



# Apealea<sup>®</sup>

(Paclitaxel Micellar)

**INVESTOR EVENT**

December 3, 2020





# Welcome and Introductions

# Speakers



**Francois Martelet, MD, MBA**

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*Chief Executive Officer*  
Oasmia Pharmaceutical AB



**Alex Kim, MA**

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*Chief Executive Officer*  
Elevor Therapeutics



**Mark Gelder, MD**

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*Head of Medical Affairs*  
Elevor Therapeutics

# Event Overview

- Oasmia & Elevar Introductions
- Apealea<sup>®</sup> (paclitaxel micellar) Overview
- Ovarian Cancer & Current Treatment Gaps
- Advancing the Apealea Development Program
- Q&A



**F.R. MARTELET, MD**

Chief Executive Officer

# Oasmia:

## An Innovation-Focused Specialty Pharmaceutical Company



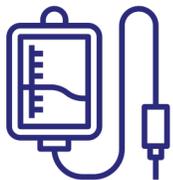
### **NASDAQ Stockholm 2010**

Market Cap ~ SEK 2,0 B



### **XR-17™ technology platform**

Enhances the intravenous delivery of established and novel drugs in diseases including oncology



A growing pipeline, focused on **Oncology** and with potential in other therapeutic areas



Agile, lean & mean structure

### **Solid cash position**



### **R&D-focused**

### **Production Lab testing**

facility, Uppsala, Sweden



### **New Leadership**

since March 2020

# The 4 Pillars of Oasmia's New Strategy in 2021



1

## Execute on Apealea® global partnership with Elevor Therapeutics

Commercialization  
deal signed with Taiba  
for Apealea® in MENA

Partnerships in Europe  
& Asia under  
evaluation

Generating resources  
to invest in pipeline  
growth

2

## Partnering & clinical development with XR-17™ / XR-19 platforms

Evaluate poorly water-  
soluble products  
using XR-17™

XR-19 platform in  
development for  
product combinations

Proven development,  
regulatory and BD  
skills

3

## Clinical development of Docetaxel micellar and new API(s)

Docetaxel micellar  
poised to enter  
clinic, agreement  
signed with SAKK

& other indications to  
follow

New API in preclinical  
development

Large global market  
opportunities

4

## In / out-licensing, partnering and M&A in oncology

Out-license or  
partner non-core  
assets (e.g. animal  
health portfolio)

In-licence oncology  
assets in clinical  
development

Agile, flexible  
structure, solid cash  
position



**Alex Kim, MA**

Chief Executive Officer

# Elevar Therapeutics

A **rapidly growing**, fully integrated biopharmaceutical company built on the promise of **elevating treatment experiences and outcomes for patients** who have limited or inadequate therapeutic options

**Elevar's mission is to transform and elevate treatment experiences for patients by developing, commercializing and acquiring promising medicines across a range of therapeutic areas, with a focus on cancer.**

- Elevar Therapeutics is a U.S. corporation headquartered in Salt Lake City, UT (USA)
  - Satellite offices in San Francisco, CA; Seoul, South Korea; Ireland
- Elevar is wholly-owned by HLB Co., LTD., a publicly-traded company on the Korean KOSDAQ exchange (028300.KQ)
- Elevar Therapeutics is a passionate and entrepreneurial biopharmaceutical company that is committed to bringing viable treatment options to patients with complex and difficult-to-treat diseases
- Our experience is rooted in oncology, and we apply the same rigor and diligence that comes with this knowledge to identifying and developing promising medicines for complex yet under-treated health conditions across a range of therapeutic areas

# Elevar's Priority Pipeline

## Rivoceranib (apatinib)

- Tyrosine kinase inhibitor (TKI)<sup>1</sup>
- Small molecule antiangiogenic<sup>2</sup>
- Inhibits VEGFR2 with high selectivity and high potency (IC<sub>50</sub> = 1nM)<sup>1</sup>
- Once-daily oral dosing<sup>3</sup>
- Approved in China (Dec 2014) as monotherapy in recurrent gastric cancer (≥ 3L for advanced GC)<sup>2</sup>
- Favorable safety profile<sup>3,4</sup>
- Elevar holds global rights to rivoceranib (ex-China)<sup>5</sup>
- Late-stage development in GC, colorectal cancer (combo with Lonsurf<sup>®</sup>), hepatocellular carcinoma (combo with camrelizumab), adenoid cystic carcinoma

## Apealea<sup>®</sup> (paclitaxel micellar)

- Non-Cremophor based formulation of paclitaxel
- Europe's first non-Cremophor formulation of paclitaxel approved for use in ovarian cancer
- Elevar has global rights with the exception of the Nordics, Russia, and select CIS and Baltic countries
- Expect to file NDA in U.S., where Apealea has Orphan Drug designation
- Elevar and Tanner Pharma launched a global named patient program to provide Apealea in areas outside of the U.S. where Apealea is not commercially available
- Elevar has partnered with Taiba Middle East for the commercialization of Apealea in the MENA region
- EU, LATAM and Asia partnerships expected to be completed soon

IC<sub>50</sub> = half maximal inhibitory concentration; VEGFR2 = vascular endothelial growth factor receptor 2.

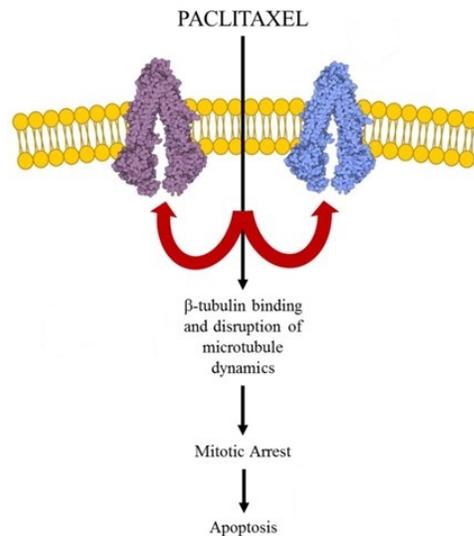
Sources: 1. Qiu et al. *Cell Cycle*. 2018;17(10):1235-1244, 2. Tian et al. *Cancer Sci*. 2011;102(7):1374-1380, 3. Chawla et al. *JCO*. 2019; 37(8) suppl:18-18, 4. Kan g et al. *Ann Oncol*. 2019 30 (suppl 5): v851-v934, 5. <https://elevartherapeutics.com/rivoceranib-apatinib/>

# Paclitaxel – A Backbone in Cancer Therapy

Paclitaxel is on the W.H.O.'s list of Essential Medicines\*

## Mechanism of Action

- Paclitaxel enters the cell
- Binds and stabilizes  $\beta$ -tubulin = inhibit cell division
- Increased apoptosis by blocking bcl-2



## Approved Indications

- Ovarian cancer
- Breast cancer
- Non-small cell lung cancer
- AIDS-related Kaposi's Sarcoma
- Pancreatic cancer

## Side Effects

- Hypersensitivity reactions
- Alopecia
- Neuropathy
- Neutropenia
- Diarrhea
- Muscle pain
- Mouth sores

# The Injectable Taxane Market Continues to Grow

The 2018 global injectable taxane market was valued at \$2.18B

The market is expected to grow to \$4.56B by the end of 2025 (CAGR 11% 2019 – 2025)

## Taxol®

- Paclitaxel – cremophor EL
- Ovarian, breast, lung and Kaposi sarcoma cancers
- Best selling cancer drug of all time
- Y2000 sales of \$1.6B prior to patent expiration<sup>1</sup>



## Taxotere®

- Docetaxel – polysorbate 80
- Breast, lung, prostate and head & neck cancers
- Peak sales \$3B (2010)
- ~\$194M (2019)<sup>2</sup>



## Abraxane®

- Paclitaxel - albumin bound
- Breast, lung, pancreatic cancers
- \$1.86B (2019)<sup>3</sup>



## Jevtana®

- Cabazitaxel- polysorbate 80
- Prostate cancer
- ~\$543M (2019)<sup>4</sup>



# No Cremophor-Free Paclitaxel Formulations Approved in the U.S. for Ovarian Cancer

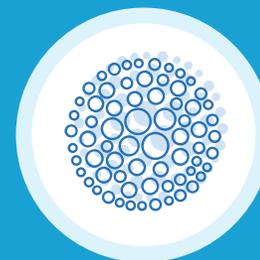
## Side effects (Cremophor EL)<sup>4</sup>



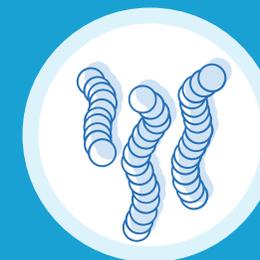
Severe hypersensitivity reactions



Hyperlipidemia



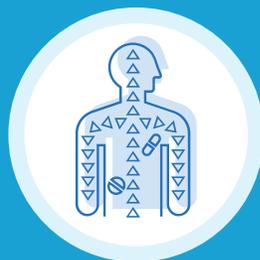
Abnormal lipoprotein patterns



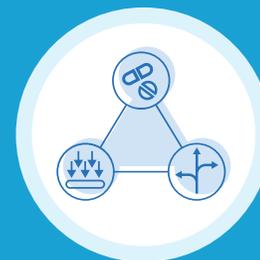
Erythrocyte aggregation



Peripheral neuropathy



Pharmacokinetics



Affects various drug dispositions



Modifies toxicity profile of co-medication

# Apealea®

(non-Cremophor / non-albumin formulation of paclitaxel)



**Apealea was developed** by Oasmia Pharmaceutical AB, Sweden (branded as Paclical® in certain countries)

Apealea (paclitaxel micellar) utilizes Oasmia's proprietary XR17 micelle platform technology



**Apealea received market authorization** by the European Commission in 2018<sup>1</sup>

First approval in Europe for a non-Cremophor EL paclitaxel in ovarian cancer



**Elevor Therapeutics acquired the exclusive global license for Apealea** in March 2020

Excluding the Nordics, Russia, and certain Commonwealth of Independent States (CIS) and Baltic countries



**Apealea has received Orphan Drug Designation** for ovarian cancer by **U.S. FDA**

The Company has conducted both pre-IND and pre-NDA meetings with the FDA

# Ovarian Cancer Population

2020 Incidence in Select Major Regions



**U.S. OC Population**

**22,839**



**EU28 OC Population**

**54,655**



**Japan OC Population**

**10,484**



# Mark Gelder, MD

Head of Medical Affairs

# Ovarian Cancer is a Heterogeneous Disease with Unique Molecular, Pathologic, and Clinical features

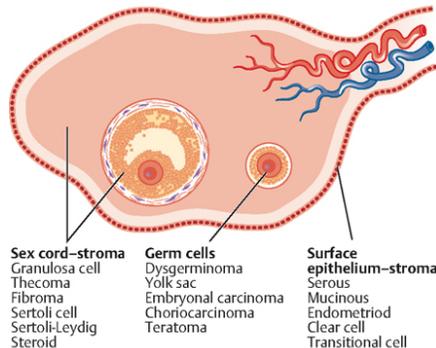
Majority diagnosed with late-stage disease given minimal early symptoms



## ETIOLOGY<sup>1</sup>

Ovarian cancer originates in one of three cell types:

- 1. Stromal Cells:** tumors form in the supportive tissue of the ovaries
- 2. Germ Cells:** tumors primarily occur in adolescents and young women
- 3. Epithelial Cells (~95% cases)**
  - Originates in epithelial cells, including the epithelium of the fallopian tube
  - Four primary histological sub-types: serous



## PRESENTATION<sup>2</sup>

- Often undetected with no symptoms during early stages; ~70% of patients present with late stage disease<sup>2</sup>
- Clinical Presentation:
  - **Acute Presentation:** Advanced disease presenting with urgent care conditions (e.g., pleural effusion, bowel obstruction, etc.)
  - **Subacute Presentation:** Early or advanced disease with pelvic or abdominal pain, bloating, gastrointestinal symptoms, etc.



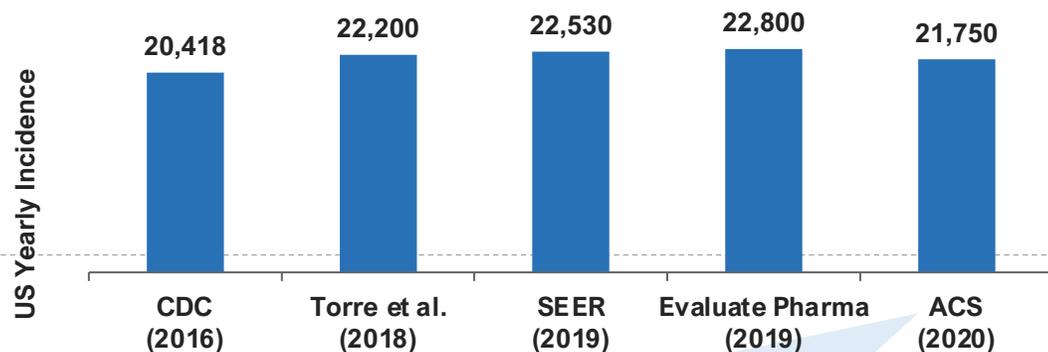
## RISK FACTORS<sup>3</sup>

- **Older Age:** Can occur at any age, but is most common in women ages **55-74 years**
- **Family History & Genetics:** **BRCA-1** and **BRCA-2** mutations, and **Lynch II syndrome** are well known indicators of **high risk for ovarian cancer**
- **There is increased risk for OC among infertile and/or obese women with a history of smoking**

# Ovarian Cancer is the 5<sup>th</sup> Most Common Cancer Among Women in the U.S., with ~230K Total Prevalent Patients

~10-15% of patients have age-related comorbidities that may influence treatment

## U.S. OVARIAN CANCER INCIDENCE<sup>1</sup>



ACS 2020 is the most recent statistic, and carries the most confidence

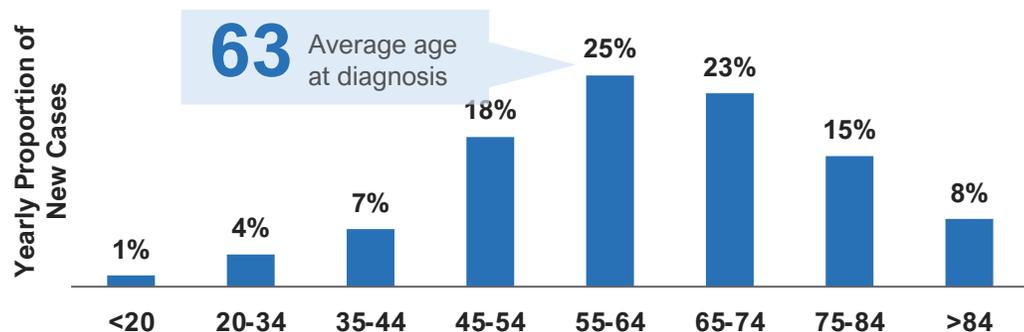
Estimated Yearly Incidence of Ovarian Cancer

~22,000

~229,875 total ovarian cancer patients in the US (2016)<sup>3</sup>

*Incidence rate has been declining since the mid-1980s, primarily in Caucasian women due to the decreased use of menopausal hormones<sup>2</sup>*

## U.S. OVARIAN CANCER INCIDENCE BY AGE<sup>3</sup>



- ~70% of patients are diagnosed at ages >50 years<sup>3</sup>
- ~10-15% patients are predisposed to other age-related comorbidities, such as diabetes, potentially influencing treatment response and prognosis<sup>4</sup>

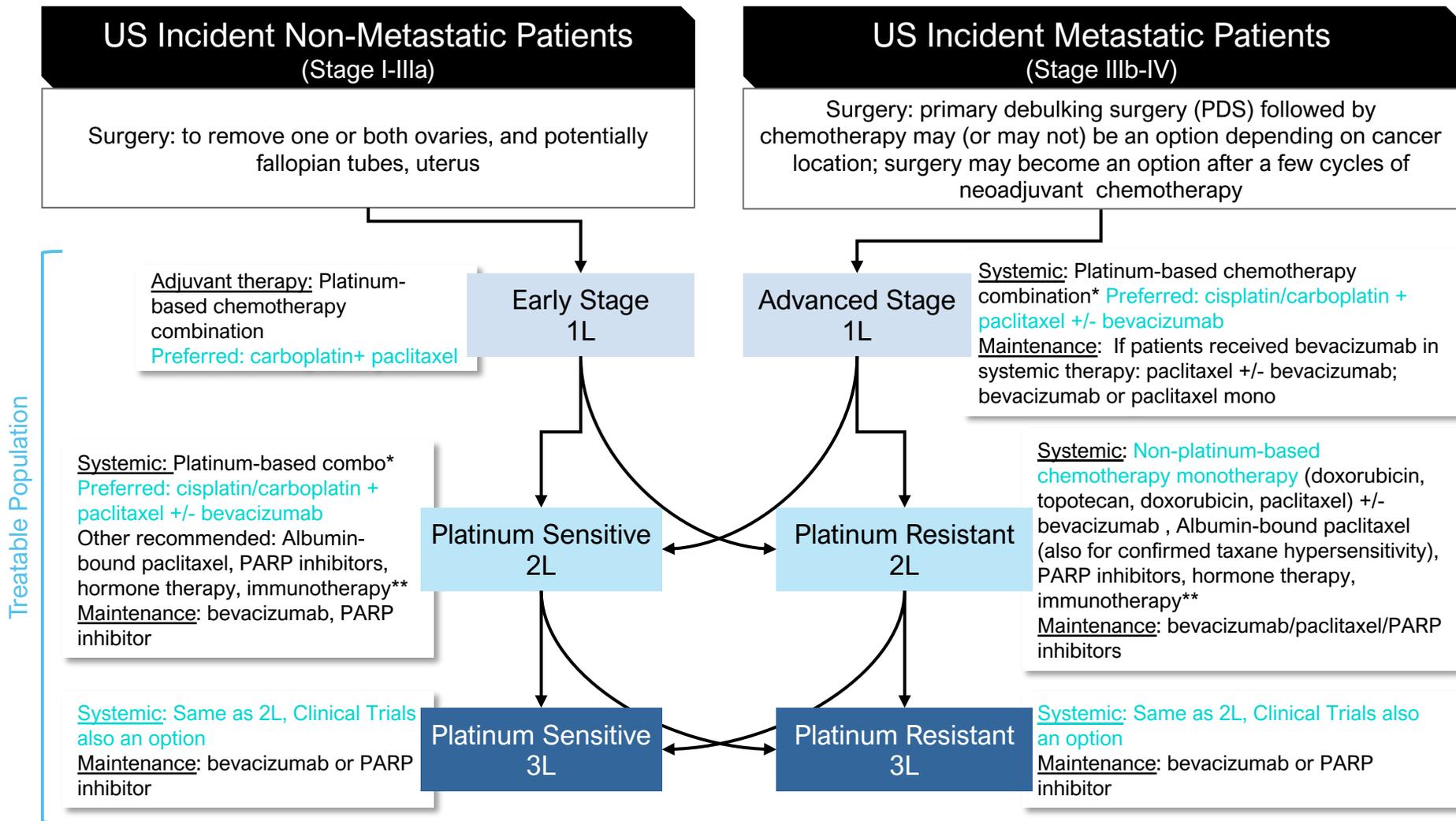
# Apealea vs. Taxol Phase 3 Non-Inferiority Study

Study Supported 2018 EU Approval

- **Primary endpoint (PFS)**
  - The study **met the primary endpoint (PFS)** in PP (HR = 0.86), mPP (HR = 0.84) and ITT populations (HR = 0.85)
- **Secondary endpoint (OS)**
  - The study **met the secondary endpoint (OS)** in PP (HR = 0.95) but not in mPP (HR = 1.01) and ITT (HR = 1.02) populations
- **Safety**
  - A comparable number of patients reported  $\geq 1$  AE in the Apealea arm vs. the Taxol arm (90% vs. 87%)
  - More patients in the Apealea arm reported  $\geq 1$  SAE (40% vs. 26%)
  - The most common adverse event was **neutropenia** (grade  $\geq 3$ ); 245 patients (79%) for Apealea vs. 213 patients (66%) for Taxol
  - The frequency of peripheral sensory **neuropathy** (any grade) was **similar** between the arms; 16% for Apealea and 20% for Taxol

**Apealea provides a treatment option of a higher paclitaxel dose with a shorter infusion time without mandatory premedication**

# 2020 NCCN Guidelines: Systemic Treatment of Ovarian Cancer Patients in the U.S.



\*Depending on paclitaxel adverse events/ other preferences, liposomal doxorubicin, or docetaxel is also administered with platinum chemo

\*\*Pembrolizumab prescribed for microsatellite instability-high or mismatch repair-deficient solid tumors

# Ovarian Cancer Experts Have Enthusiasm for Apealea

“ The clinical benefit of paclitaxel has been well-established in oncology. Having a non-Cremophor formulation such as Apealea<sup>®</sup> (paclitaxel micellar) has the potential to significantly contribute to improved clinical outcomes and treatment experiences for epithelial ovarian cancer patients.

”

**David M. O'Malley, M.D.**

*Professor and Director, Division of Gynecologic Oncology  
Co-Director, Gyn Oncology Phase I Program  
The Ohio State University and the James Cancer Center*

**Deborah Armstrong, M.D.**

**Robert Coleman, M.D.**

**Larry Copeland, M.D.**

**Ramez Eskander, M.D.**

**Stephanie Gaillard, M.D., PhD**

**Thomas Herzog, M.D.**

**Susan Jerian, M.D.**

**Brad Monk, M.D.**

**Kathleen Moore, M.D.**

**David O'Malley, M.D.**

**Bhavana Pothuri, M.D.**

**Ignace Vergote, M.D., PhD**

# FDA Interactions and Upcoming Milestones

Date	Interaction	Focused Topics
Q2, 2010	Pre-IND/End-of-Phase 2	Comparative efficacy/safety study
Q2, 2020	Pre-NDA Meeting	Discuss proposed 505(b)(2) NDA submission: content of nonclinical information, PK data, safety and efficacy, and orphan drug exclusivity
Q4, 2020	Pre-IND	PK and CMC and logistical considerations

## Upcoming Milestones:

- Q1 2021: Elevar filing IND
- First Half 2021: Initiating PK study
- First Half 2021: Initiating Ph 3 safety & efficacy study of Apealea in epithelial ovarian cancer

# Elevar Therapeutics: Summary

Elevar Therapeutics is a **rapidly growing**, fully integrated biopharmaceutical company built on the promise of **elevating treatment experiences and outcomes** for patients who have limited or inadequate therapeutic options.

We engage with purpose and are focused on evolving the therapeutic potential of medicines to improve clinical outcomes and **address the underserved needs of patients**, caregivers and healthcare providers.

We have a deeply committed and **engaged team** whose **roots are in oncology** and we apply this rigor and discipline to all of the work that we do.





Q&A



Thank you!