neurology	13%	12%
	3 rd	Neurology	Infectious.	12%	9%
	4 th	Immunology	Immunology	8%	8%

I-II. Top 10 M&As

Retrieved from Nat Rev Drug Disc(2023), GlobalData

❖ Top 10 M&As of 2022 (>\$1Bn)

Top 10 M&As					
Acquirer	Target focus	Acquired company	Deal value (US\$ Bn)	Announced Month	
1 Amgen	Rare autoimmune and severe inflammatory diseases	Horizon Therapeutics	27.80	2022/12	
2 Pfizer	Migraine treatment and prevention	Biohaven Pharmaceuticals	11.60	2022/5	
3 Pfizer	Sickle cell other haematological diseases	Global Blood Therapeutics	5.204	2022/8	
4 BMS	Targeted oncology therapies	Turning Point Therapeutics	4.100	2022/6	
5 Amgen	Autoimmune diseases	ChemoCentryx	3.736	2022/8	
6 Biocon Biologics	Insulin, oncology and autoimmune disease biosimilars	Viatis's biosimilars business	3.000	2022/2	
7 GSK	Infectious disease vaccines	Affinivax	3.300	2022/5	
8 Samsung Biologics	Biosimilars in immunology, oncology and ophthalmology	Biogen's stake in Samsung Bioepis joint venture	2.350	2022/1	
9 GSK	Targeted oncology therapies	Sierra Oncology	1.900	2022/4	
10 Sumitovant Biopharma	Mainly women's health drug candidates(also developing drugs in oncology)	Myovant Sciences	1.700	2022/10	

I-III. Top 10 Partnerships

Retrieved from Nat Rev Drug Disc(2023), GlobalData

❖ Top 10 Partnerships of 2022 by tot. deal value (>\$3Bn)

Top 10 Partnerships					
Company	Partner	TA	Deal focus (Blue: Ab, Green: CGT, Gray: Others)	Deal value (US\$ Bn)	Announced Month
1 Kelun-Biotech	MSD	Oncology	ADC	9.475	2022/12
2 IGM Biosciences	Sanofi	Autoimmune/Immunology Oncology	IgM Ab agonists	6.165	2022/3
3 Poseida Therapeutics	Roche	Oncology	Allo. CAR-T	6.135	2022/8
4 Nimbus Therapeutics	Takeda	Autoimmune/Immunology	Oral allosteric TYK2 inhibitor	6.000	2022/12
5 Exscientia	Sanofi	Autoimmune/Immunology Oncology	AI-driven precision medicines	5.245	2022/1
6 Akeso	Summit Therapeutics	Oncology	BsAb(α PD-1 x α VEGF)	5.000	2022/12
7 Arcturus Therapeutics	CSL Seqirus	Infectious disease	Self-amplifying mRNA tech. for COVID-19 vaccine develop.	4.500	2022/11
8 Immatics	BMS	Oncology	Allo. TCR-T cell Allo. CAR-T cell programs	4.260	2022/6
9 Arcellx	Kite Pharma	Oncology	Auto. CAR-T cell therapy	4.225	2022/12
10 Orna Therapeutics	MSD	Infectious disease Oncology	Circular RNA platform	3.650	2022/8

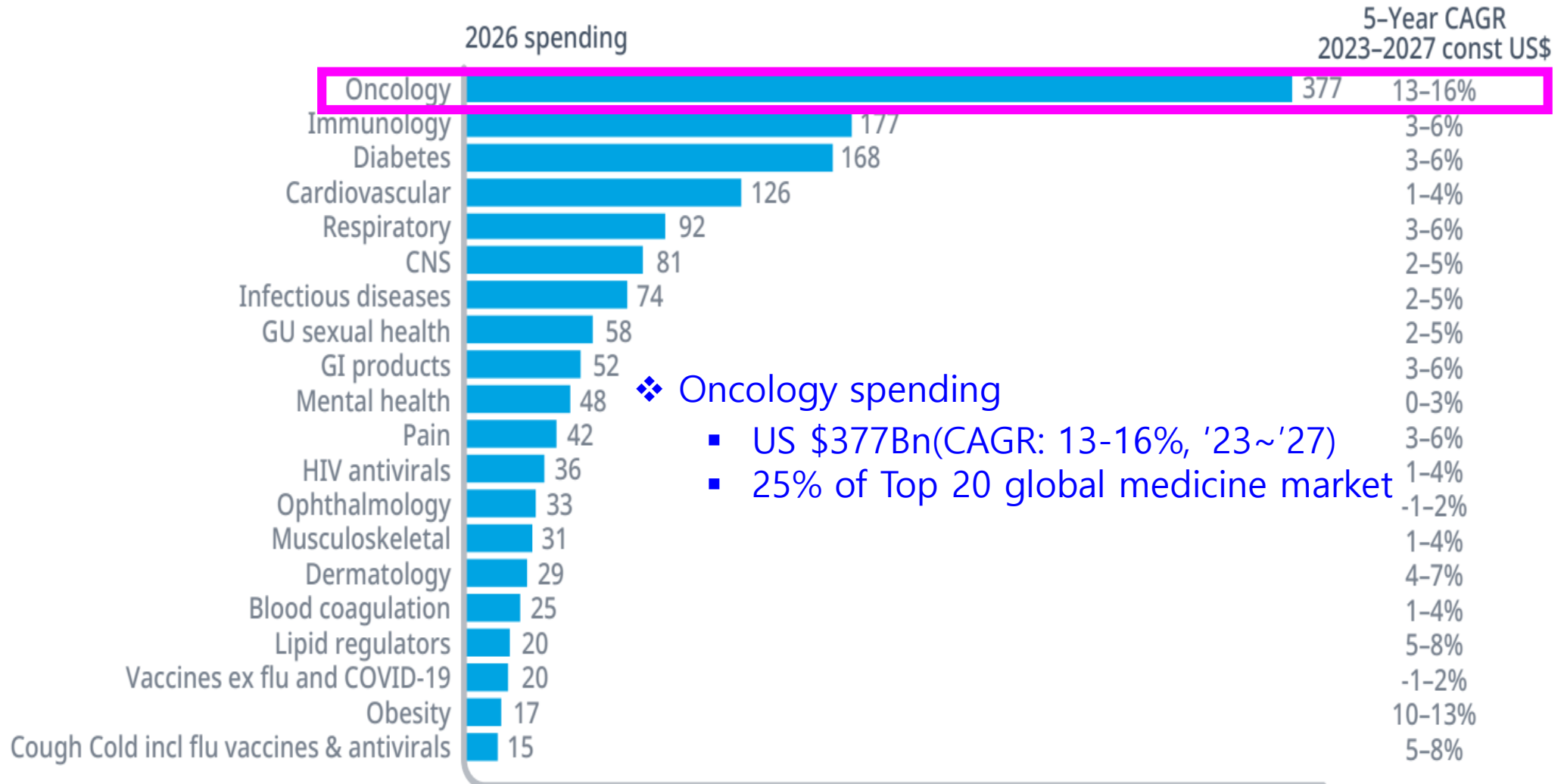
II. Oncology Trends in 2022

II-I. Oncology spending(2026)

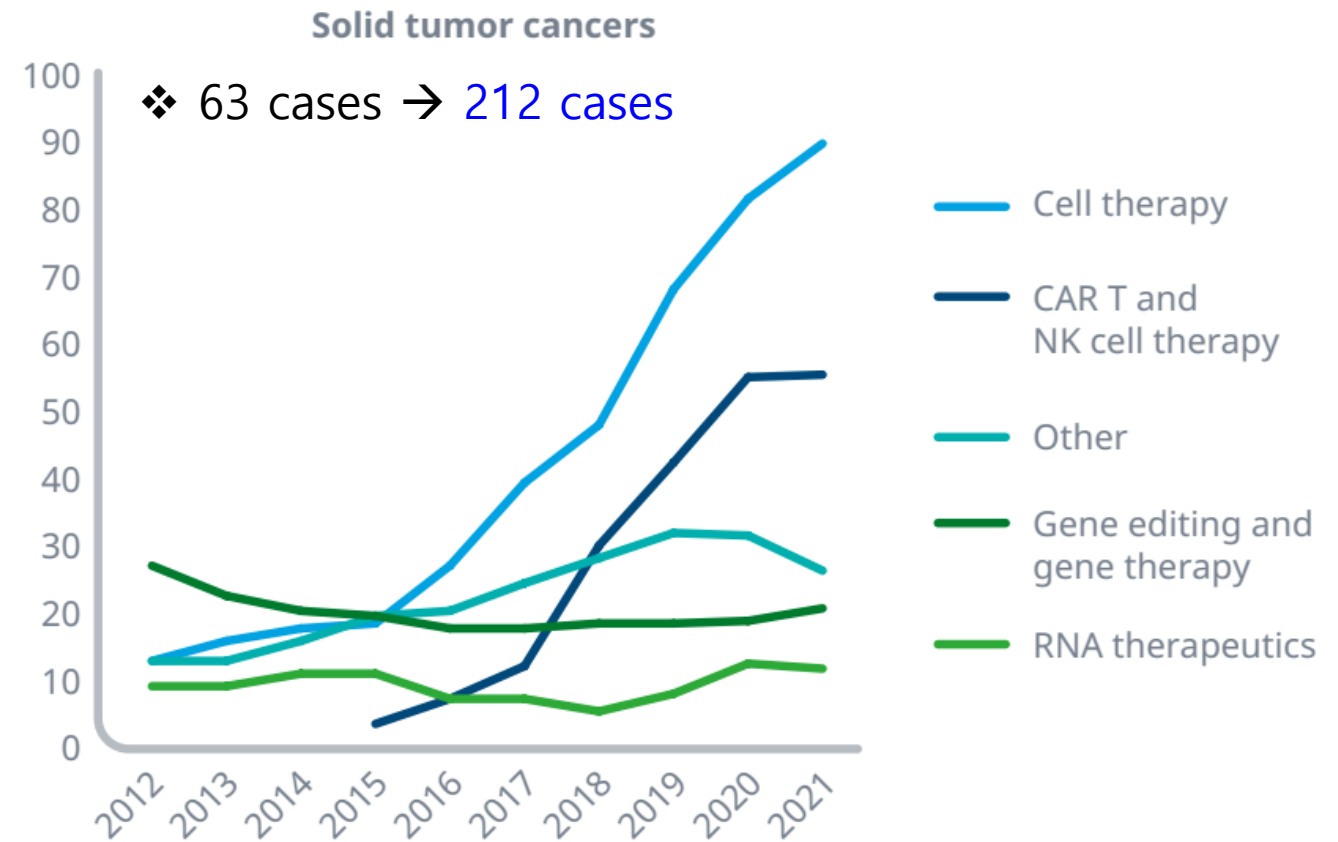
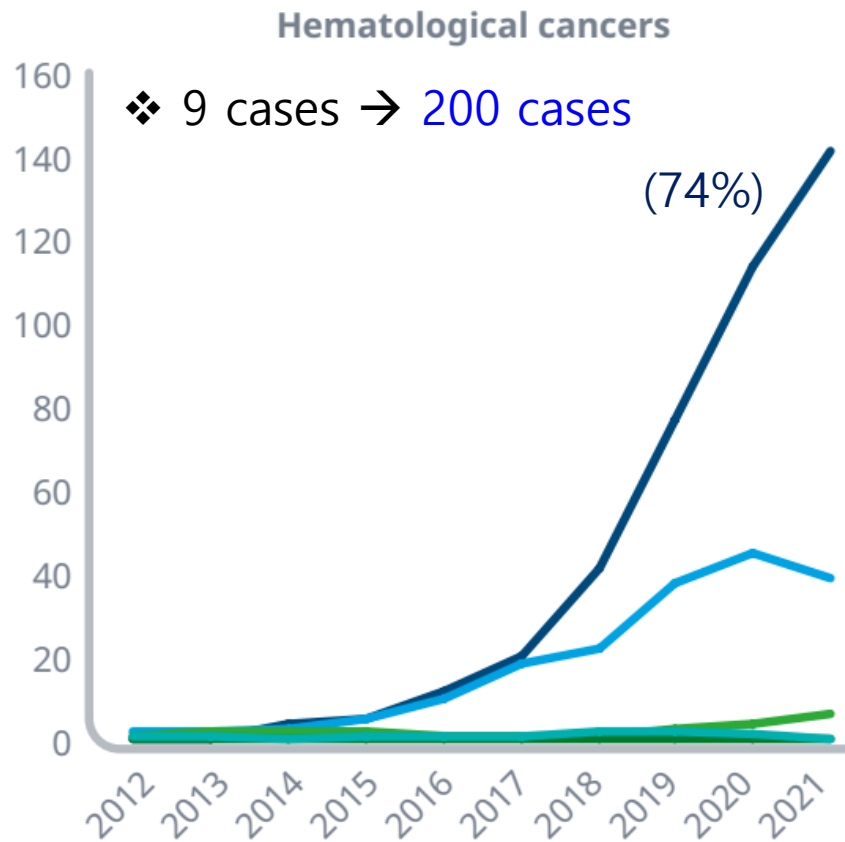
II-II. 2021 R&D_CGT, IO, ADC, BsAb

II-III. 2023 R&D_Valuable R&D projects

II-I. Oncology spending(2026)



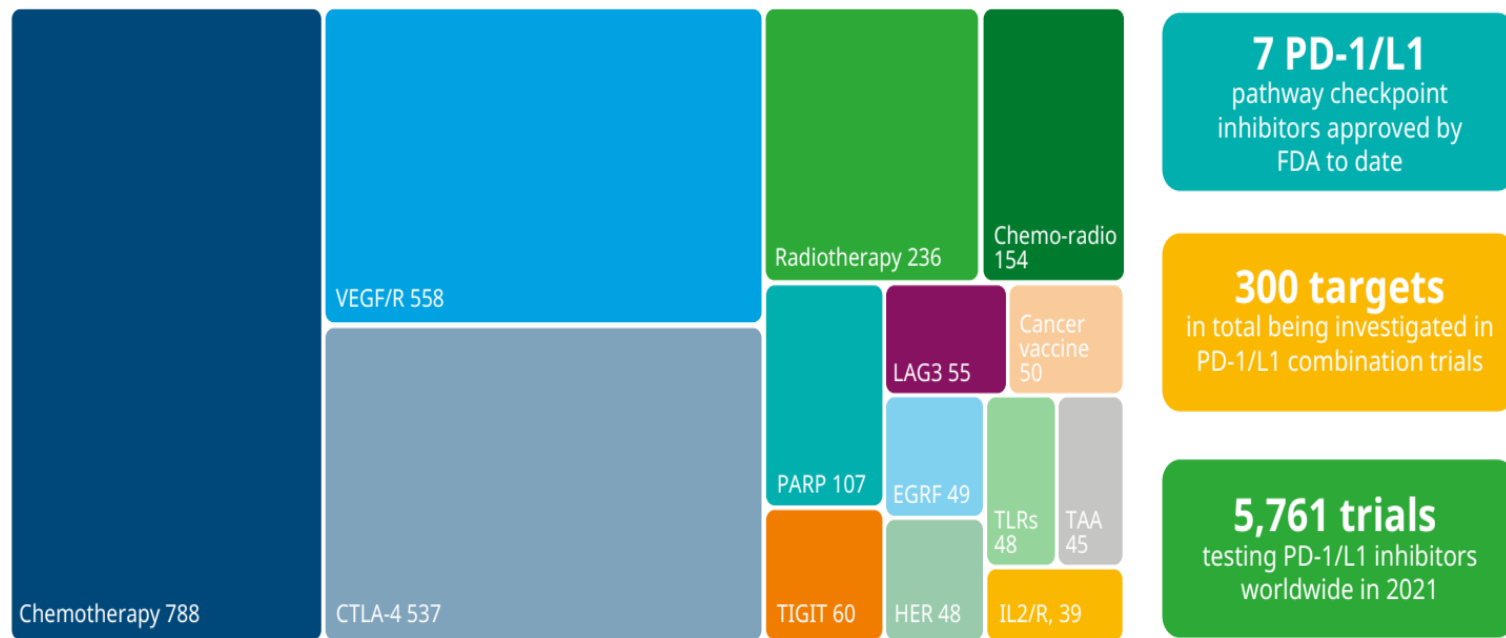
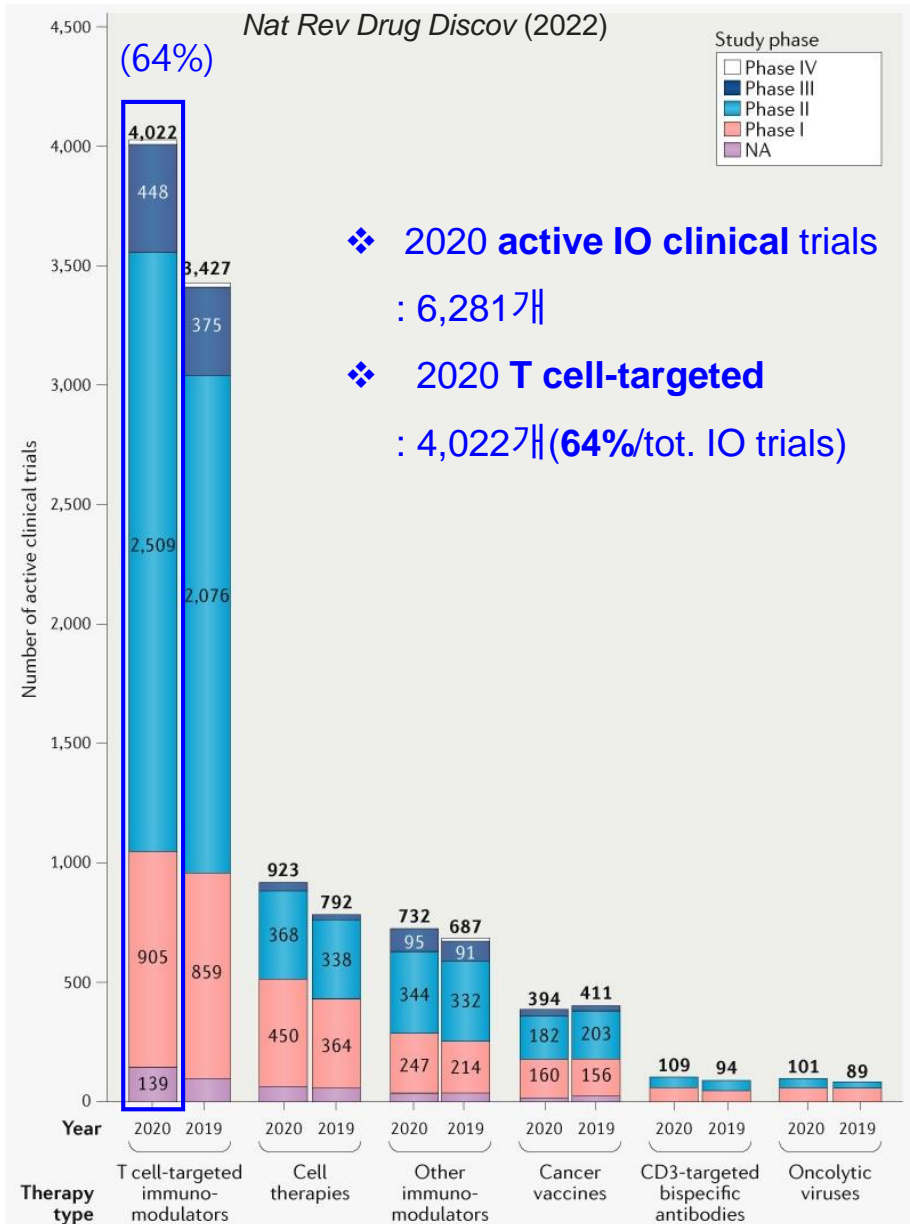
II-II. 2021 R&D_CGT



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-II. 2021 R&D_Immuno-Oncology

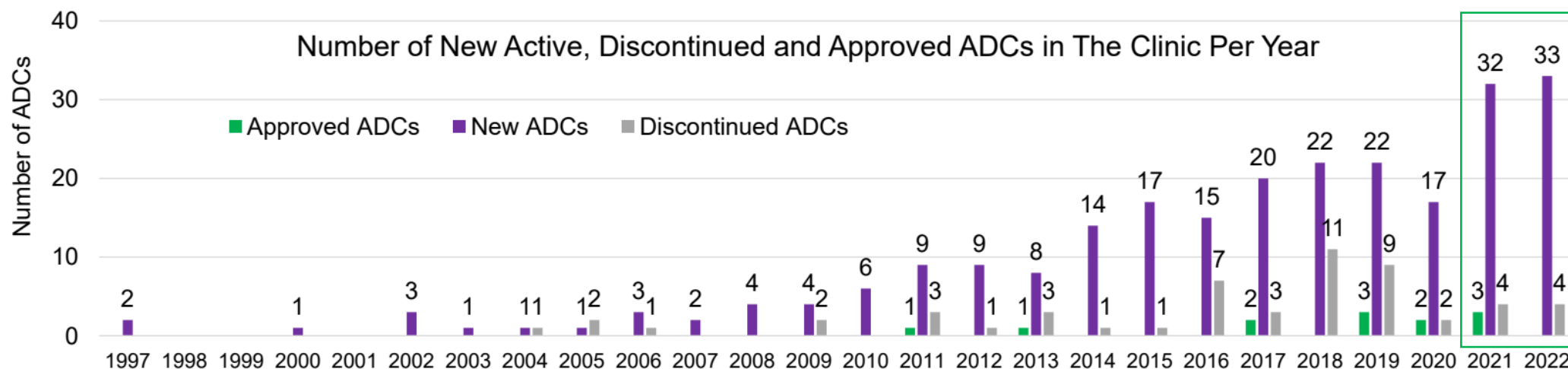


IQVIA Institute, The Global Use of Medicines, 2022

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

II-II. 2021 R&D_ADC

Retrieved from BEACON ADC Targeted Therapies, 2022



* Due to a lack of publicly available information, one discontinued drug and five active drugs are not included in this analysis. .

[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
 - Tubulin₁(7) > DNA damaging agent(5) > Topoisomerase₁ (4) > ISAC(3) > RNA pol. ₁(2), undisclosed(12)

*Tubulin₁: Eribulin(1), MMAE(6)

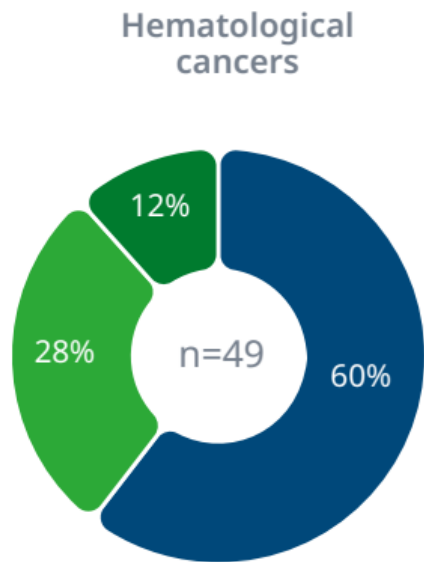
*DNA damaging: Duocarmycin(1), PBD(2), Anthracycline(2)

*Topoisomerase₁: Exatecan(2), Tubulysin(1), SN-38(1)

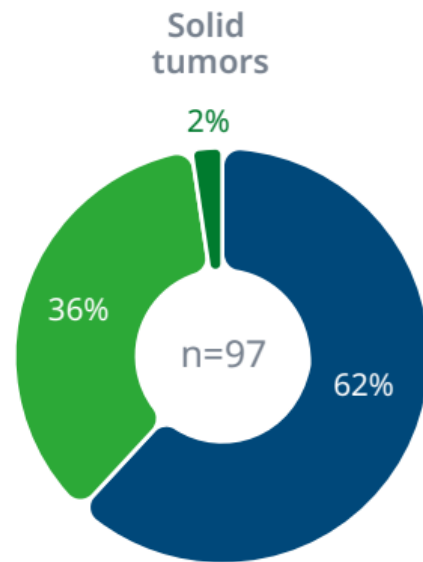
*ISAC: TLR8(1), TLR9(1), STING(1)

*RNA pol. ₁: Amanitin(2)

II-II. 2021 R&D_BsAb

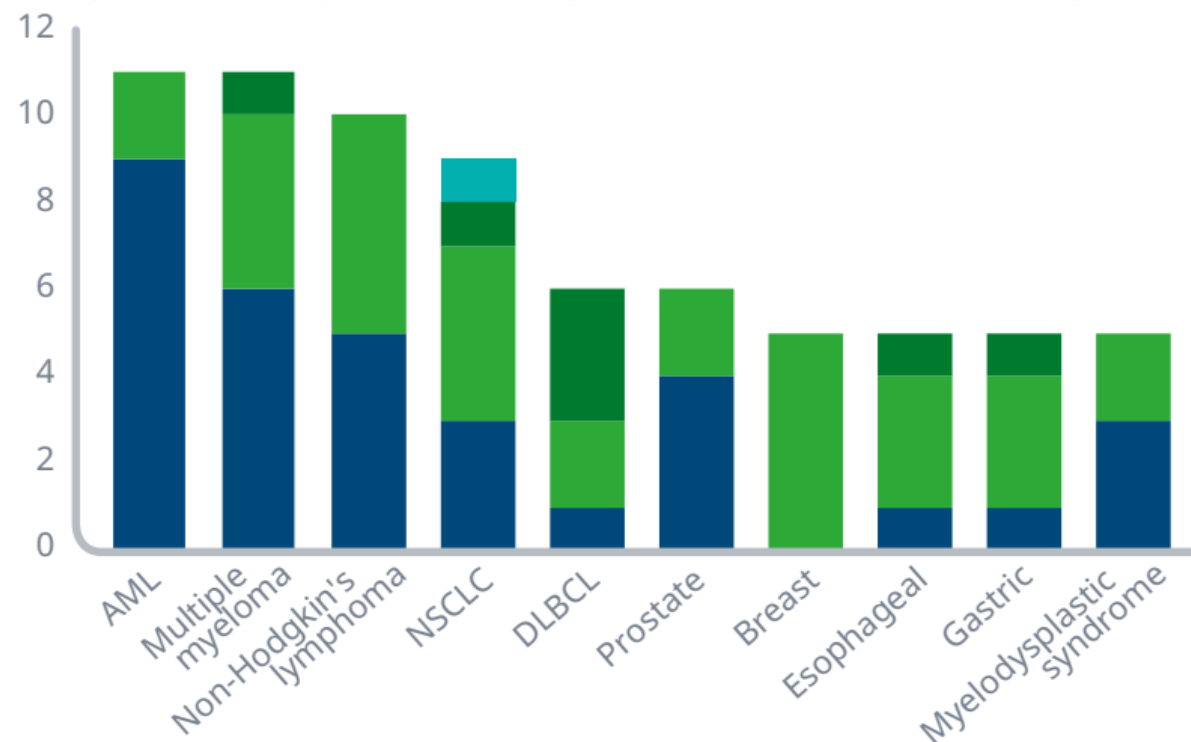


1 marketed = **blinatumomab** for ALL



1 marketed = **amivantamab** for NSCLC

Top 10 cancers by number of bispecific antibodies under development



Phase I Phase II Phase III Marketed

IQVIA Institute, The Global Use of Medicines, 2022

❖ About 130 BsAbs (Hema: 30%, Solid: 60%, Both: 10%)
 ❖ Early trials (>60%), Phase III (Hema: 12%, Solid: 2%)

II-III. 2023 R&D_Valuable R&D projects

Waiting the results from clinical trials						
Company	Product	MoA	Indication	Stage	Expectation	NPV
1 DS/AZ	Datopotamab deruxtecan	Trop2 ADC	Breast CA NSCLC	Phase 3	1 st P3 data due H1'23	\$9.6Bn
2 Intellia /Regeneron	NTLA-2001	CRISPR/CAS9 Gene editing	ATTR-PN ATTR-CM	Phase 1	Further cuts of P1, pivotal plans awaited P3 ongoing,	\$6.3Bn
3 J&J	Nipocalimab	FcRn antagonist	Myasthenia Gravis	Phase 3	further pivotal plans awaited	\$5.4Bn
4 Moderna	mRNA-1647	Vaccine	CMV	Phase 3	P3 ongoing	\$4.7Bn
5 J&J/Genmab	Talquetamab	BsAb(α GPRC5D x α CD3)	MM	Phase 3	Mid-stage readouts due over the year	\$4.5Bn
6 Karuna Therapeutics	KarXT	M1/M4-muscarinic agonist	Schizophrenia	Phase 3	Pivotal ongoing, Further data & US filing slated for 2023	\$4.2Bn
7 Cytokinetics	Aficamten	Cardiac myosin inhibitor	HCMP	Phase 3	ph3 data due H2'23	\$3.7Bn
8 Roche	Tiragolumab	mAb(α TIGIT)	NSCLC	Phase 3	Further OS due in '23	\$3.2Bn
9 DS	Patritumab deruxtecan	HER3 ADC	Breast CA NSCLC	Phase 2	Pivotal P2 data due '23	\$2.9Bn
10 CRISPR/Vertex	Exagamglogene autotemcel (Exa-cel)	CRISPR/CAS9 Gene editing	TDT SCD	Registration Phase 3	US & EU filings anticipated by Q1'23	\$2.4Bn

III. ADC in Oncology

**III-I. Top 8 Partnerships of 2022,
Mersana Therapeutics**

III-II. FDA approval

III-III. R&D 2022, Clinical trials(2022)

III-IV. Enhertu, Trodelvy

III-V. Ongoing clinical trials

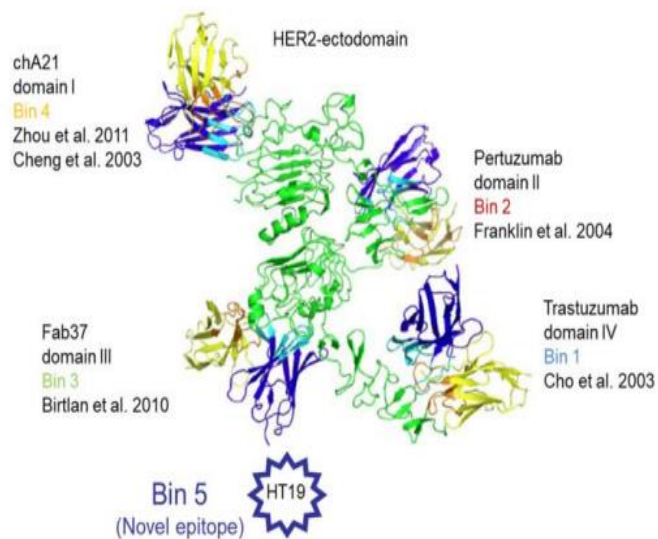
III-I. Top 8 Partnerships of 2022

❖ Top 8 Partnerships of 2022 by tot. deal value (around \$1 Bn) (2022/disclosed value only)

Top 8 Partnerships				
Company	Partner	Focus	Deal value (US\$ Bn)	Announced Month
1 MSD	Sichuan Kelun Biotech Biopharmaceutical	7 preclinical assets + α	9.3	2022/12
2 Eli Lilly	ImmunoGen	Camptothecin-linker payload technology	1.73	2022/2
3 GSK	Mersana Therapeutics	XMT-2056(HER2-targeting STING agonistic ADC)	1.463	2022/8
4 Amgen	LegoChem Biosciences	ADCs, 5 targets selected by Amgen based on LCB's proprietary ConjuAll ADC	1.248	2022/12
5 Elevation Oncology	CSPC Megalith Biopharmaceutical	EO-3021(Claudin18.2 ADC)	1.175	2022/7
6 J&J	Mersana Therapeutics	3 ADCs co-development Dolasynthen platform	1.040	2022/2
7 MSD	Sichuan Kelun Biotech Biopharmaceutical	Undisclosed ADC candidates	0.936	2022/7
8 Merck KGaA	Mersana Therapeutics	STING agonistic ADC(2 targets)	0.830	2022/12

III-I. Mersana Therapeutics

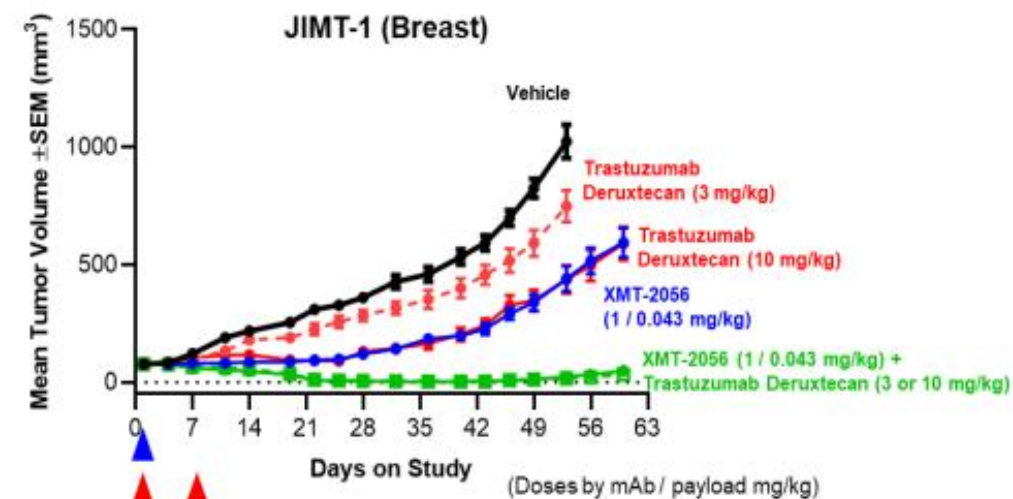
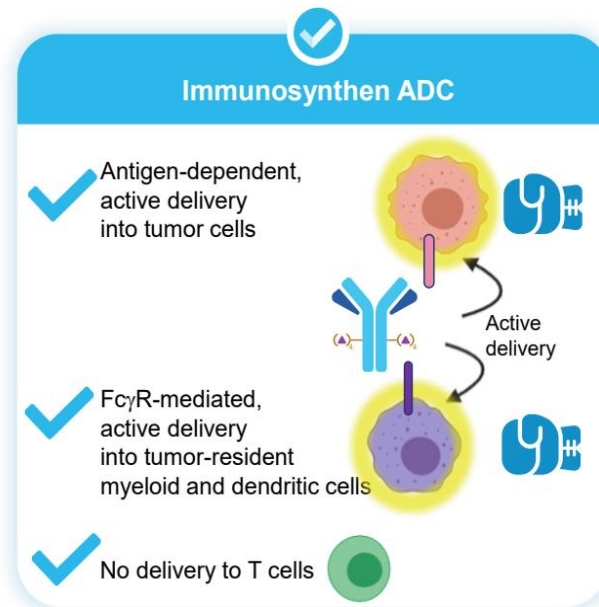
Novel epitope of HER2 Ab



-XMT-2056-

- 전임상중
- Novelty (신규 epitope, sting, 신규 MoA)
- Effective to HER2hi/HER2lo
- Combi. 가능(w 트라스트주맙, 퍼투주맙, aPD-1, 엔허투 ADC)
- ODD(위암, FDA)

ISAC(STING)



-Deal-

- (22/8) with GSK: Tot. 13.6억 달러
- (22/12) with 독일 머크: Tot. 8.3억 달러

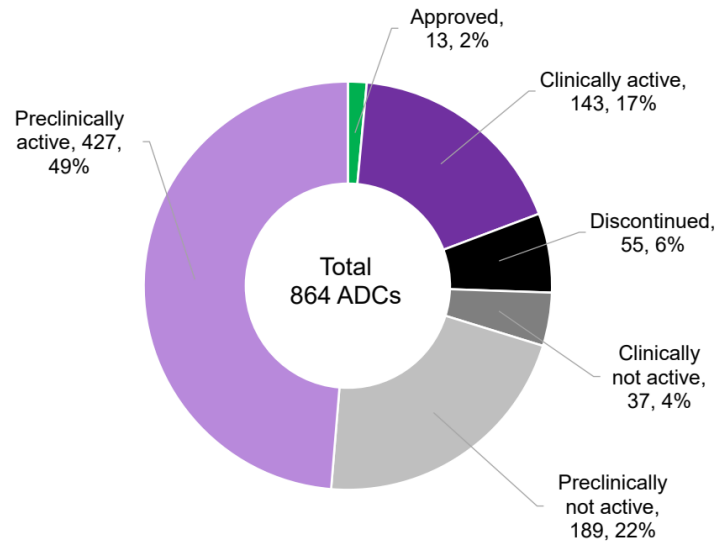
III. ADC in Oncology

III-II. FDA approval

FDA approved ADCs (Blood CA: 5, Solid CA: 6)

Approval	Company	ADC	Target	Indication	Linker	Payload	
1	2000, 2017	Pfizer/Wyeth	Mylotarg	CD33	급성 골수성 백혈병	AcBut	Calicheamicin
2	2011	Seagen/Astellas	Adcetris	CD30	재발성 또는 난치성 호지킨 림프종 및 전신 역형성 대세포 림프종	Val-cit	MMAE
3	2013	Genentech/Roche	Kadcyla	HER2	Trastuzumab 내성 유방암	SMCC	DM-1
4	2017	Pfizer/Wyeth	Besponsa	CD22	재발성 또는 불응성 B세포 전구체 급성 림프모구 백혈병	AcBut	Calicheamicin
5	2018	AstraZeneca/Innate Pharma	Lumoxiti	CD22	털세포백혈병(Hairy cell leukemia)	Mc-VC-PABC	Pseudotox
6	2019	Genentech/Roche	Polivy	CD79	미만성 대 B-세포 림프종	Mc-Val-Cit	MMAE
7	2019	Seagen/Astellas	Padcev	Nectin-4	국소 진행성 또는 전이성 요로암	Mc-Val-Cit	MMAE
8	2019	AstraZeneca/Daiichi Sankyo	Enhertu	HER2	절제 불가능 혹은 전이성 유방암 진행성 위암	Tetrapeptide	DXD
9	2020	Gilead/ImmunoMetrics	Trodelvy	Trop-2	삼중음성 유방암	Carbonate	SN-38
10	2020	GSK	Blenrep	BCMA	재발성 또는 불응성 다발성 골수종	MC	MMAF
11	2021	ADC Therapeutics	Zynlonta	CD19	미만성 대 B-세포 림프종	Valine-Ala	PBD
12	2021	Seagen/Genmab	Tivdak	Tissue factor	재발성 또는 전이성 자궁경부암	Mc-Val-Cit	MMAE
13	2022	ImmunoGen	Elahere	FR- α	백금 저항성 난소암	sulfo-SPDB	DM4

III-III. R&D 2022

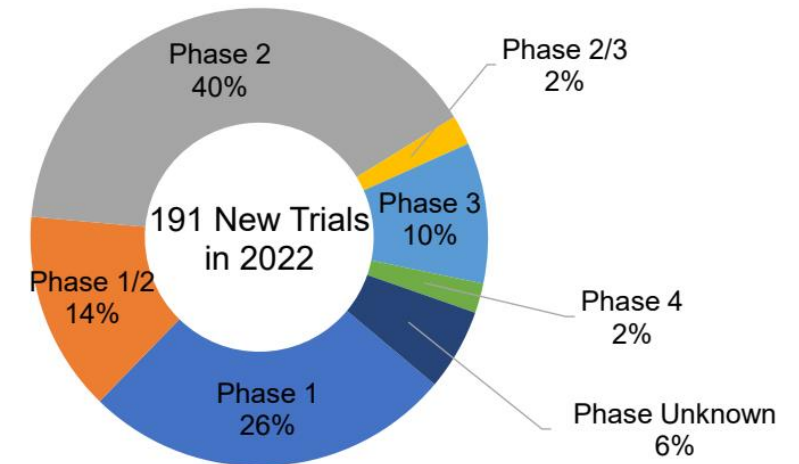
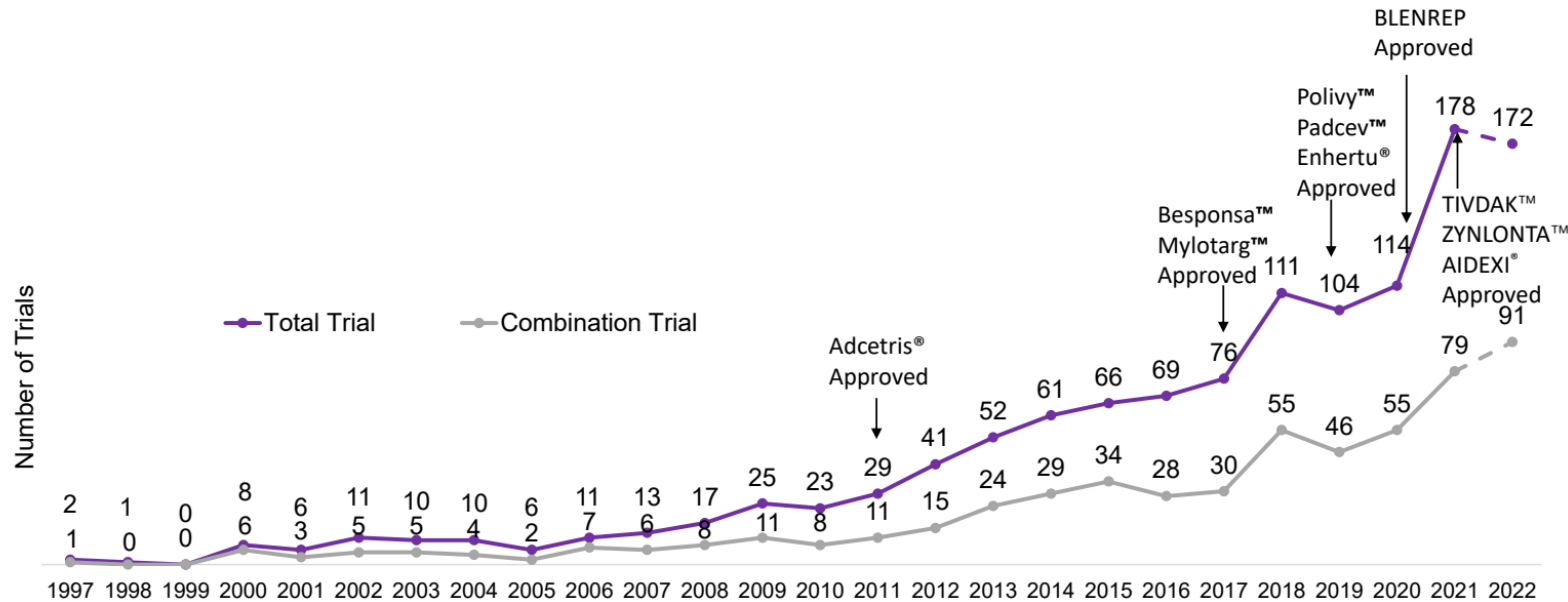


[Tot. 864 ADCs]

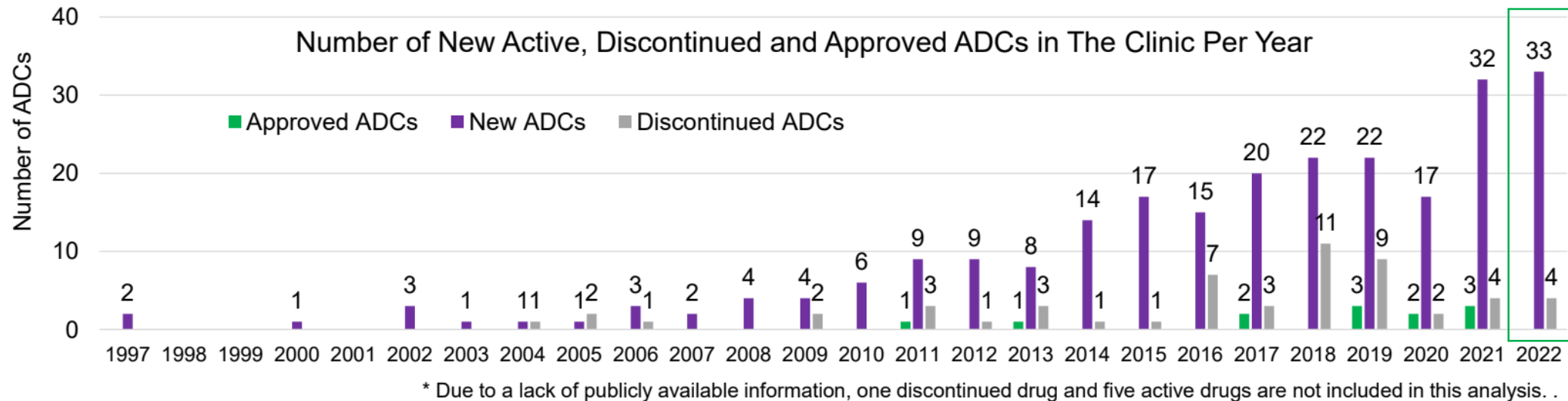
→ Active **preclinical** research 49% (427개)

→ Active **clinical** trial 17% (143개)

* **33 new ADCs** entered clinical trial this year.



III-III. R&D 2022_Clinical trials, first in human (2022)



[33 new ADCs initiated clinical trial]

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

*Tubulin ι : Eribulin(1), MMAE(6)

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

*Topoisomerase ι : Exatecan(2), Tubulysin(1), SN-38(1)

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

*RNA pol ι : Amanitin(2)

III-IV. Enhertu, Trodelvy_Significant clinical benefits

Enhertu_DESTINY-Breast04

유효성 평가지표	HR-양성 (n=494) ⁱ		전체 환자 (n=557)		HR-음성 (n=58) ⁱ	
	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)
무진행생존기간(PFS)						
무진행생존기간 중앙값 (months) ⁱⁱ	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			
전체생존기간(OS)						
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) ^{iii,iii}	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) ⁱⁱ	10.7	6.8	10.7	6.8	8.6	4.9
임상적 이득률(CBR, %) ^{ii,iv}	71.2%	34.3%	70.2%	33.7%	62.5%	27.8%
질병조절률(DCR, %) ^v	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>

III-V. Ongoing clinical trials

연번	개발단계	제품명/물질명	개발사	타겟	구분
1	적응증 확장(PDUFA 23.02)	Trodelvy	Gilead	Trop 2	고형암
2	적응증 확장(임상 3 결과 Readout 23년)	Enhertu	AstraZeneca/DaiichiSankyo	HER2	고형암
3	Pre-Registration(PDUFA 23.05.12)	trastuzumab duocarmazine	Byondis	HER2	고형암
4	임상3상	ARX-788	Ambrix Biopharma	HER2	고형암
5	임상3상	BAT-8001	Bio-Thera Solutions	HER2	고형암
6	임상3상	datopotamab deruxtecan	Daiichi Sankyo	Trop 2	고형암
7	임상3상	iodine i 131 apamistamab	Actinium Pharmaceuticals	CD45	혈액암
8	임상3상	patritumab deruxtecan	Daiichi Sankyo	HER3	고형암
9	임상3상	SHRA-1811	Jiangsu Hengrui Medicine	HER2	고형암
10	임상3상	SKB-264	Merck & Co	Trop 2	고형암
11	임상3상	TAA-013	TOT Biopharm	HER2	고형암
12	임상3상	telisotuzumab vedotin	AbbVie	c Met	고형암
13	임상3상	TLX-591	Telix Pharmaceuticals	PSMA	고형암
14	임상3상	tusamitamab ravtansine	Sanofi/ImmunoGen	CEACAM5	고형암
15	임상3상	upifitamab rilsodotin	Mersana Therapeutics	NaPi2b	고형암
16	임상3상	zilovertamab vedotin	Merck & Co	ROR1	혈액암

※ 출처: IBK 투자증권, 기업분석 자료(2022.11.)



국가신약개발사업단
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IV. Learning & Takeaways

Learning & Key Takeaways

I. Dealmaking trends in 2022

- ❖ **M&A:** volume ↓ & value ↓ (volume: 196(2021) → 171(2022), value: \$153Bn(2021) → \$87Bn(2022))
 - Big Pharma → Small-to-Mid company, Big Pharma's patent cliff
 - Various modalities, Oncology/Immunology/CNS, etc.
- ❖ **Partnership:** volume ↓ & value(=) (volume: 1,200(2021) → 971(2022), value: \$178Bn(2021) → \$179Bn(2022))
 - Big Pharma ↔ Smaller company
 - Oncology, various modalities
- ❖ There were no mega deals in 2022.

II. Oncology R&D in 2022

- ❖ Oncology is a key driver in the global medicine market. (\$377Bn, CAGR: 13-16%)
- ❖ Novel target & modality emerging: CGT, ADC, BsAb, Small molecule with new target/MoA, etc.
- ❖ Needs: Data-driven evidences(ex: clinical trials, RWD)
- ❖ **ADC**
 - Growing, be a game-changer with significant clinical benefit
 - Global Big Pharma's key interest area

Learning & Key Takeaways

