

2023 글로벌 제약·바이오 R&D 동향 : Oncology

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I. Biopharma Dealmaking in 2022

I-I. Overall current deals

I-II. Top 10 M&As

I-III. Top 10 Partnerships

I-I. Overall current deals

Retrieved from Nat Rev Drug Disc(2023)
Retrieved from Nat Rev Drug Disc(2022)

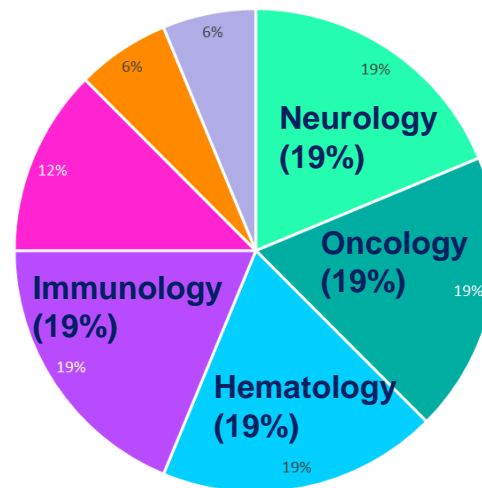
❖ Dealmaking

- M&As & Partnerships(2021, 2022) -

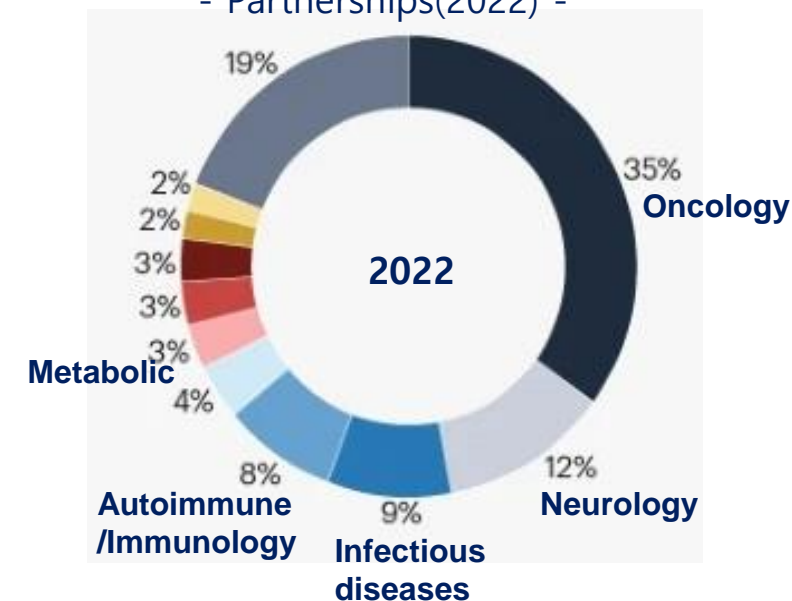
Deals in 2021, 2022				
	Deal Volume		Deal Value(disclosed tot.)	
	2021	2022	2021	2022
M&A	196	171(↓)	\$153Bn	\$87Bn(↓)
Partnership	1,200	971(↓)	\$178Bn	\$179Bn

❖ Breakdown by TA

- M&As(2022) -



- Partnerships(2022) -



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 by tot. deal value

Top 10 M&As				
Acquirer	Target focus	Acquired company	Deal value (US\$ Bn)	Announced Month
1 Pfizer	Solid tumor medicines and hematologic malignancies	Seagen	43.00	2023/3
2 Amgen	Autoimmune and severe inflammatory diseases	Horizon Therapeutics	27.80	2022/12
3 Pfizer	Migraine treatment and prevention	Biohaven Pharmaceuticals	11.60	2022/5
4 MSD	Autoimmune diseases(IBD, SSc-ILD, etc.)	Prometheus Biosciences	10.80	2023/4
5 Astellas	Ophthalmic disease	Iveric bio	5.900	2023/4
6 Pfizer	Sickle cell disease other haematological diseases	Global Blood Therapeutics	5.204	2022/8
7 BMS	Targeted oncology therapies(METi, RETi, etc.)	Turning Point Therapeutics	4.100	2022/6
8 Amgen	Autoimmune diseases	ChemoCentryx	3.736	2022/8
9 GSK	Infectious disease vaccines	Affinivax	3.300	2022/5
10 Biocon Biologics	Insulin, oncology and autoimmune disease biosimilars	Viartis's biosimilars business	3.000	2022/2

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 M&As						
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(αPD-1 x αVEGF)	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

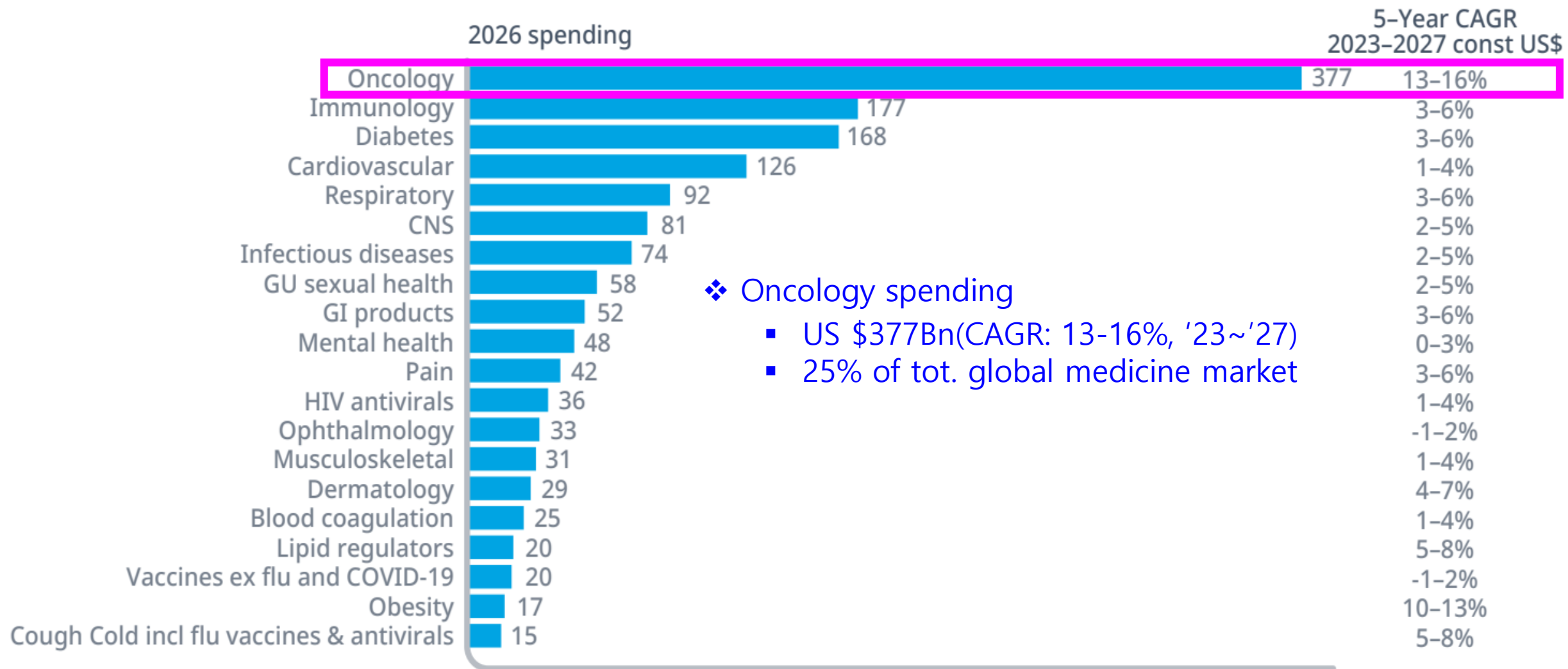
II-I. Oncology spending_(forecast for 2026), R&D(2022)

II-II. 2023 Valuable clinical trials

II-III. 2022 Approvals(FDA, EMA)

II-IV. Modality

II-I. Oncology spending (forecast for 2026)

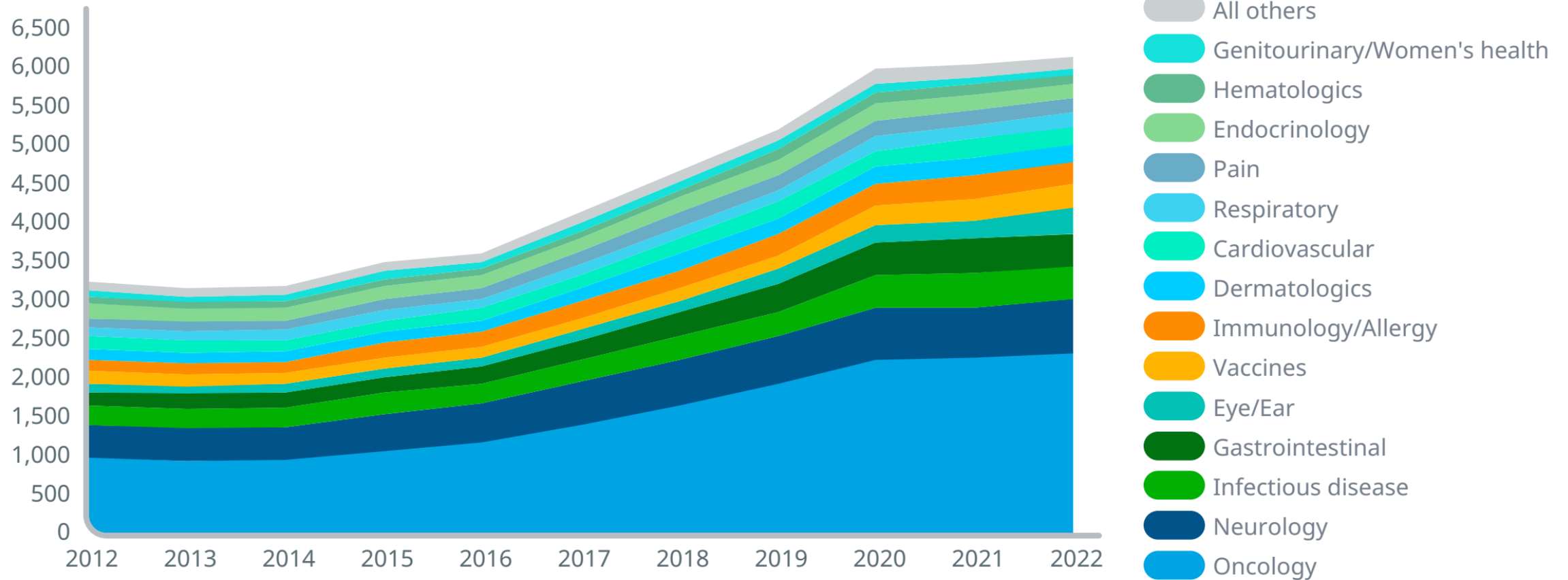


- ❖ Oncology spending
 - US \$377Bn(CAGR: 13-16%, '23~'27)
 - 25% of tot. global medicine market

II-I. Oncology R&D(2022)

(Phase I ~ Regulatory submission)

(No. of assets)



Source: IQVIA Pipeline Intelligence, Dec 2022; IQVIA Institute, Jan 2023.

II-II. 2023 Valuable clinical trials

Waiting the results from clinical trials						
Company	Product	MoA	Indication	Stage	Expectation	rNPV
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	\$6.3Bn
3 J&J	Nipocalimab	FcRn antagonist	Myasthenia Gravis	Phase 3	P3 ongoing, 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

II-III. (FDA) 12 Approvals

Retrieved from Nat Rev Drug Disc(2023), A Mullard et al.

Oncology drugs FDA CDER approved in 2022

연번	성분명	제품명	제약사	작용기전	적응증
1	Tebentafusp	Kimmtrak	Immunocore	gp100 peptide-HLAxCD3 bispecific T cell engager	포도막 흑색종
2	Relatlimab+nivolumab	Opdualag	BMS	LAG3-targeted mAb+PD1-targeted mAb	흑색종
3	Lutetium Lu-177 vipivotide tetraxetan	Pluvicto	Novatis	PSMA-binding radioligand therapeutic agent	PSMA 양성 전립선암
4	Futibatinib	Lytgobi	Taiho Oncology	FGFR kinase inhibitor	FGFR2 유전자 융합 또는 재배열을 보이는 간내담관암
5	Tremelimumab	Imjudo	AstraZeneca	CTLA4-targeted mAb	간세포암
6	Teclistamab	Tecvayli	J&J	BCMAxCD3 bispecific antibody	다발성 골수종
7	Mirvetuximab soravtansine	Elahere	Immunogen	FR α -targeted ADC	난소암
8	Olutasidenib	Rezlidhia	Rigel/Forma	IDH1 inhibitor	IDH1 변이 급성 골수성 백혈병
9	Adagrasib	Krazati	Mirati	KRAS-G12C inhibitor	KRASG12C 변이 비소세포폐암
10	Mosunetuzumab	Lunsumio	Roche/Genentech	CD20xCD3 bispecific antibody	여포성 림프종

Oncology drugs FDA CBER approved in 2022

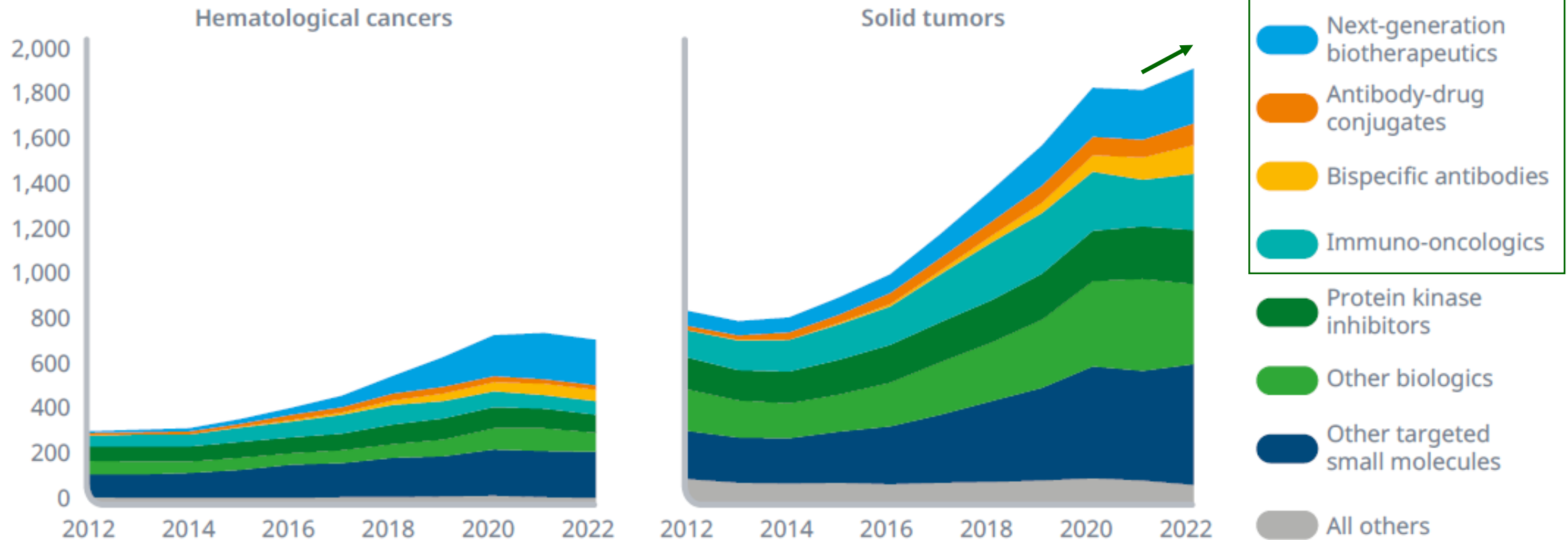
연번	성분명	제품명	제약사	작용기전	적응증
1	Ciltacabtagene autoleucel	Carvykti	Legend Biotech/J&J	BCMA-targeted genetically modified autologous T cell immunotherapy	Multiple myeloma
2	Nadofaragene firadenovec	Adstiladrin	Ferring	Interferon α -2b-encoding adenovirus vector gene therapy	BCG-unresponsive non-muscle invasive bladder cancer

II-III. (EMA) 12 Approvals

Oncology drugs EMA approved in 2022					
연번	성분명	제품명	제약사	작용기전	적응증
1	Lisocabtagene maraceucel	Breyanzi	BMS	CD19 CAR-T	Diffuse large B-cell lymphoma primary mediastinal large B-cell lymphoma follicular lymphoma grade 3B
2	Ciltacabtagene autoleucel	Carvykti	Janssen	BCMA CAR-T	Multiple Myeloma
3	Tabelecleucel	Ebvallo	Pierre Fabre Medicament	T-cell immunotherapy	Lymphoproliferative Disorders
4	Tremelimumab	Imjudo	AstraZeneca	CTLA-4 monoclonal Ab	Carcinoma, Hepatocellular
5	Tebentafusp	Kimmtrak	Immunocore	gp100 peptide-HLAxCD3 bispecific T cell engager	Uveal melanoma
6	Mosunetuzumab	Lunsumio	Roche	CD20xCD3 bispecific antibody	Follicular Lymphoma
7	Relatlimab+nivolumab	Opdualag	BMS	LAG3-targeted mAb+PD1-targeted mAb	Melanoma
8	Lutetium Lu-177 vipivotide tetraxetan	Pluvicto	Novartis	PSMA-binding radioligand therapeutic agent	Prostatic Neoplasms, Castration-Resistant
9	Capmatinib	Tabrecta	Novartis	MET Kinase inhibitor	Carcinoma, Non-Small-Cell Lung
10	Teclistamab	Tecvayli	Janssen	BCMAxCD3 bispecific antibody	Multiple Myeloma
11	Tremelimumab	Tremelimumab AstraZeneca	AstraZeneca	CTLA4-targeted mAb	Carcinoma, Non-Small-Cell Lung
12	Loncastuximab tesirine	Zynlonta	ADC Therapeutics	CD19 target ADC	Diffuse large B-cell lymphoma, high-grade B-cell lymphoma

II-IV. Modality

(Phase I to regulatory submission)



- Focused on solid CA with ADC, BsAb, IO, CAR-T

III. IO, BsAb, CGT, ADC in Oncology 2022

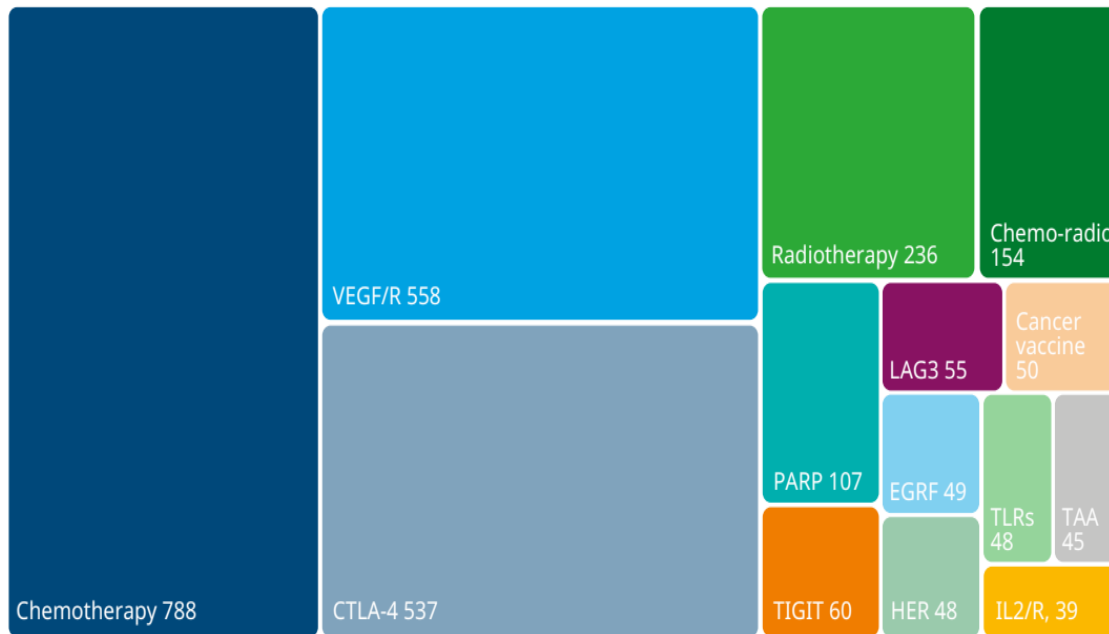
III-I. IO(R&D 2021, 2022)

III-II. BsAb(R&D 2022, Current deals)

III-III. CGT(R&D 2022)

III-IV. ADC(R&D 2022)

III-I. IO(R&D 2021, 2022)



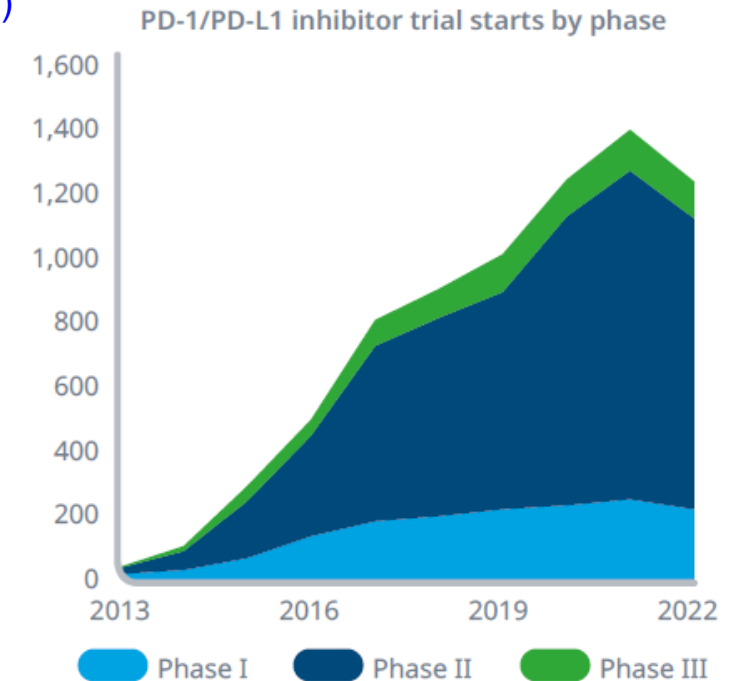
+ αPD-1 mAb Approval in 2023
: Zynyz(Retifanlimab, Incyte)

7 PD-1/L1
pathway checkpoint
inhibitors approved by
FDA to date

300 targets
in total being investigated in
PD-1/L1 combination trials

5,761 trials
testing PD-1/L1 inhibitors
worldwide in 2021

(Phase I to regulatory submission)



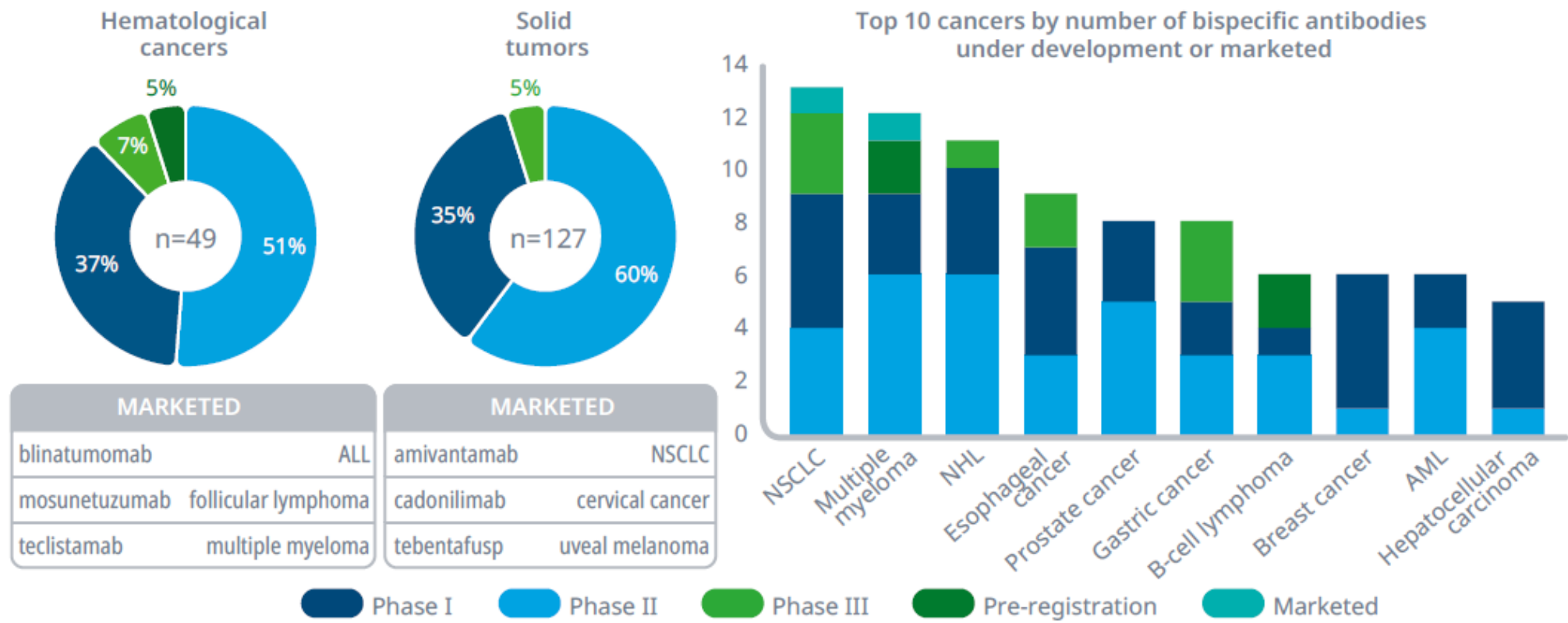
Challenges and opportunities in the PD1/PDL1 inhibitor clinical trial landscape, Nature Reviews Drug Discovery, Feb 2022.

Source: Citeline Trialtrove, IQVIA Institute, Apr 2023.

- ❖ 5,761('21) & 3,368('22) testing PD-1/PD-L1 inhibitors
- ❖ >80% of clinical trials with αPD-1/αPD-L1 inhibitor as a combination therapy(monotherapy trials ↓)
- ❖ 300 combi. Targets/pathways

III-II. BsAb(R&D 2022)

(Phase I to regulatory submission)



Source: IQVIA Pipeline Intelligence, Dec 2022; IQVIA Institute, Apr 2023.

IQVIA Institute, Global Oncology Trends 2023

- ❖ About 130 BsAbs(Hema: 24%, Solid: 67%, Both: 9%)
- ❖ Early trials(>50%), Phase III(Hema:7%, Solid: 5%)

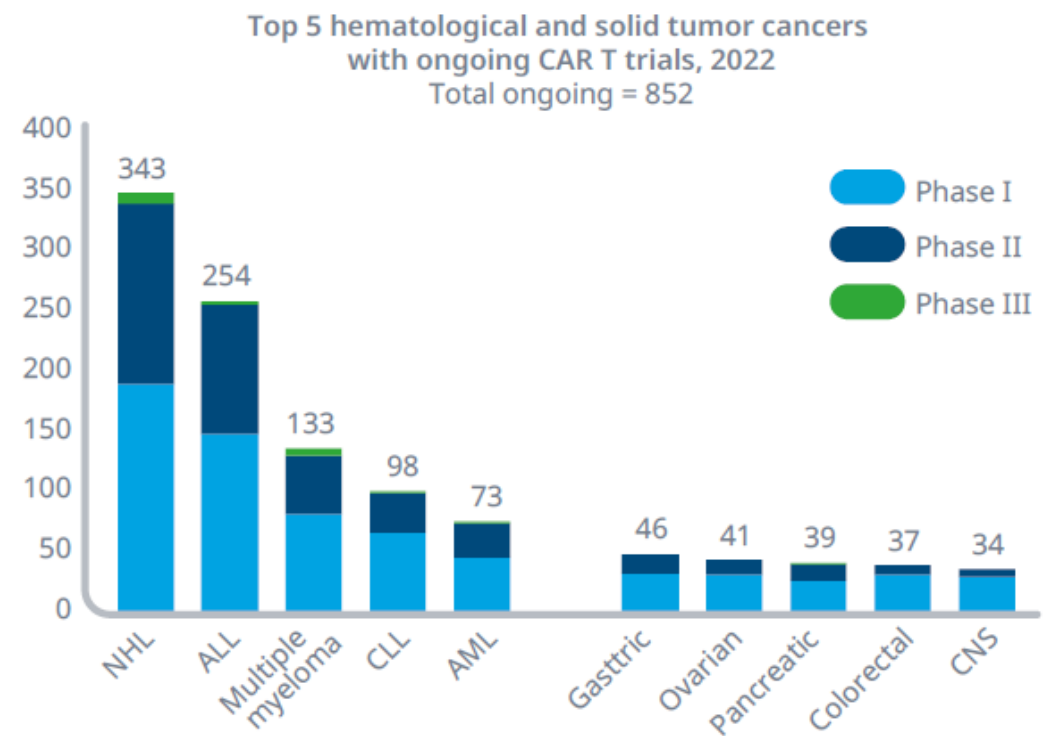
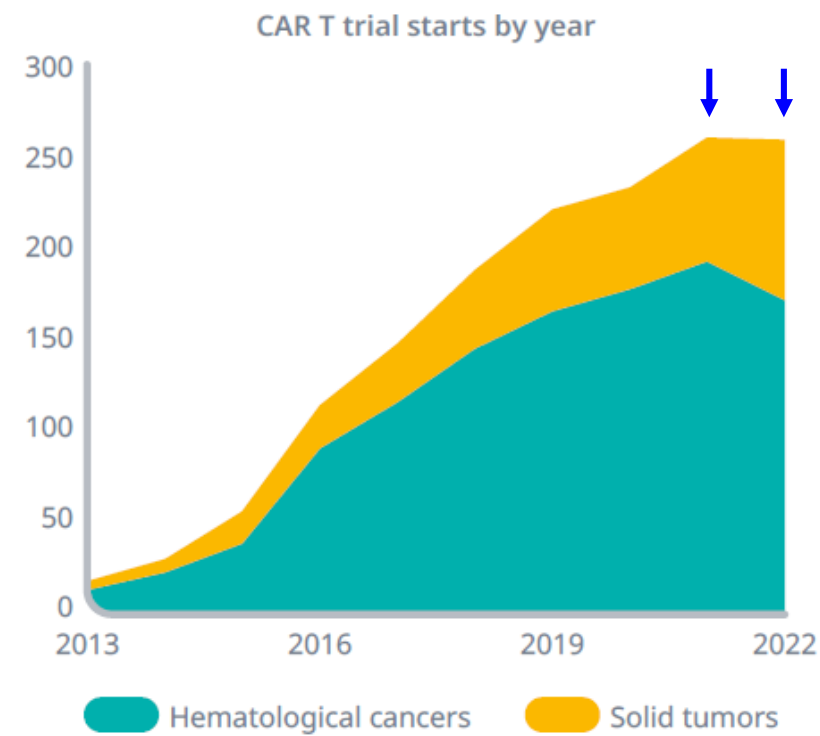
III-II. BsAb(Current Deals)

Retrieved from GlobalData

Top 8 Deals by tot. deal value (> \$1 Bn) (disclosed value only)					
Company	Partner	Focus	Deal value (US\$ Bn)	Announced Month	
1 Akeso Biopharma	Summit Therapeutics	α PD-1x α VEGF BsAb	5.0	2022/09	
2 Cytomx Therapeutics	Regeneron Pharmaceuticals	Probody platform	2.0	2022/11	
3 Zymeworks	Jazz Pharmaceuticals	Zanidatamab(α HER2 BsAb)	1.8	2022/10	
4 MacroGenics	Gilead	MGD024(α CD3 x α CD123 BsAb)	1.8	2022/10	
5 Abpro	CellTrion	ABP102(α HER2 x α CD3 BsAb)	1.8	2022/09	
6 Wuxi Biologics	GSK	Bi-, Multi-specific T cell Engaging Antibodies(TCE)	1.5	2023/01	
7 Dren Bio Inc	Pfizer Inc	Targeted Myeloid Engager and Phagocytosis platform	1.0	2022/01	
8 LAVA Therapeutics NV	Seagen Inc	Bispecific $\gamma\delta$ T cell engager	0.7	2022/09	

III-III. CGT(R&D 2022)

(Phase I to regulatory submission)



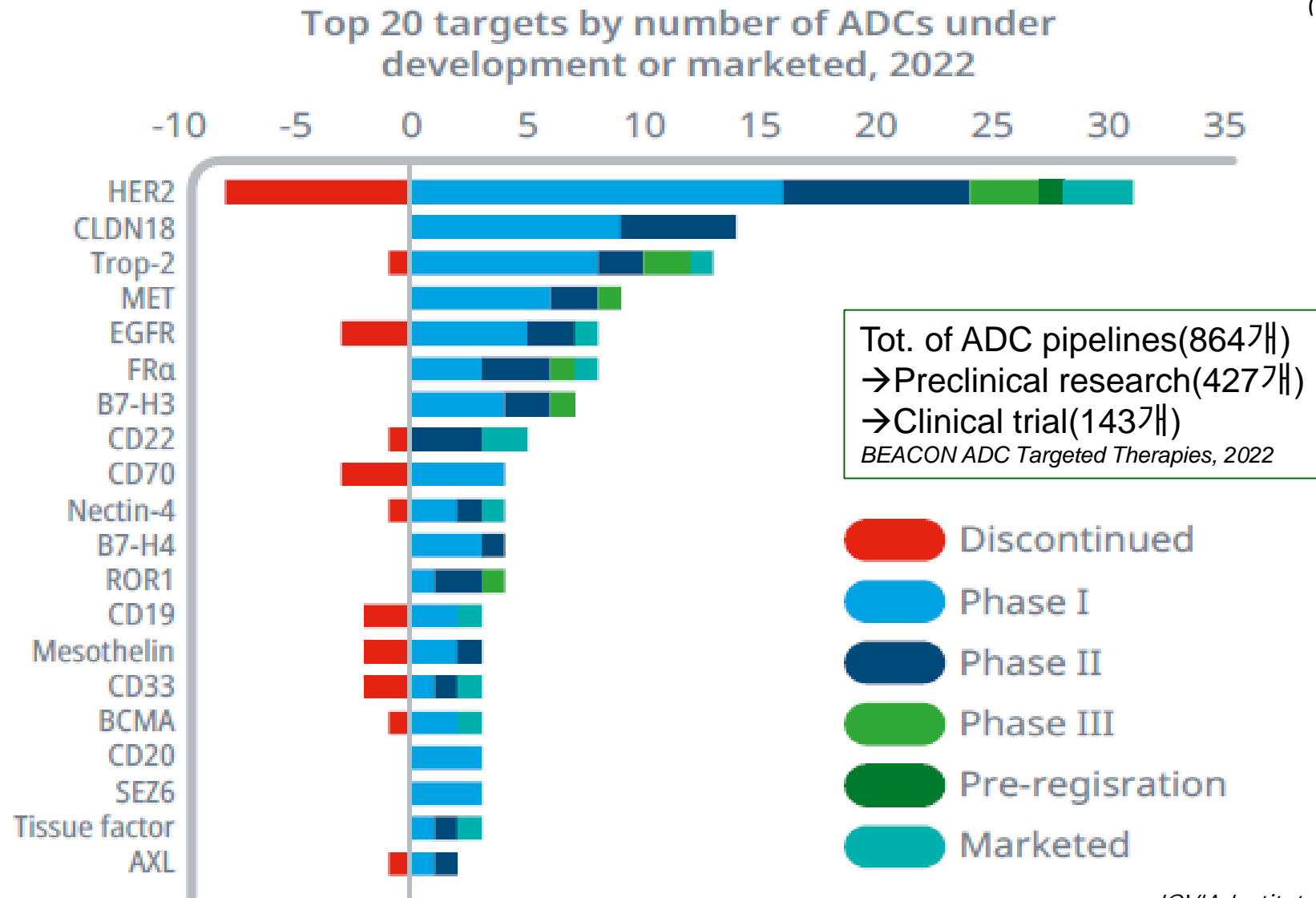
Source: Citeline Trialtrove, IQVIA Institute, Apr 2023.

IQVIA Institute, Global Oncology Trends 2023

- ❖ **Oncology(42%)/Next-generation therapy**
- ❖ **CAR-T & CAR-T/NK in Hema. & solid CA**
- ❖ **(‘22)Tot. 250 pipelines, growing in Solid CA with UMN^{hi}**

III-IV. ADC(R&D 2022)

(Phase I to regulatory submission)



IV. ADC in Oncology

IV-I. FDA approval

IV-II. ADC(R&D 2022)

IV-III. Current Top 14 Deals(2022~2023.05.)

IV-IV. Major modality in current Dealmaking

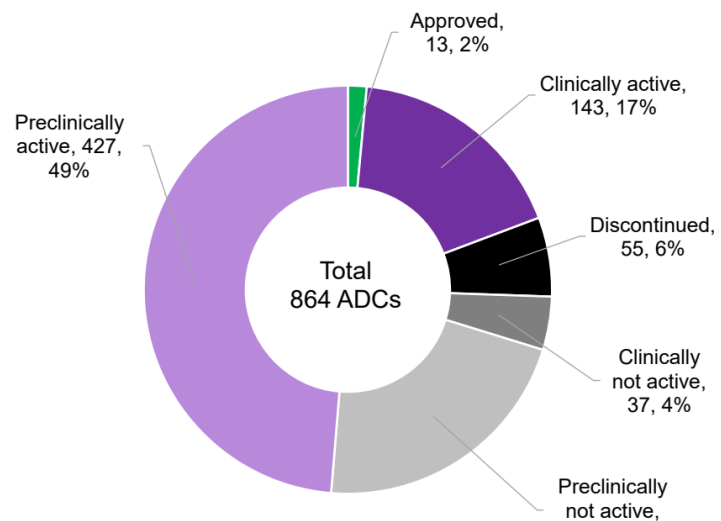
IV-V. Ongoing clinical trials

IV-I. FDA approval

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

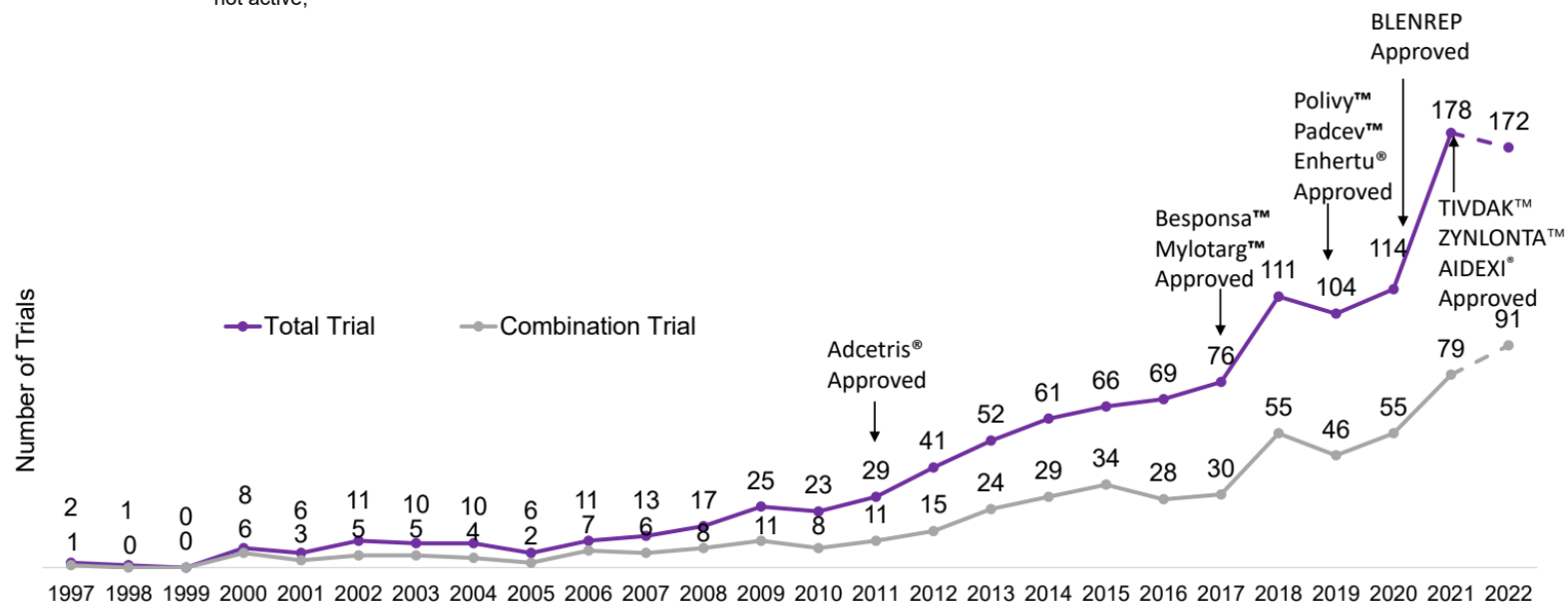
Approval	Company	ADC	Target	Indication	Linker	Payload
1 2000, 2017	Pfizer/Wyeth	Mylotarg	CD33	급성 골수성 백혈병	AcBut	Calicheamicin
2 2011	Seagen/Astellas	Adcetris	CD30	재발성 또는 난치성 호지킨 림프종 및 전신 역형성 대세포 림프종	Val-cit	MMAE
3 2013	Genentech/Roche	Kadcyla	HER2	Trastuzumab 내성 유방암	SMCC	DM-1
4 2017	Pfizer/Wyeth	Besponsa	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/Immuno- matics	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

IV-II. ADC(R&D 2022)



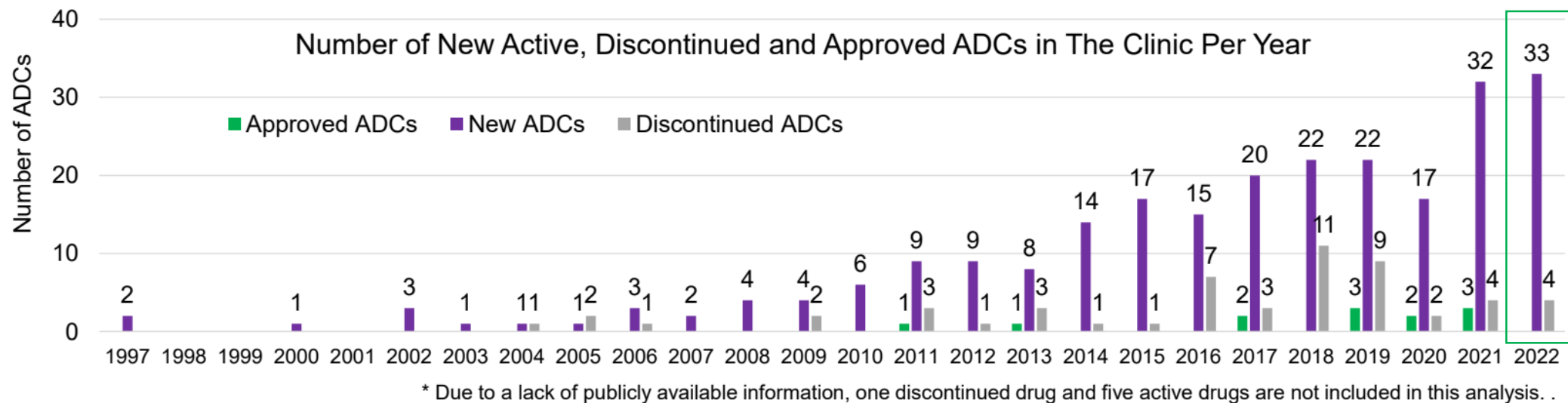
[Tot. 864 ADCs]

- Active **preclinical** research 49% (427개)
- Active **clinical** trial 17% (143개)
- * **33 new ADCs** entered clinical trial this year.



IV-II. ADC(R&D 2022)

Retrieved from BEACON ADC Targeted Therapies, 2022

[33 new ADCs initiated clinical trial]

- Disease: Solid CA(29), Blood CA(4)
- Antigen
 - HER2, CLDN18.2, TROP2, FR- α , B7-H4, B7-H3, 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)

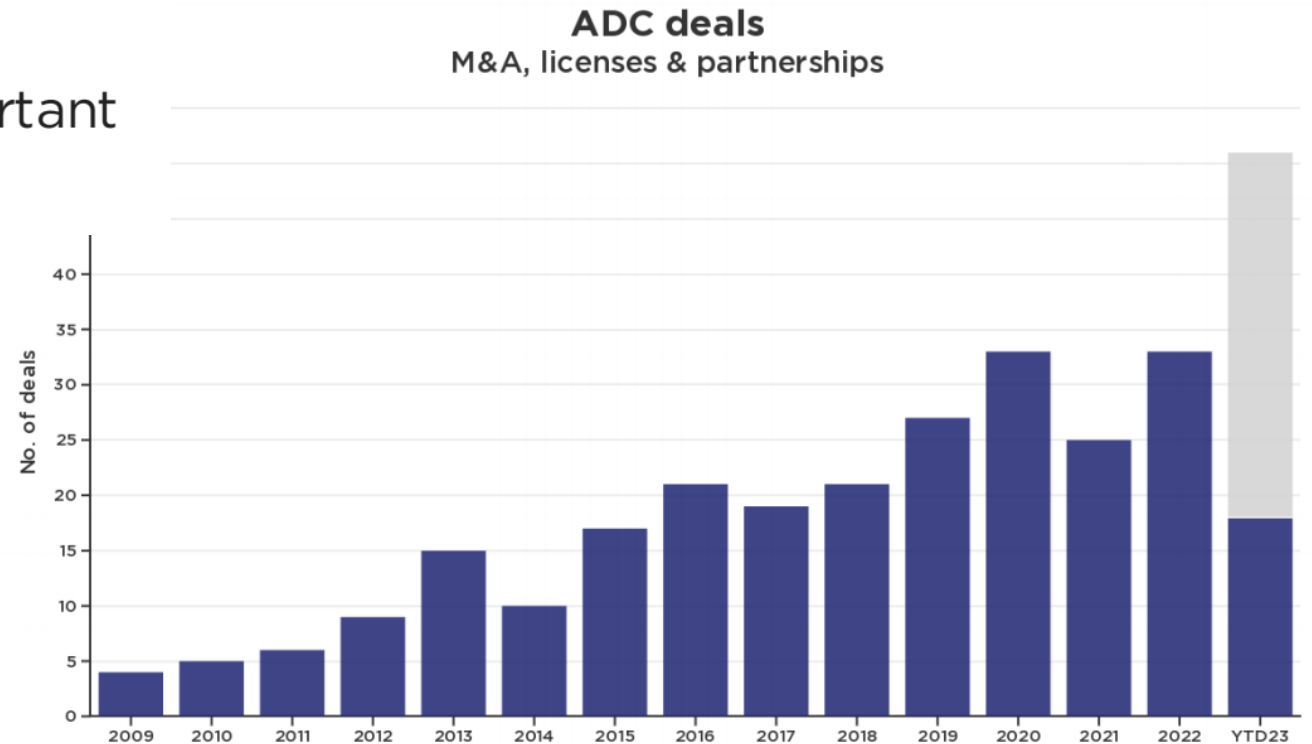
IV-III. Top 14 Deals(2022~2023.05.)

Top 13 Deals by tot. deal value (> \$1 Bn) (disclosed value only)					
Company	Partner	Focus	Deal value (US\$ Bn)	Announced Month	
1 Pfizer	Seagen	ADC pipelines including Adcertis, Padcev, Tivdak, Tukysa	43.0	2023/3	
2 Merck & Co	Sichuan Kelun Biotech Biopharmaceutical	7 preclinical assets + α	9.3	2022/12	
3 MacroGenics	Synaffix	7 preclinical assets	2.2	2023/3	
4 Blissbio	Eisai	4 assets(including BB-1701)	2.0	2023/5	
5 Amgen	Synaffix	GlycoConnect™, HydraSpace™, toxSYN™ 5 assets	2.0	2023/1	
6 Eli Lilly	ImmunoGen	Camptothecin-linker payload technology	1.73	2023/2	
7 BioNTech	Duality Biologics	Phase II asset(DB-1303/HER2), Preclinical asset(DB-1311)	1.7	2023/4	
8 Mersana Therapeutics	GSK	Preclinical asset(XMT-2056/HER2-targeting STING agonistic ADC)	1.463	2022/8	
9 Celltrion	Pinotbio	PINOT-ADC™	1.3	2022/10	
10 Amgen	Legochem	ADCs, 5 targets selected by Amgen based on LCB's proprietary ConjuAll ADC	1.248	2022/12	
11 Elevation Oncology	CSPC Megalith Pharmaceuticals	Phase I asset(EO-3021/CLDN18.2)	1.175	2022/7	
12 Janssen Biotech	Mersana Therapeutics	3 ADCs co-development Dolasynten platform	1.040	2022/2	
13 Merck & Co	Sichuan Kelun Biotech Biopharmaceutical	SKB-264(Trop-2 ADC)	0.936	2022/7	
14 Merck KGaA	Mersana Therapeutics	STING agonistic ADC(2 targets)	0.830	2022/12	

IV-IV. Major modality in current Dealmaking

ADCs' recent resurgence is just the beginning

Dealmaking analysis shows antibody-drug conjugates becoming a strategically important modality for many cancer companies



Source: BCIQ • 2023 data as of May 8; gray bar estimates 2023 full-year number if the deal frequency seen so far were to remain steady. Chart excludes collaborations solely to test approved ADCs in combination trials.

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IV-V. Ongoing clinical trials

연번	개발단계	제품명/물질명	개발사	타겟	구분
1	적응증 확장(PDUFA 23.02)	Trodely	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	Ambrx 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.)

V. Learning & Takeaways

Learning & Key Takeaways

I. Dealmaking trends in 2022

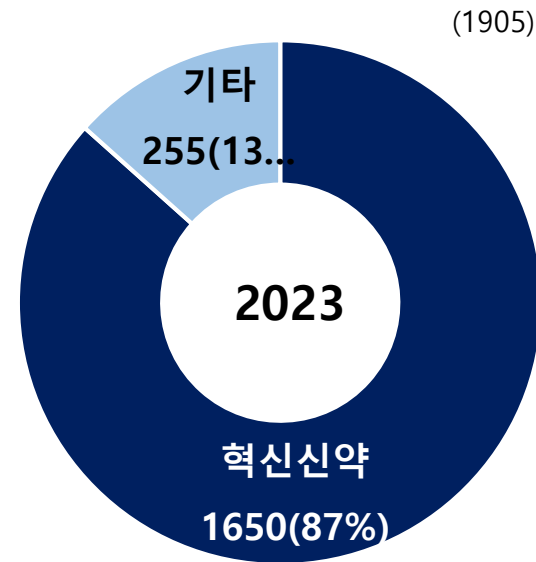
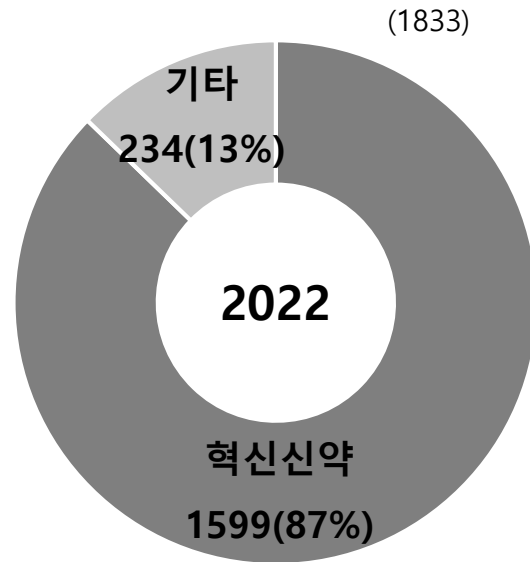
- ❖ **M&A:** volume ↓ & value ↓ (volume: 196(2021) → 171(2022), value: \$153Bn(2021) → \$87Bn(2022))
 - Big Pharma → Small-to-Mid company, Big Pharma's patent cliff
 - Various modalities, Oncology/Immunology/CNS, etc.
- ❖ **Partnership:** volume ↓ & value(=) (volume: 1,200(2021) → 971(2022), value: \$178Bn(2021)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

II. Oncology R&D in 2022

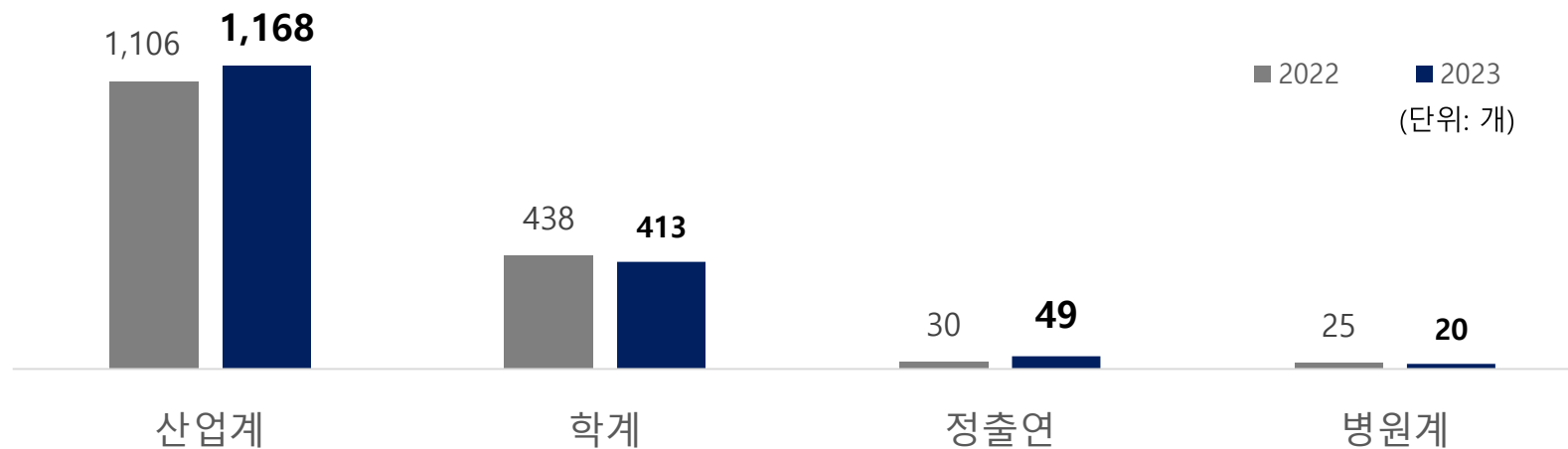
- ❖ Oncology is a key driver in the global medicine market. (\$377Bn, CAGR: 13-16%)
- ❖ Novel target & modality emerging: ADC, BsAb, Cell & Gene therapy, small molecule with new target/MoA, etc.
- ❖ Needs: Data-driven evidences(ex: clinical trials, RWD)
- ❖ **ADC**
 - Growing, be a game-changer with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

2023 국내 파이프라인 조사

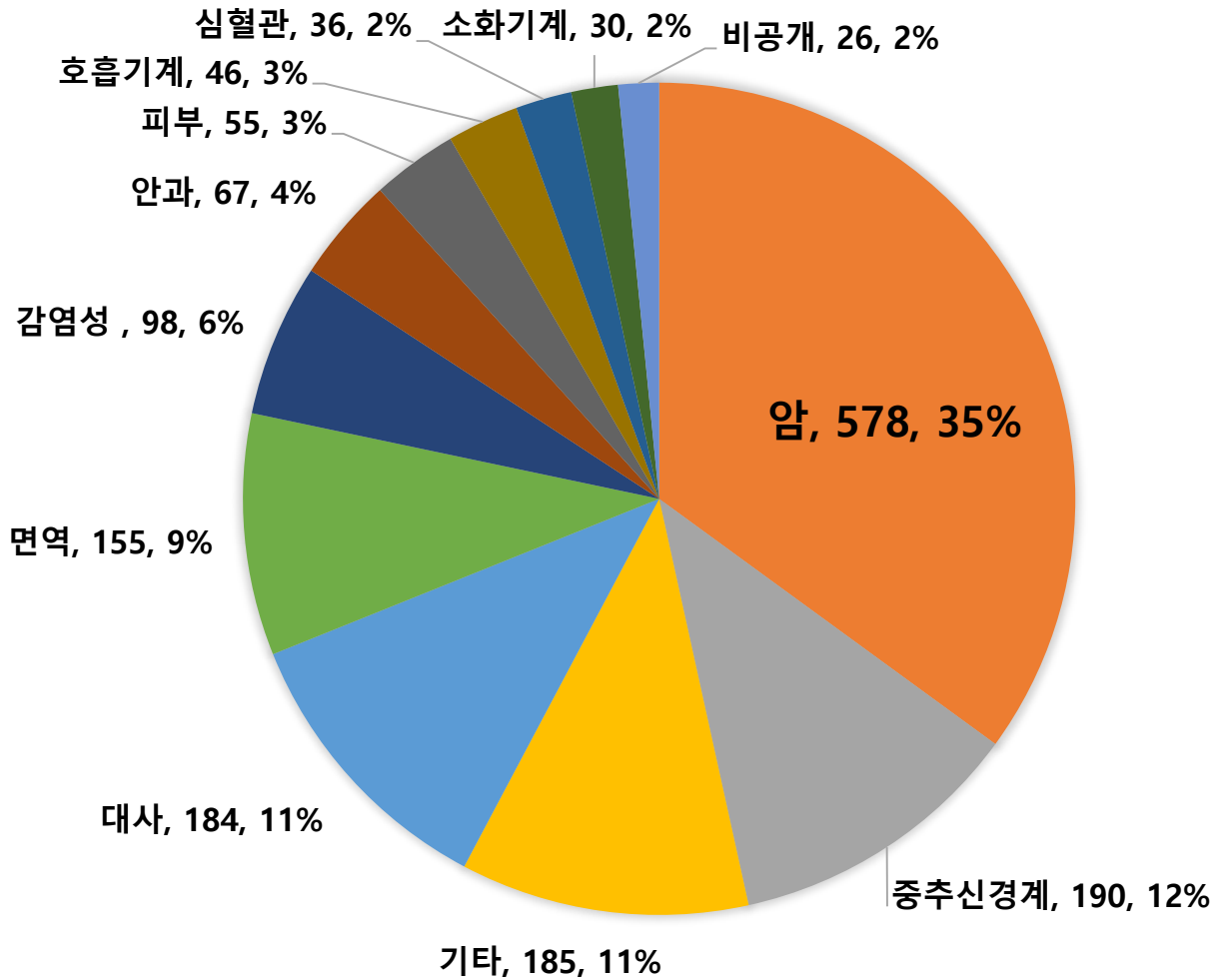
혁신신약



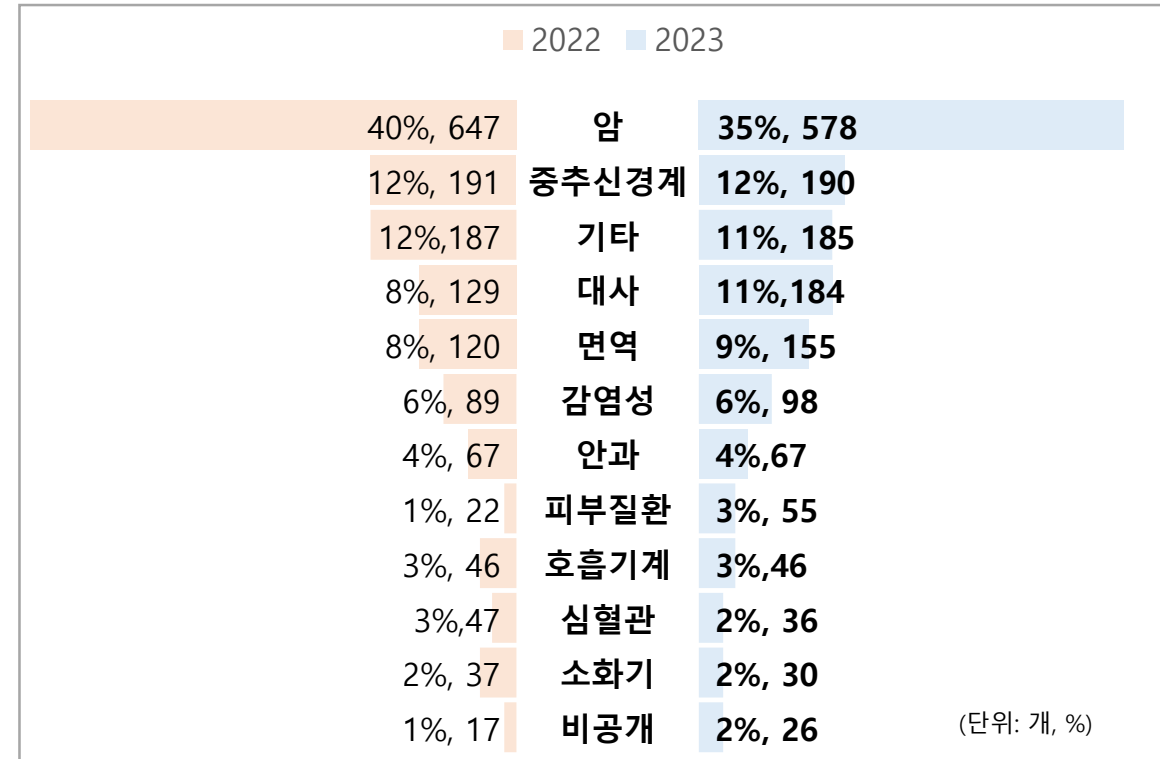
기관



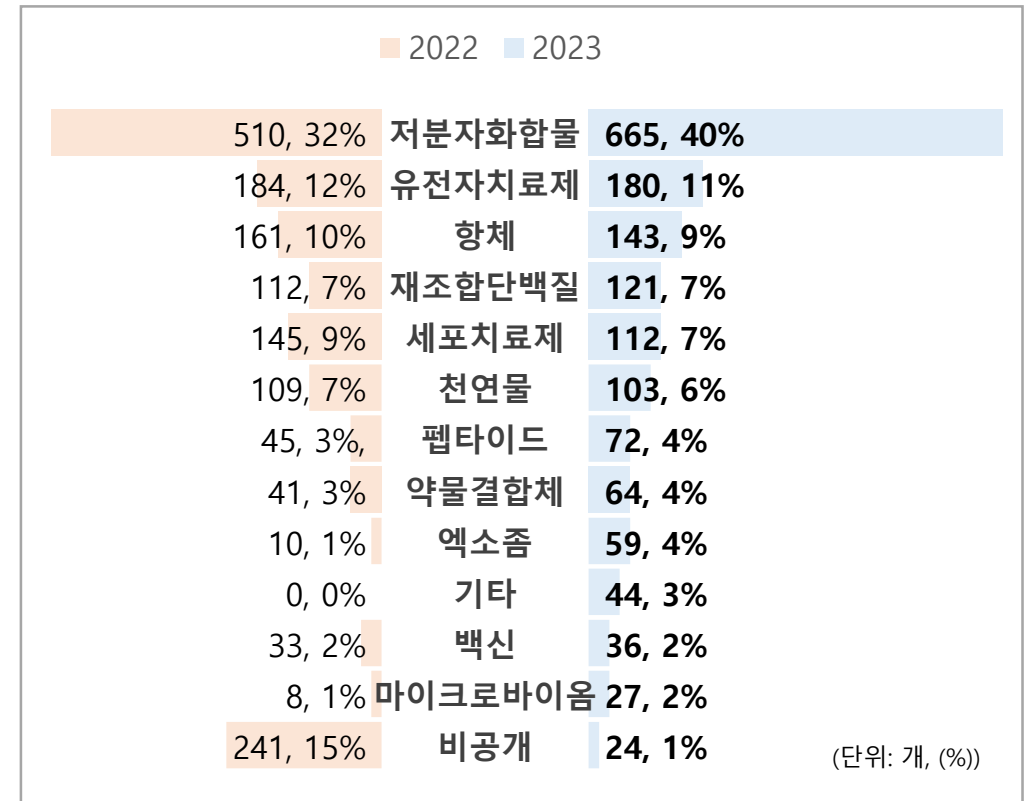
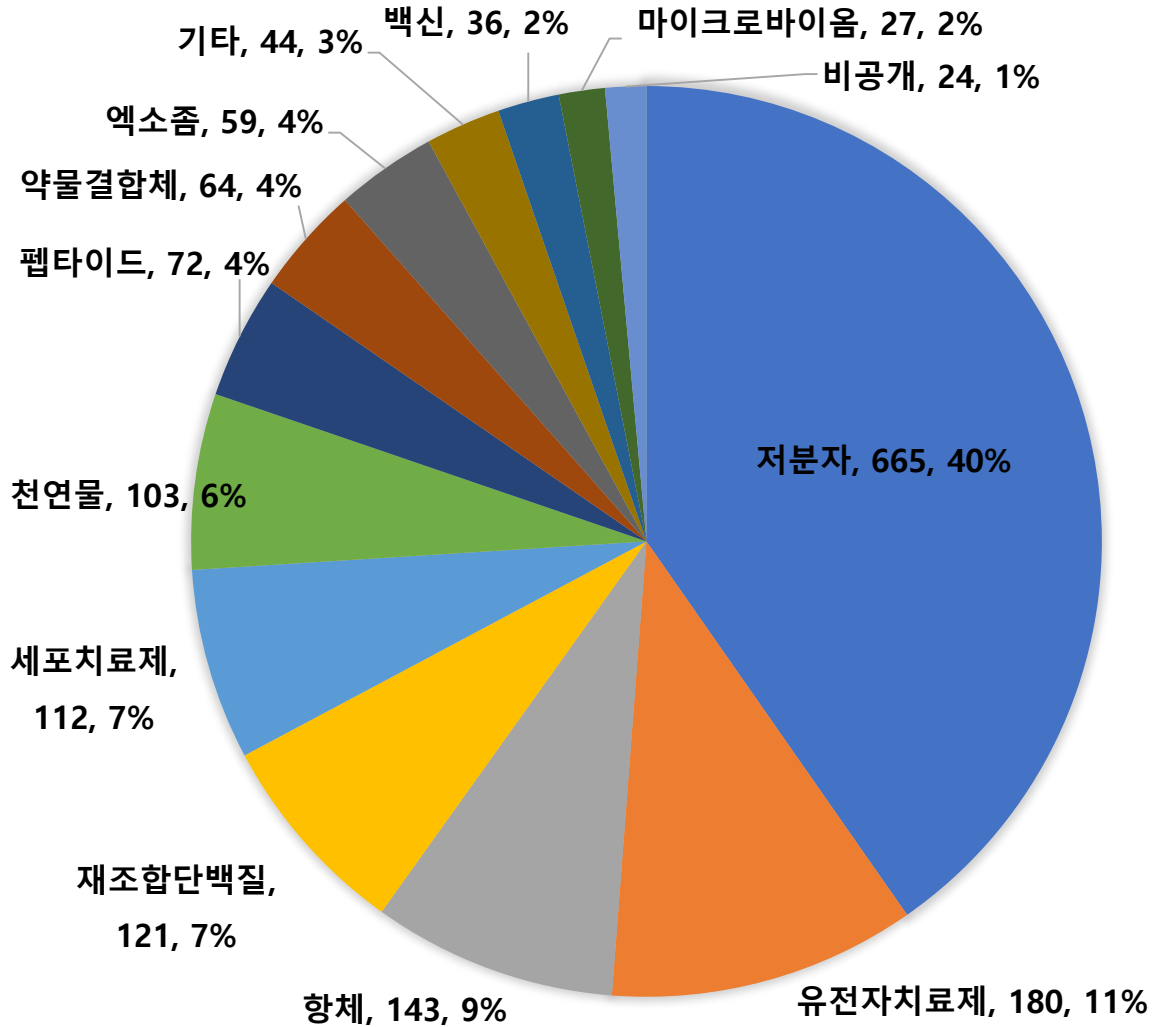
질환별 파이프라인



(단위: 개, %)



(단위: 개, %)



국내 파이프라인 및 KDDF 지원현황

