

# 知己知彼 百战不殆



C&E Consulting  
Oct. 2019

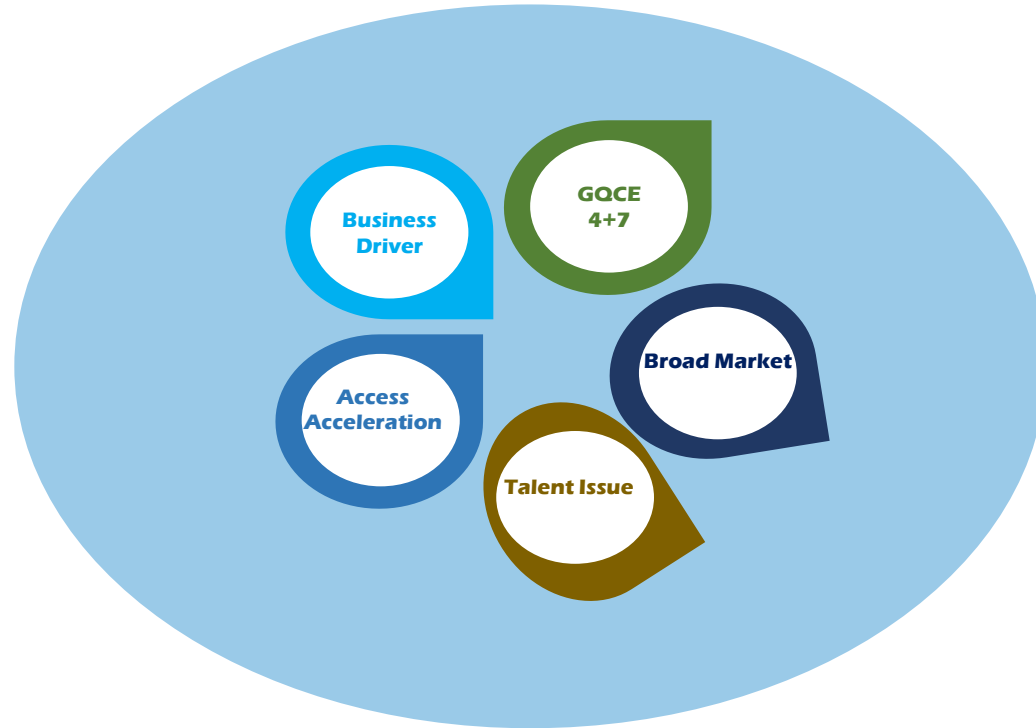


# 市场环境不断变化，制药企业面临决定命运的转折

01 药品注册审评大幅提速，  
为创新药物的市场准入  
大开绿色之门

02 价格谈判常规化为创新  
药物、高价药物提升可  
及性

03 多渠道营销模式逐步成  
熟，为企业带来更多发  
展空间



04 成熟产品面临VBP带量采  
购政策影响，原研药市  
场份额面临流失严重的风险

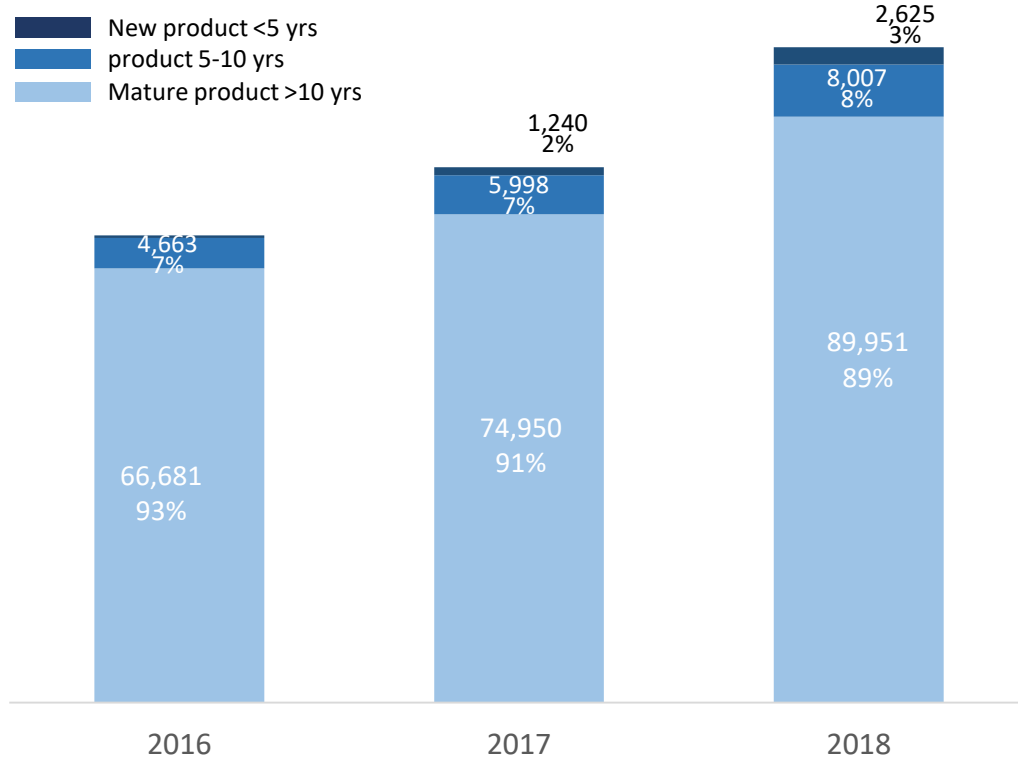
05 众多企业面临产品线老  
化、缺乏新药储备，新  
产品准入周期长的压力

06 核心市场已趋饱和，广  
阔市场的开拓势在必行

07 高级管理人才频繁流动

# 以MNC为例来说，成熟产品仍然是生意的基石，但新产品的贡献和地位是逐年提升的

Top 5 MNC Revenue Contribution



- 从近两年开始，在华MNC的发展出现了分水岭
- 成熟产品目前遭遇多重压力，未来支持MNC增长的主力会由新产品接棒

# 回顾第一轮4+7：MNC原研产品断臂之痛

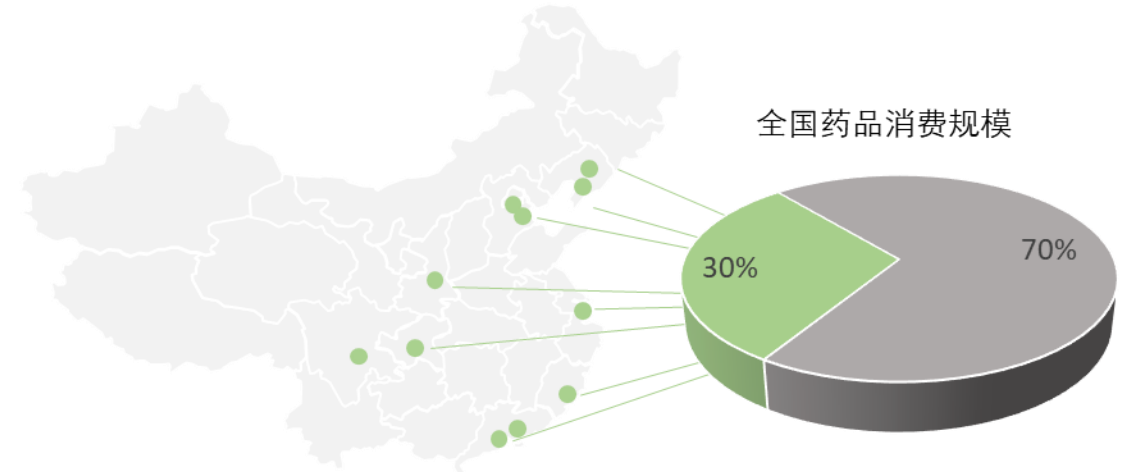
- 4+7带量采购中标品种绝大多数与原研单价差距巨大

TA	到期原研产品	原研价格 <sup>1</sup> RMB Yuan/PIC	4+7中标品种 价格 RMB Yuan/PIC	价差 <sup>2</sup>
高血压	 NORVASC 5mg	4.43	0.15	<b>-96.1%</b>
高血脂	 CRESTOR 10mg	7.53	0.78	<b>-89.6%</b>
抗感染	 BARCLUDE 0.5mg	27.45	0.62	<b>-97.7%</b>
抗肿瘤	 GLEEVEC 100mg	165.83	10.4	<b>-97.7%</b>
	 IRESSA 250mg	228	54.7	<b>-76%</b>

1 Refer to latest tender price in Shanghai

2 Price gap between originators and generic tender (4+7 volume-based procurement) price

- 4+7带量采购意味着占全国30%份额的市场中有一半以上的生意无法染指



- 4+7城市 (11 cities) 占据全国药品消费总额的30%
- 政府及医保管理部门承诺4+7城市中25个品种药品的50%销量给中标产品独享
- 第一批带量采购中标产品的平均降价幅度高达52%
- 政府要求非中标品种3年内平稳降价至中标产品价格
- 4+7带量采购既是对MNC利润的挤压，也是对仿制药行业的洗牌

# 回顾第一轮4+7：MNC应对之举

## 企业层面



### 市场扩面下沉

广阔市场团队扩容  
销售贡献增长明显



### 产品线调整

加速上市进程  
剥离成熟产品  
加大新产品引进力度



### 多渠道分流

提升Digital推广力度  
基于健康物联网技术的创新模式  
零售市场的开拓

## 产品层面



### 管理优化

调整人力部署  
优化激励政策  
聚焦内外资源



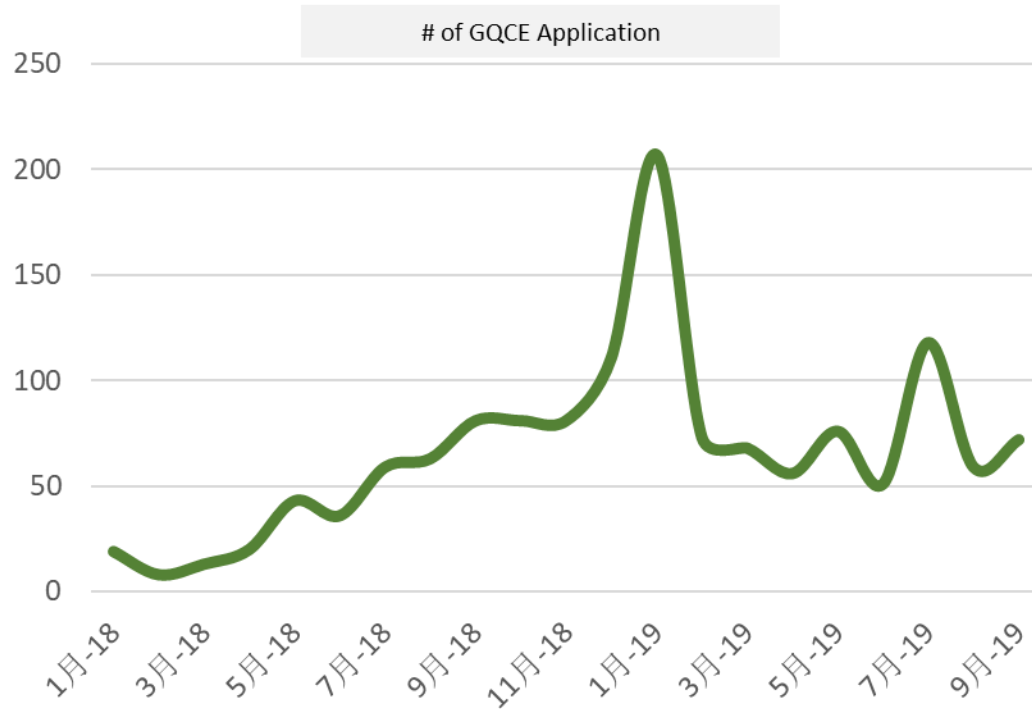
### 提升患者准入 延长DoT

规范治疗流程  
降价和创新的支付方式

# 这还仅仅是开始.....VBP政策影响还会继续

## 一致性评价及其配套的带量采购模式有进一步**扩大**的趋势

- 完成GQCE并提交审批申请的品规从2018H2开始明显增加
- 带量采购有扩大执行范围，扩大治疗领域，增加招标频率的趋势



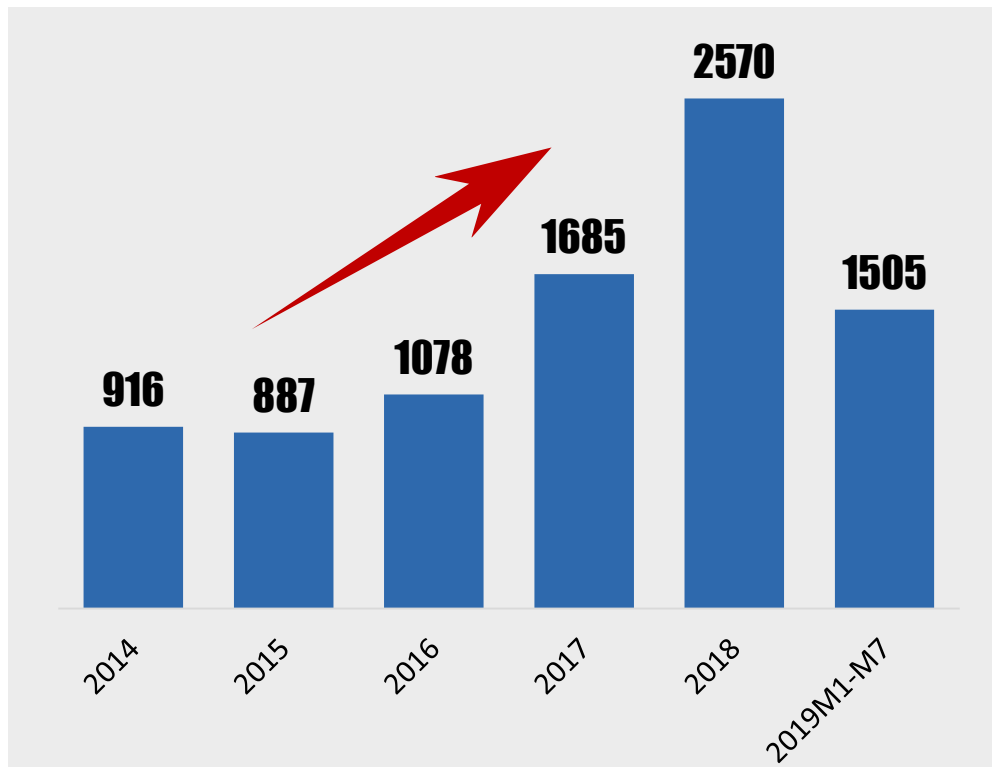
## ” 4+7 “25个品种扩围到全国

- 已执行省市：4+7、河北、福建
- 扩围范围：剩余25个省份
- 品种：25个品种
- 采购量：各地区首年约定采购量计算基数的 50%-70%

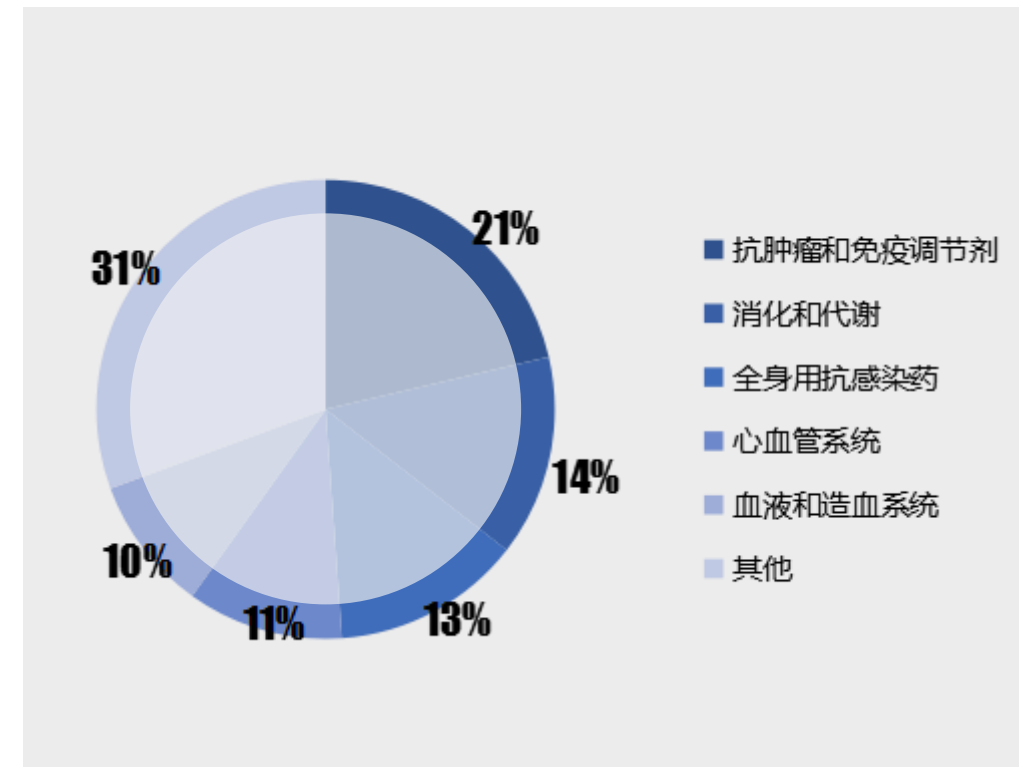
部分省份落地执行时间								
	Jun-19	Jul-19	Aug-19	Sep-19	Oct-19	Nov-19	Dec-19	Jan-20
福建	█							
河北		█						
湖南							█	
吉林							█	
河南							█	
安徽							█	
湖北							█	
广东								█
海南								█
浙江								█
贵州								█

# 此消彼长，成熟产品面临挑战，创新药物研发成为热点

## 历年获得CTR编号的临床数量

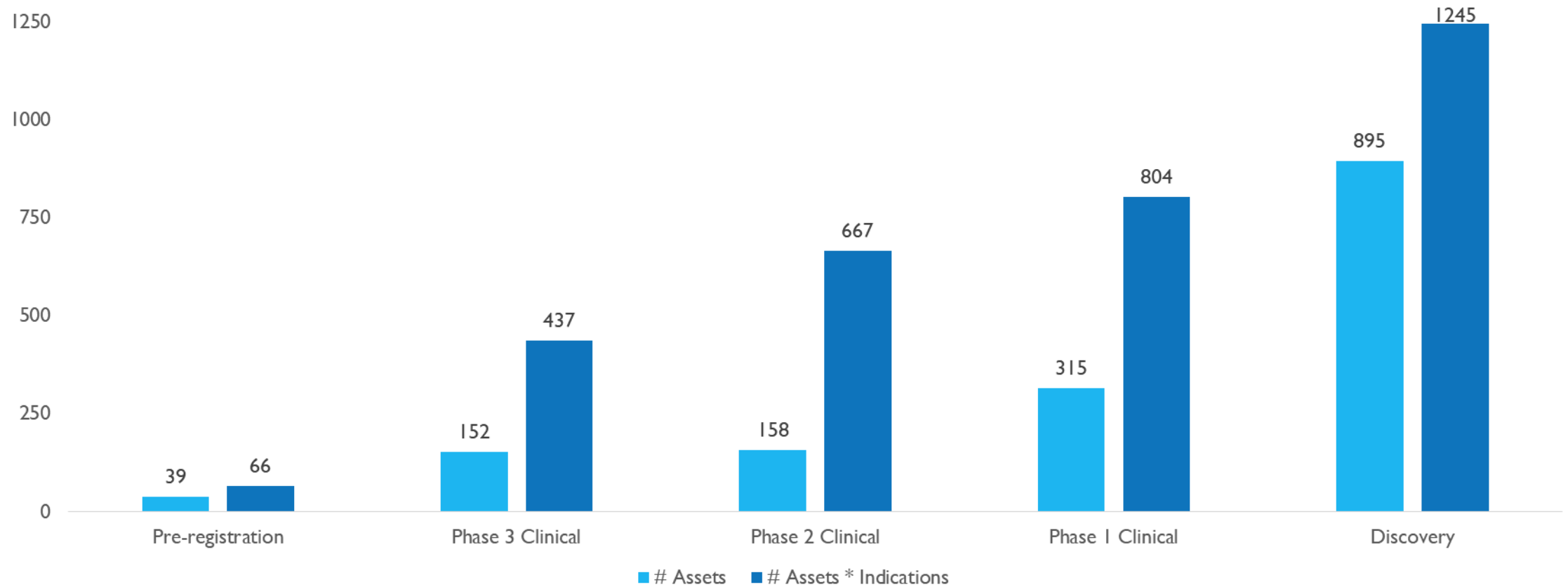


## 目前临床试验分领域统计



数据来源：国家药品监督管理局药品评审中心（截至2019年7月24日）

# 单就肿瘤领域，目前国内进入临床在研产品660以上















Note: # Assets \* Indications, count by indications by assets

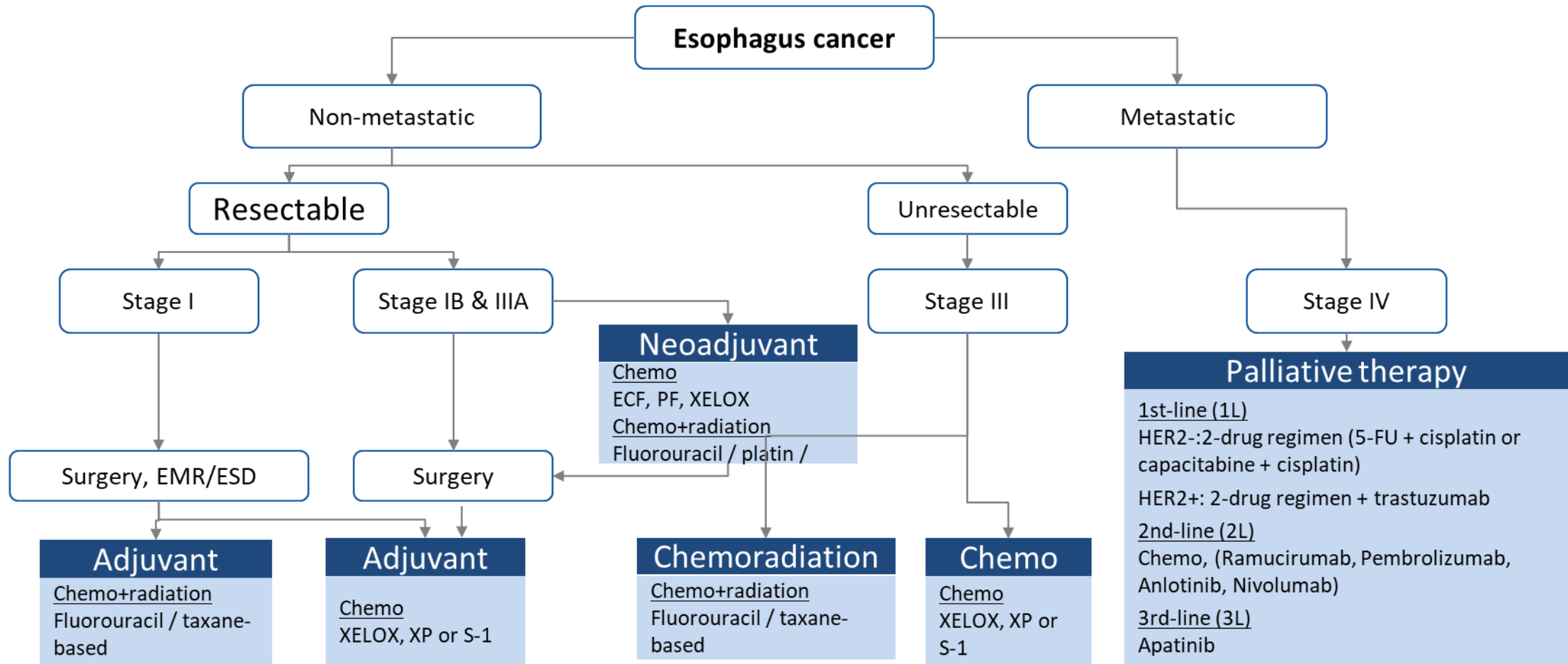
Source: CDE NDA/BLA and CTA database; Public releases, etc.; C&E analysis



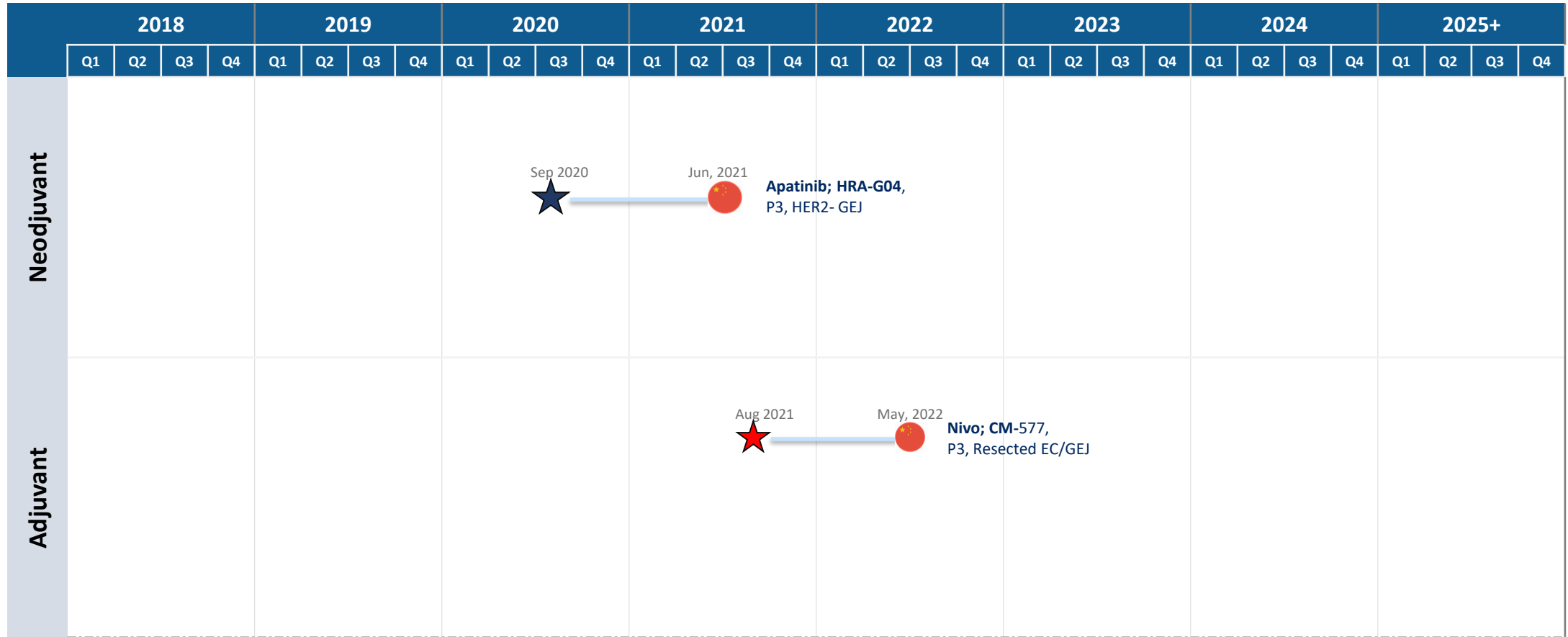
# 关注竞争对手的Pipeline, 及时跟踪竞品动向, 掌握先机

Oncology Pipeline Scan - Master Data													
													
Asset	Drug Ref ID	Type	Brand	Molecule	Corporation (Simplified)	Originator	Active Companies	Technologies	Categories	Antibody Type	MoA	Approval Timeline	
Imfinzi	OPS1804		Imfinzi	Durvalumab	AstraZeneca	MedImmune LLC	Celgene Corp	Biological Therapeutic	Antibody	Monoclonal antibody	(PD-L1)		2020
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Imfinzi	OPS1804				AstraZeneca	MedImmune LLC		Biological Therapeutic	Antibody	Monoclonal antibody	PD-L1		2020
AZD-2281	OPS1071				AstraZeneca	The University of Newcastle Upon Tyne	AstraZeneca plc; Merck & Co	Small Molecule Therapeutic	TKI		PARP,		2020
AZD-2281	OPS1071				AstraZeneca	The University of Newcastle Upon Tyne		Biological therapeutic; Infusion; Intravenous formulation; Monoclonal Biological therapeutic;	TKI		PARP,PARP1,PARP2, Poly ADP ribose polymerase 3		2019
AZD-2281	OPS1071				AstraZeneca	The University of Newcastle Upon Tyne		Biological therapeutic; Infusion; Intravenous formulation; Monoclonal Biological therapeutic;	TKI		PARP,PARP1,PARP2, Poly ADP ribose polymerase 3		2020
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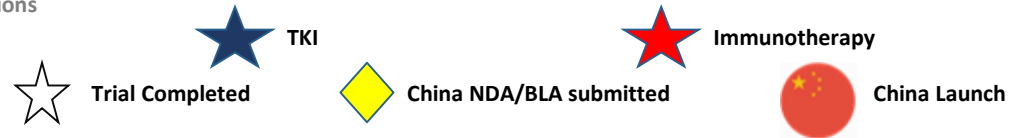
# Case Share: Summary for patient flow (Esophagus cancer)



# Key Competitor Launch Timelines (Neodjuvant & Adjuvant)

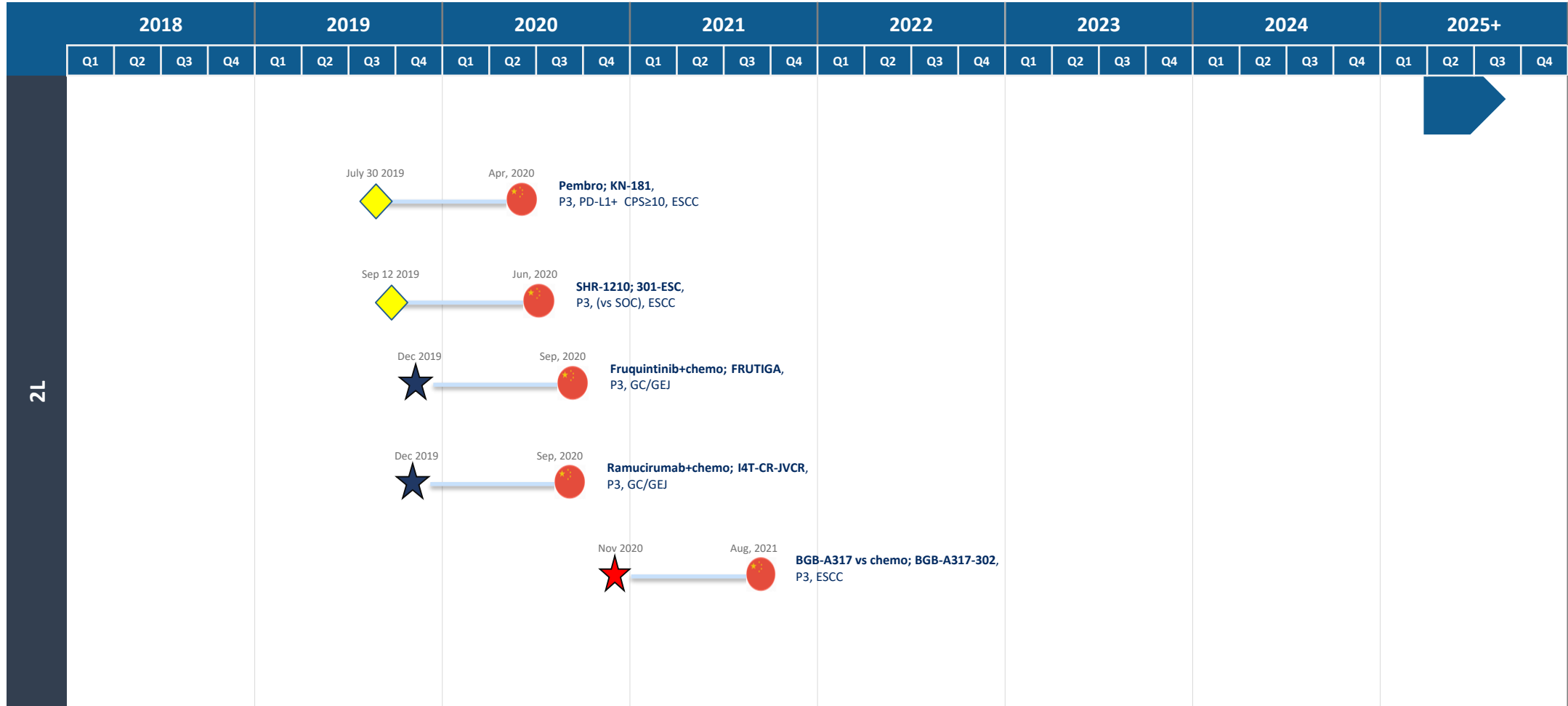


Please refer Notes section for launch timelines calculations





# Key Competitor Launch Timelines (2L)



Please refer Notes section for launch timelines calculations








# Population positioning of key current therapies in EC

MOAs	Brand	Drug	Corp.	[neo]adjuvant	first-line	second line	third line and subsequent	Global	Global EC	China	China EC
HER2 / EGFR targeting agents	Herceptin	Trastuzumab	Roche	→	★	→		√	√	☆	★
	Perjeta	Pertuzumab	Roche		→			√		☆	
	Erbix	Cetuximab	Merck		→			√		☆	II
	泰欣生	Nimotuzumab	百泰生物		→					☆	III
	凯美纳	Icotinib	贝达药业		→	→				☆	II
	Gilotrif	Afatinib	BI			→		√			II
	na	Larotinib	东阳光药业			△				I/II	I/II
	na	KN026	康宁杰瑞			△				II	II
	na	SCT200	神州细胞			△				II	I/II
	VEGF / VEGFR / FGFR / PDGFR targeting agents	Cyramza	Ramucirumab	Lilly			→		√	√	
爱优特		Fruquintinib	和记黄埔			→				☆	III
艾坦		Apatinib	Hengrui	→	→	→	★			☆	★
福可维		Anlotinib	CTTQ		→	→	→			☆	II/III
恩度		Endostar	Simcere	→	→	→				☆	II
Balversa		Erdafitinib	Janssen			→		√			II
na		Gentuximab	GeneScience				△			I/II	I/II
na		Donafenib	苏州泽璟				△			III	I/II
na		Bemarituzumab	FPRX			△				III	III

√	Global Approved
☆	China Approved in other indication
★	China Approved in EC/ESCC/GEJ
→	Expected label expansion
△	Emerging therapy in pipeline
Green	HER2/EGFR targeting agents
Yellow	Immune checkpoint inhibitors
Blue	cMET/PI3K/AKT pathway inhibitors
Orange	VEGF/VEGFR/FGFR/PDGFR targeting agents
Grey	AKR1C3/MUC-1 targeting agents

# Population positioning of key emerging therapies in EC

	MOAs	Brand	Drug	Corp.	[neo]adjuvant	first-line	second line	third line and subsequent	Global	Global EC	China	China EC	
									Global	Global EC	China	China EC	
IO	PD-1 / PD-L1 / CTLA4 / BiSpecific	Keytruda	Pembrolizumab	MSD		→	→		√	√	☆	BLA	
		Opdivo	Nivolumab	BMS	→	→			√		☆	III	
		Tecentriq	Atezolizumab	Roche					√				
		Bavencio	Avelumab	Merck		→	→		√			I	
		艾瑞卡	Camrelizumab	Hengrui	→	→	→				☆	BLA	
		达伯舒	Sintilimab	Innovent	→	→	→	→			☆	III	
		拓益	Toripalimab	Junshi	→	→	→				☆	III	
		na	Tislelizumab	BeiGene		△	△					BLA	III
		na	Teripalimab	na		△						II/III	II
		na	CS1001	Cstone		△						III	III
		na	HLX10	Henlius		△						III	III
		na	SHR-1316	Hengrui		△						III	II
		na	GLS-010	Gloria				△				II	I
		na	AK104	Akeso Biopharma			△					I/II	I/II
		na	KN035	康宁杰瑞			△					II	II
na	KN046	康宁杰瑞			△	△				II	II		
Others	cMET / PI3K / AKR1C3	MetMab	Onartuzumab	Roche					√				
		na	zolbetuximab / claudiximab	Astellas		△					III	III	
		na	CYH33	上海海和药物				△			I	I	
		na	AST-3424	深圳艾欣达伟医药					△		I/II	I/II	
		na	CAR-T	科济生物					△		I/II	I/II	

√	Global Approved
☆	China Approved in other indication
★	China Approved in EC/ESCC/GEJ
→	Expected label expansion
△	Emerging therapy in pipeline
	HER2/EGFR targeting agents
	Immune checkpoint inhibitors
	cMET/PI3K/AKT pathway inhibitors
	VEGF/VEGFR/FGFR/PDGFR targeting agents
	AKR1C3/MUC-1 targeting agents

# C&E Business Scope

We provide a variety of services and products to meet your needs.

## Competitive Strategy

- + Policy environment and trends
- + Holistic competitive company study
- + Launch readiness
- + Inline product CI
- + DA monitoring
- + Screening and profiling
- + Due-diligence investigation
- + Innovative business model
- + Conference monitoring

## Syndicate reports

- + Maximize value with excellent Competitive Intelligence technology
- + Keep in step with industry hot topics, including industry development trend, popular therapeutic areas, policy move, and any creative initiatives
- + Cover over 20 therapeutic areas and based on 5+ years of historical data



## Pipeline tracking

- + Pipeline scan
- + Development states tracking
- + Competitor profiling
- + NDA/BLA assumption
- + Screening and profiling
- + Launch readiness

## Market Access Consulting

- + MNC's access into China
- + (Market and hospital potential, evaluation, Clinical trial and regulatory, Pricing, Tendering, Medical insurance, Hospital listing)
- + Indication expansion
- + Broad market (county hospitals, CHC, retails, third terminals, online, etc.)



THANKS



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