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# LSK BioPharma Historical Highlights

**2005**

- Company Established as Consulting Company



**2010**

- Management Invests in Company – Focus on Drug Development

**2015**

- HLB acquires majority ownership of LSK Biopharma



**2018**

- Immunotherapy combination trials begin

**2019**

- Pivotal HCC SHR-1210 Combo trial begins in collaboration with Jiangsu Hengrui

**2009**

- Pre-Clinical Development starts of Rivoceranib

**2012**

- Clinical Development of Rivoceranib

**2017**

- ANGEL Study Begins

**2018**

- GC 2<sup>nd</sup> line Clinical Development begins

**2019**

- ANGEL Study Completed

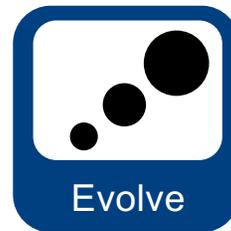
LSKB is flying to new heights with a new name...



September 2019



# elevate therapeutics



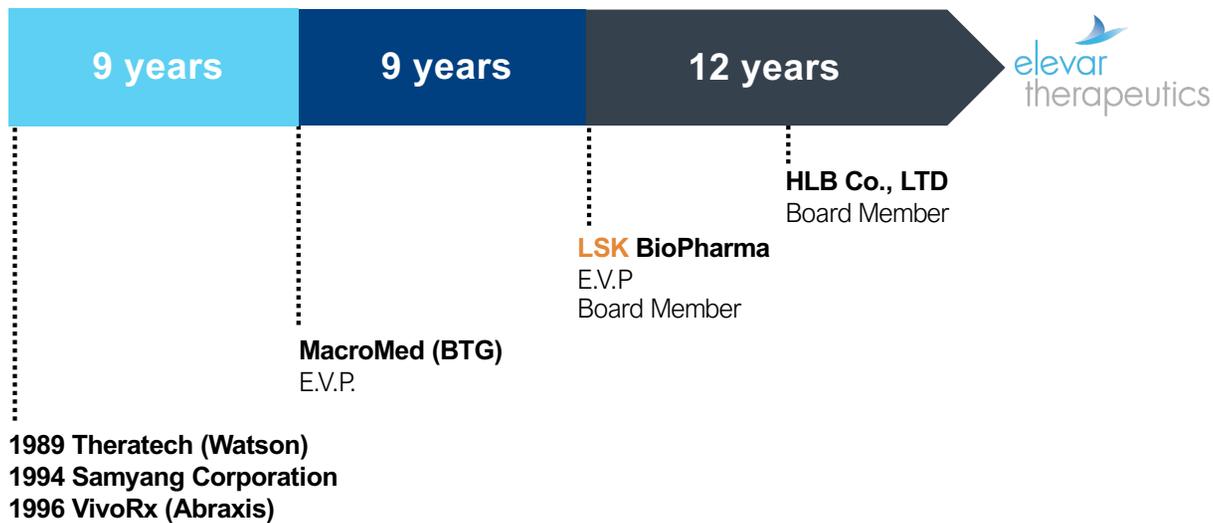


Raising Outcomes.

Elevar Therapeutics aims to provide patients and their caregivers with exceptional choices for **effective** and **well-tolerated therapies**.



- Executive Management
- Business Development
- Operations
- Fund Raising, M&A



**Alex Kim**  
Chief Executive Officer



# Elevar Staffing and Offices



## Salt Lake City HQ



## San Francisco Office



Seoul & Ireland -- Satellite Offices

L.A., Raleigh-Durham, Jacksonville – Remote Staff

# Current Corporate Ownership



# Near term corporate plan



## M&A with HLB Co. LTD.

HLB to acquire 100% of shares of Elevart  
Elevart to remain as US Corporation as wholly owned sub



## Partnership with HLB-LS

Asia-Pacific Rivoceranib BD  
Asia Pacific Rivoceranib Commercialization



## JV with NeoPharma

Founding a 50/50 JV in U.A.E.  
Commercialize Rivoceranib in Middle East / North Africa / India  
Leveraging NeoPharma manufacturing and R&D



## 5 Year Targets – Raising Outcomes



- Rivoceranib Approval in 5 Indications
- Commercialize Rivoceranib in the US
- Rivoceranib License & Distribution Deals R.O.W.
- New In-House Asset in Clinical Development
- In-License Asset for Pipeline



# Elevar Current Assets

## Rivoceranib (commonly known as Apatinib)

Highly-selective oral angiogenesis inhibitor targeting solid tumors

Known as best-in-class for activity and tolerability

Approved & marketed in China (\$350M+ annual sales)

Hundreds of clinical studies in numerous indications active worldwide

Elevar has exclusive rights ex-China and is developing in 5 indications

## Selective JAK3 Inhibitor

Selective Inhibitor of Janus Kinase 3

Potential for T-Cell Lymphoma, RA, autoimmune disorders

Developed in-house at Elevar

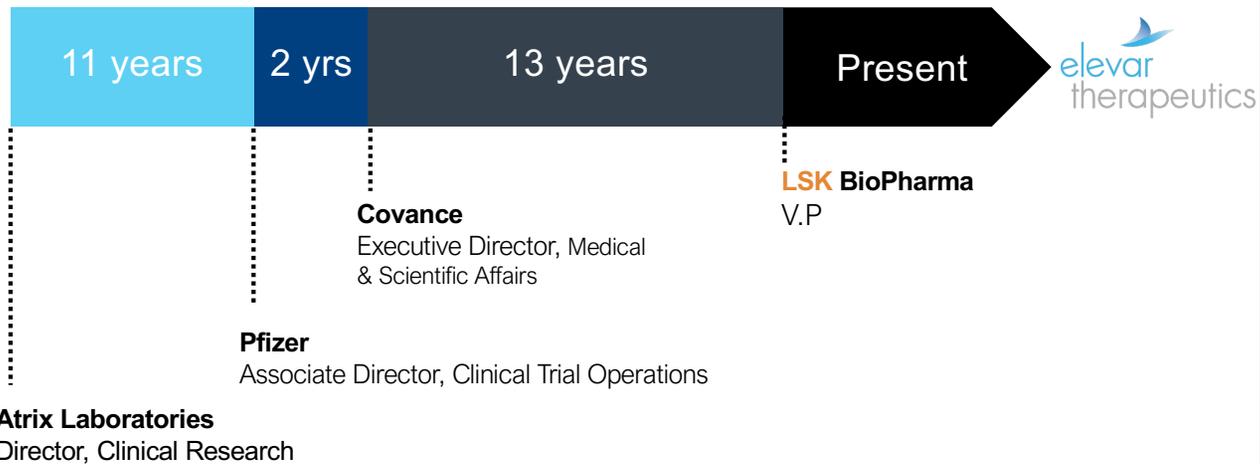
Preclinical Development in 2020

Expect to file IND in early 2021



# Leading Drug Development

- Establishing High Performance Teams
- Clinical Strategy and Development
- Medical and Scientific Affairs



**Dr. Steven Norton**

Vice President  
Clinical Development



# Elevar Clinical Development Team

Vice President	<ul style="list-style-type: none"><li>• N=1 (MBA, PhD)</li><li>• 26+ years experience</li></ul>
Clinical Pharmacology	<ul style="list-style-type: none"><li>• N=2 (2x PhD)</li><li>• 10+ years experience</li></ul>
Clinical Operations	<ul style="list-style-type: none"><li>• N=5 (PhD, MD, 2x Masters)</li><li>• 60+ years experience</li></ul>
Biometrics	<ul style="list-style-type: none"><li>• N=3 (PhD, Masters)</li><li>• 20+ years experience</li></ul>
Medical & Scientific Affairs	<ul style="list-style-type: none"><li>• N=4 (2x PhD, 2x MD, 3x Masters)</li><li>• 60+ years experience</li></ul>
Drug Safety & Pharmacovigilance	<ul style="list-style-type: none"><li>• N=2 (PhD, PharmD, MD)</li><li>• 25+ years experience</li></ul>



200+ years of experience  
17 employees and growing  
20 post graduate degrees

# Elevar Development



Stomach



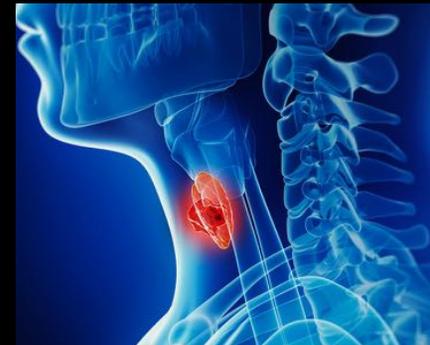
Colon



Liver



Bone & Soft Tissue



Head & Neck

# Stomach Cancer (GC)

Treatment:  $\geq$  3<sup>rd</sup> Line rivoceranib monotherapy

## ANGEL Study Scope

Global / 100 sites / 460 patients

## ANGEL Study Status

Reviewing full data set / preparing final report

## Regulatory

Designated orphan drug status in US, EU and Korea / pre-NDA meeting  
Potential NDA Filing Strategies (3<sup>rd</sup> line + w/ PFS, 4<sup>th</sup> line + w/ OS)

## PIVOTAL PHASE 3 (ANGEL)



# ANGEL Study Important 2019 Milestones

February – Completion of Primary Endpoint

June – Opening of Topline Results

July through August – Internal Review of Full Data Set

August 15 – Pre-NDA Meeting Request Sent

August 23- KSMO Abstract Submitted

August 30 – ESMO Abstract Accepted

Sept 27 – Oct 2 – ESMO Presentation (Abstract #4088)

Mid-October– Pre-NDA Meeting with US FDA



# Stomach Cancer (GC)

Treatment:  $\geq 2^{\text{nd}}$  Line Combination – rivoceranib + paclitaxel (Taxol)

- **Study Scope**

Korea / up to 5 sites / up to 38 patients

- **Study Status**

Enrollment Ongoing

- **Regulatory**

Designated orphan drug status in US, EU and Korea

PHASE 1b/2



# Colon Cancer (CRC)

Treatment: 3<sup>rd</sup> Line Combination – rivocecanib + Trifluridine/Tipiracil (LONSURF®)

## Study Scope

- Global / up to 16 sites / 100 patients

## Study Status

- Enrollment Starting

## Regulatory

- US Investigational New Drug (IND)

## LONSURF supply

- Taiho

# PHASE 1b/2



# Liver Cancer (HCC)

Treatment: 1<sup>st</sup> Line Combination – rivoceranib + Camrelizumab (SHR-1210)

## Study Scope

- Global / 100 sites / 510 patients

## Study Status

- Enrollment Started

## Regulatory

- US Investigational New Drug (IND)

## Partner

- Jiangsu Hengrui

# PIVOTAL PHASE 3



# Head and Neck Cancer (ACC)

Treatment: 1<sup>st</sup> Line Monotherapy

## Study Scope

- US and Korea / up to 15 sites / 55 patients

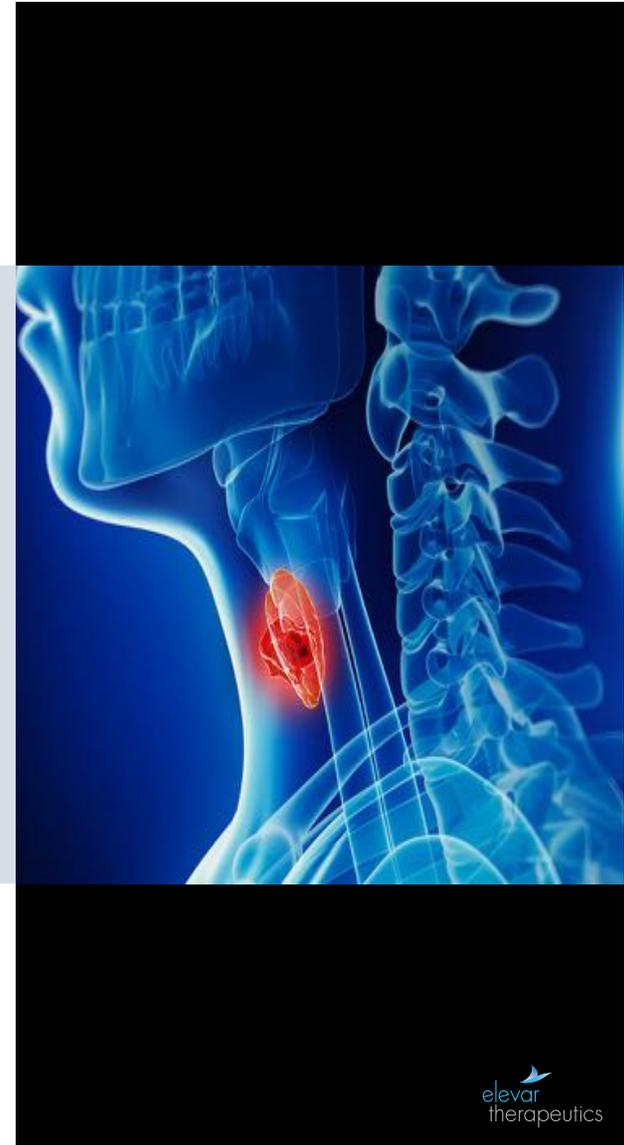
## Study Status

- Start-up

## Regulatory

- US Investigational New Drug (IND) / Filing for orphan drug status

# PIVOTAL PHASE 2



# Bone and Soft Tissue (Sarcoma)

Treatment: Combination – rivoceranib + Nivolumab (OPDIVO®)

## Study Scope

- US/ Single Site / 24 patients

## Study Status

- Enrolled Completed

## Regulatory

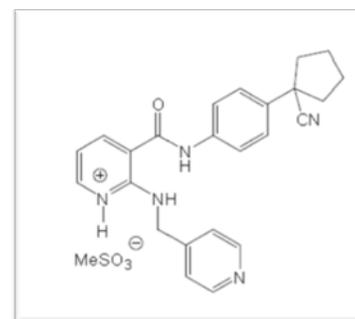
- US Investigational New Drug (IND)

PHASE 1b/2



# FDA NDA Supporting Studies - Status

Study Type	Phase 1 – Drug-Drug Interactions
Study Scope	US / 2 Sites / 48 subjects
Study Status	Enrollment Completed



Study Type	Phase 1 – Effect of Stomach pH
Study Scope	US / 2 Sites / 24 subjects
Study Status	Enrollment Completed

Study Type	Phase 1 – Drug Metabolism
Study Scope	US / Single Site / 8 subjects
Study Status	Enrollment Completed

Study Type	Phase 1 – Cardiac Effects
Study Scope	US / 2 Sites / 72 subjects
Study Status	Enrollment Completed

Study Type	Phase 1 – Effect of Liver Impairment
Study Scope	US / 2 Sites / up to 28 subjects
Study Status	Enrollment Ongoing

# Rivoceranib Clinical Status

Therapy	Indication	Preclinical	Phase I	Phase II	Phase III	Approval
Monotherapy	3 <sup>rd</sup> /4 <sup>th</sup> Line Stomach					
Taxane Combination	2 <sup>nd</sup> Line Stomach					
Lonsurf® Combination	3 <sup>rd</sup> /4 <sup>th</sup> Line Colorectal					
Camrelizumab Combination	1 <sup>st</sup> Line Hepatocellular					
Nivolumab Combination	Bone & Soft Tissue					
Monotherapy	1 <sup>st</sup> Line Head & Neck					

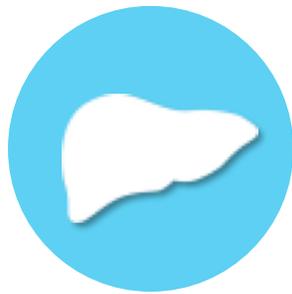
The safety and efficacy of the agents and/or uses under investigation have not been established. There is no guarantee that the agents will receive healthy authority approval and become commercially available country for the uses being investigated.

# Elevar is targeting 5 approvals in 5 years



**Stomach Cancer**  
Late Stage  
Monotherapy

2020/21



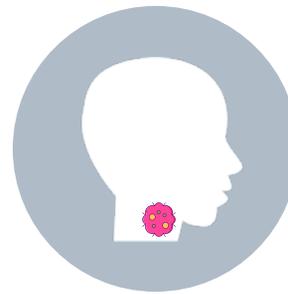
**Liver Cancer**  
1<sup>st</sup> line

2023



**Colorectal Cancer**  
3<sup>rd</sup> line

2023



**Adenoid Cystic  
Carcinoma**  
1<sup>st</sup> line

2024



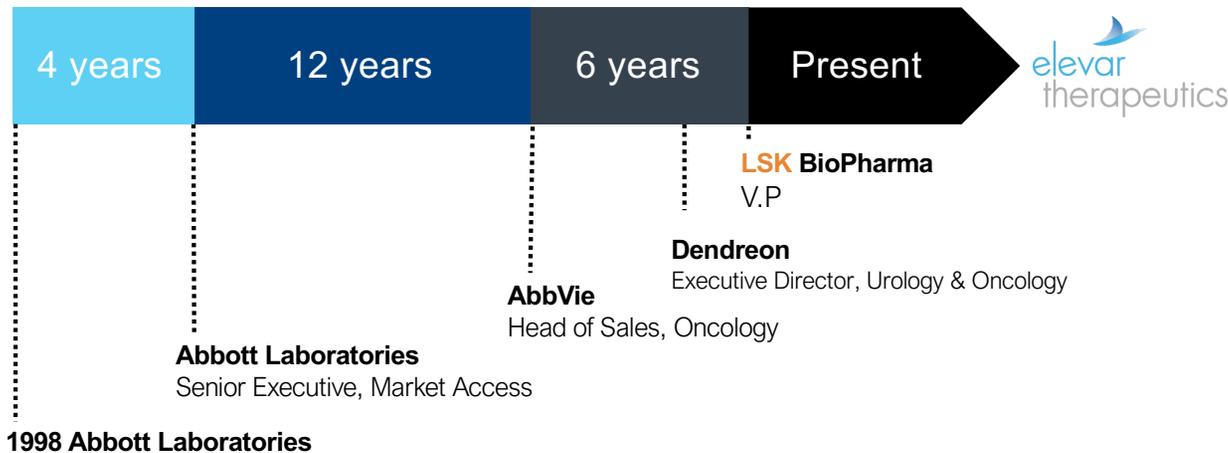
**Stomach Cancer**  
2<sup>nd</sup> line

2024

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# Global Patient Access to Rivoceranib

- Product Launch & Commercialization
- Sales & Marketing Leadership
- Market Access & Training



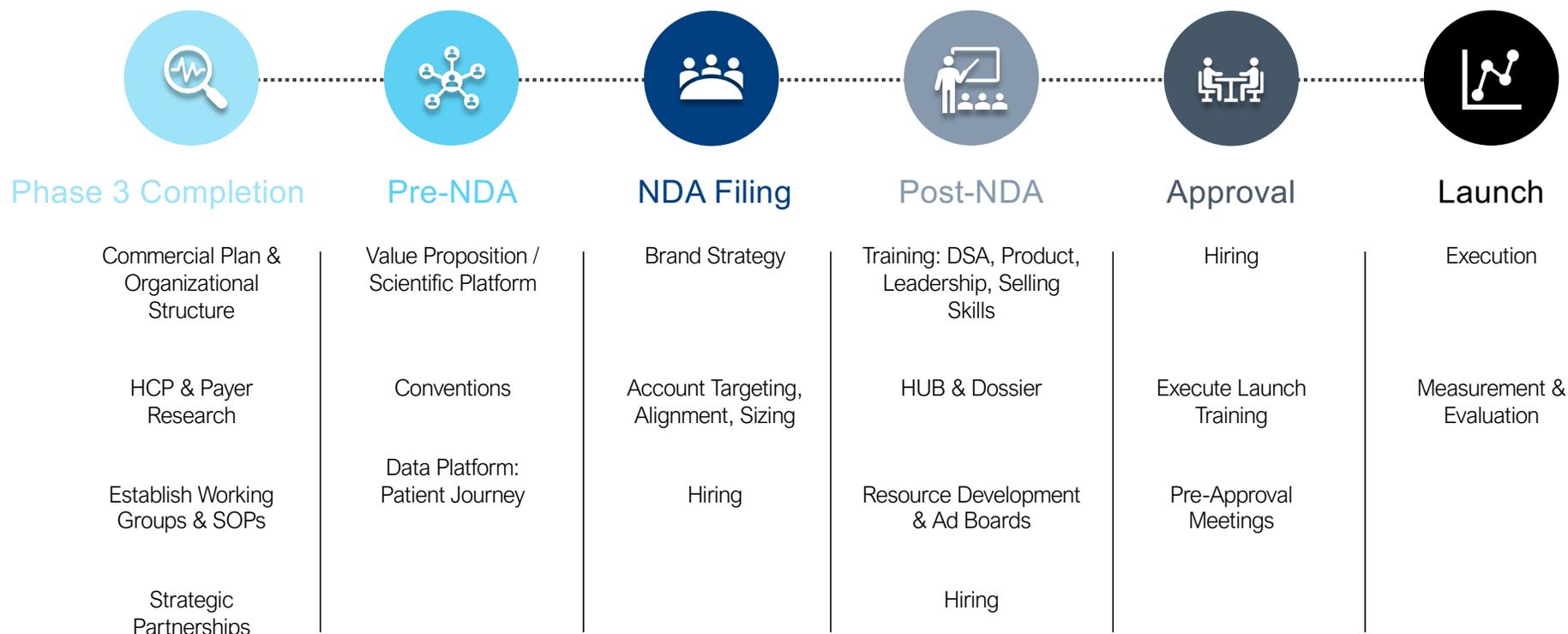
**Kate McKinley**  
Vice President  
Commercial and Business  
Development



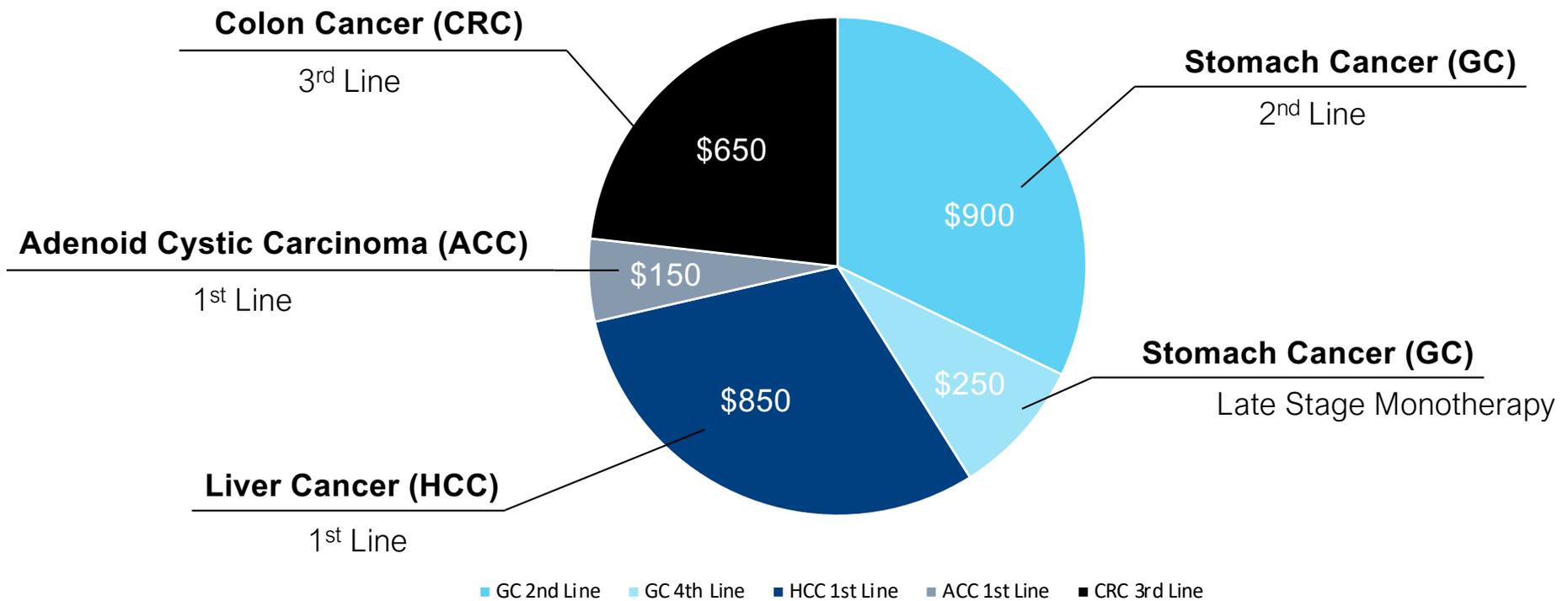
# Plans for Launching Rivoceranib



# Rivoceranib US Commercial Plan



# Rivoceranib peak annual sales potential (\$MM)



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# Elevar Therapeutics



Raising Outcomes.



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