



# Company Overview

February, 2020

*Oral and IV treatment for serious bacterial infections*

# Forward-looking Statements & Disclaimer

This presentation contains forward-looking statements. These forward-looking statements include, without limitation, statements regarding the development, therapeutic and market potential of sulopenem, the sufficiency of cash resources, the granting or issuing of patents, the timing, progress and results of clinical trials, and the expected timing of NDA and EMA filings. In some cases, forward-looking statements can be identified by words such as “may,” “believes,” “intends,” “seeks,” “anticipates,” “plans,” “estimates,” “expects,” “should,” “assumes,” “continues,” “could,” “will,” “future,” “potential” or the negative of these or similar terms and phrases. Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Forward-looking statements include all matters that are not historical facts. Actual future results may be materially different from what is expected due to factors largely outside our control, including the results of clinical trials, clinical trial patient enrolment, changes in regulatory requirements or decisions of regulatory authorities, commercialization plans and timelines if approved, the actions of third-party clinical research organizations, suppliers and manufacturers and other factors discussed under the caption “Risk Factors” in the most recently filed Annual Report on Form 10-K or Quarterly Report on Form 10-Q (as the case may be) and other documents filed with the Securities and Exchange Commission from time to time. Forward-looking statements represent our beliefs and assumptions only as November 12, 2019. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in the forward-looking statements, even if new information becomes available in the future.

Certain information contained in this presentation relates to, or is based on, studies, publications, surveys and other data obtained from third-party sources and our own internal estimates and research. While we believe these third-party sources to be reliable as of the date of this presentation, it has not been independently verified, and we make no representation as to the adequacy, fairness, accuracy or completeness of, any information obtained from third-party sources. In addition, all of the market data included in this presentation involves a number of assumptions and limitations, and there can be no guarantee as to the accuracy or reliability of such assumptions. Finally, while we believe our own internal research is reliable, such research has not been verified by any independent source.

# Investment Summary

## De-risked Lead Asset

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  - Oral formulation has IP in U.S. into 2034 (2029 plus potential extensions)
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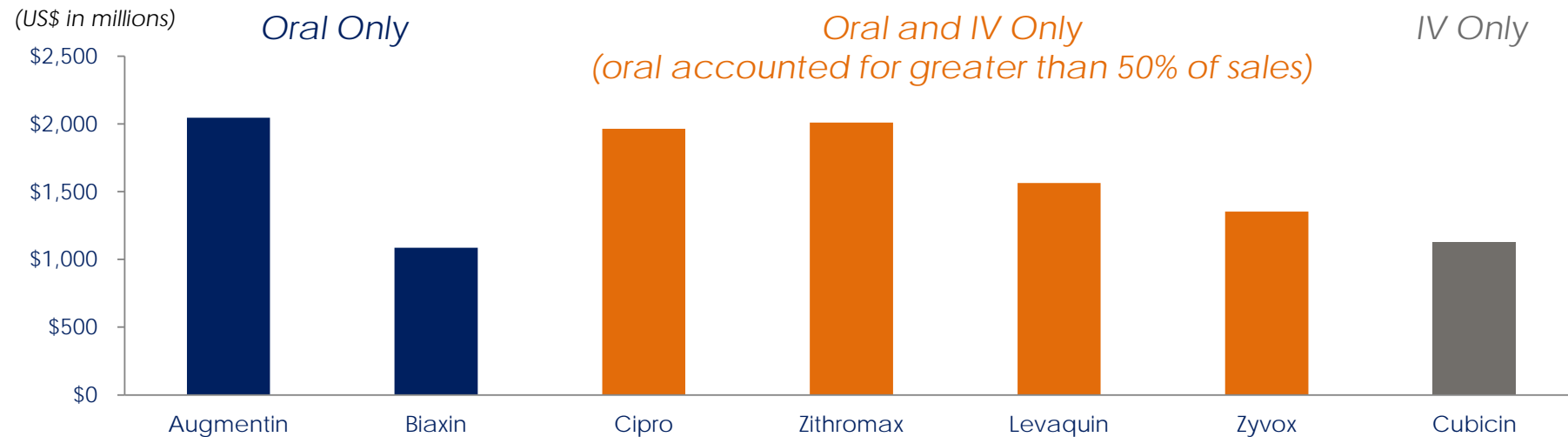
# Why is Oral Sulopenem Different?

<b>Challenges Faced by Recent Antibiotic Launches</b>	<b>Oral Sulopenem Differentiation</b>
IV Only Antibiotics	Oral Antibiotic
Hospital Focused	Community Focused + Hospital Step-Down
Single Indication	Multiple Indications at Launch
Unproven and Challenging Antibiotic Classes	Proven & Trusted Penem Class
Fierce Competition	Dominant Share of Voice

# Sulopenem has the Potential to Achieve Blockbuster Status

Historic blockbuster<sup>(1)</sup> antibiotics share key characteristics

- ✓ High unmet need
- ✓ Oral product
- ✓ Community focus
- ✓ Multiple Indications
- ✓ Payer access & reimbursement outside the hospital



Source: (1) Company Filings; blockbuster defined as > \$1 billion in peak year sales

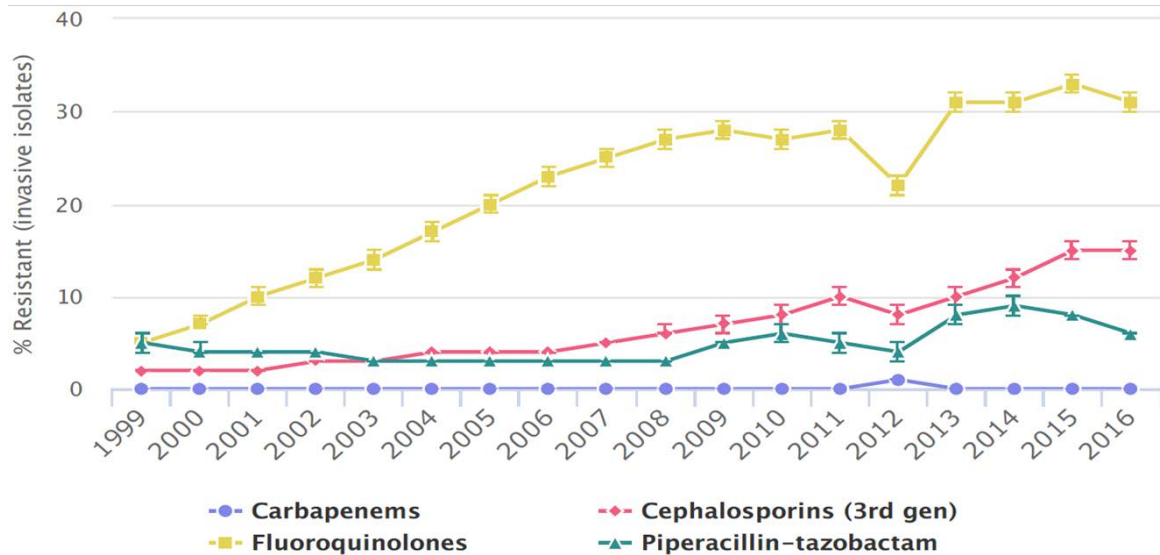
# Quinolone Resistance Driving Need for New Therapies

High resistance rates affecting the most populous regions of the U.S.

## 1999-2016 trends for antibiotic resistance to *E.coli* in the United States

Antibiotic resistance continues to trend higher with quinolone and cephalosporin efficacy steadily eroding

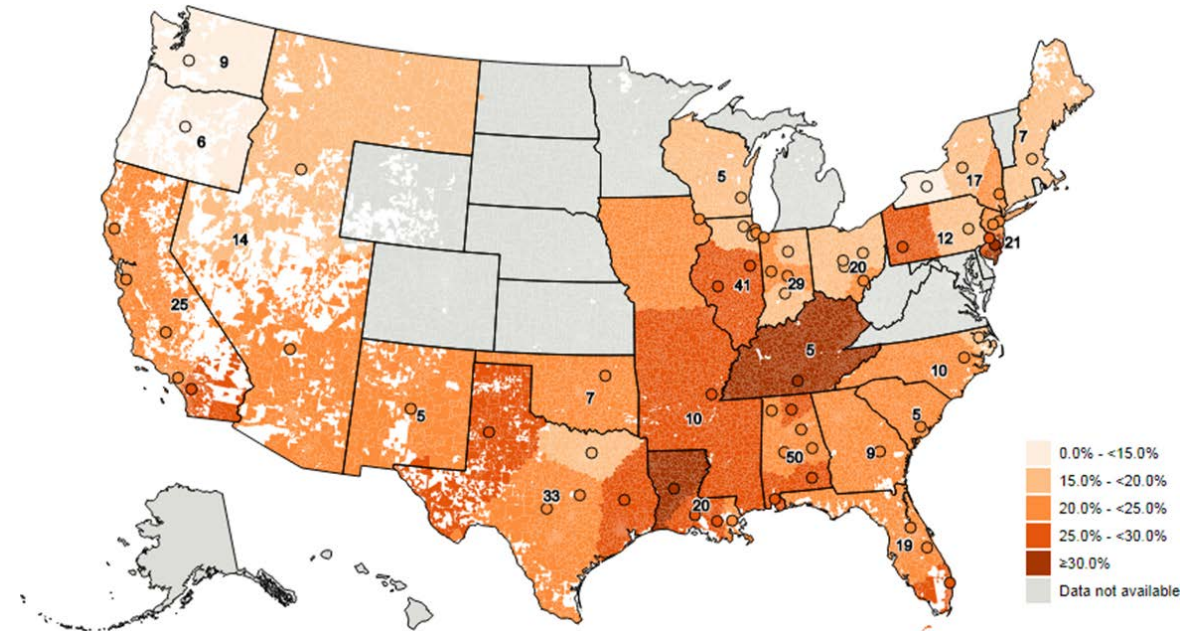
Antibiotic Resistance of *Escherichia coli* in United States



Center for Disease Dynamics, Economics & Policy (cddep.org)

## 2017 outpatient *Enterobacteriaceae* quinolone resistance, by zip code

>20% of outpatient urinary gram negative isolates are resistant to quinolones in the most populous areas of the US



Source: Center for Disease Dynamics, Economics Policy (CDDEP) & The Surveillance Network (TSN); Data analytics provided by BD Insights

# Significant Resistance to Available Oral Therapy

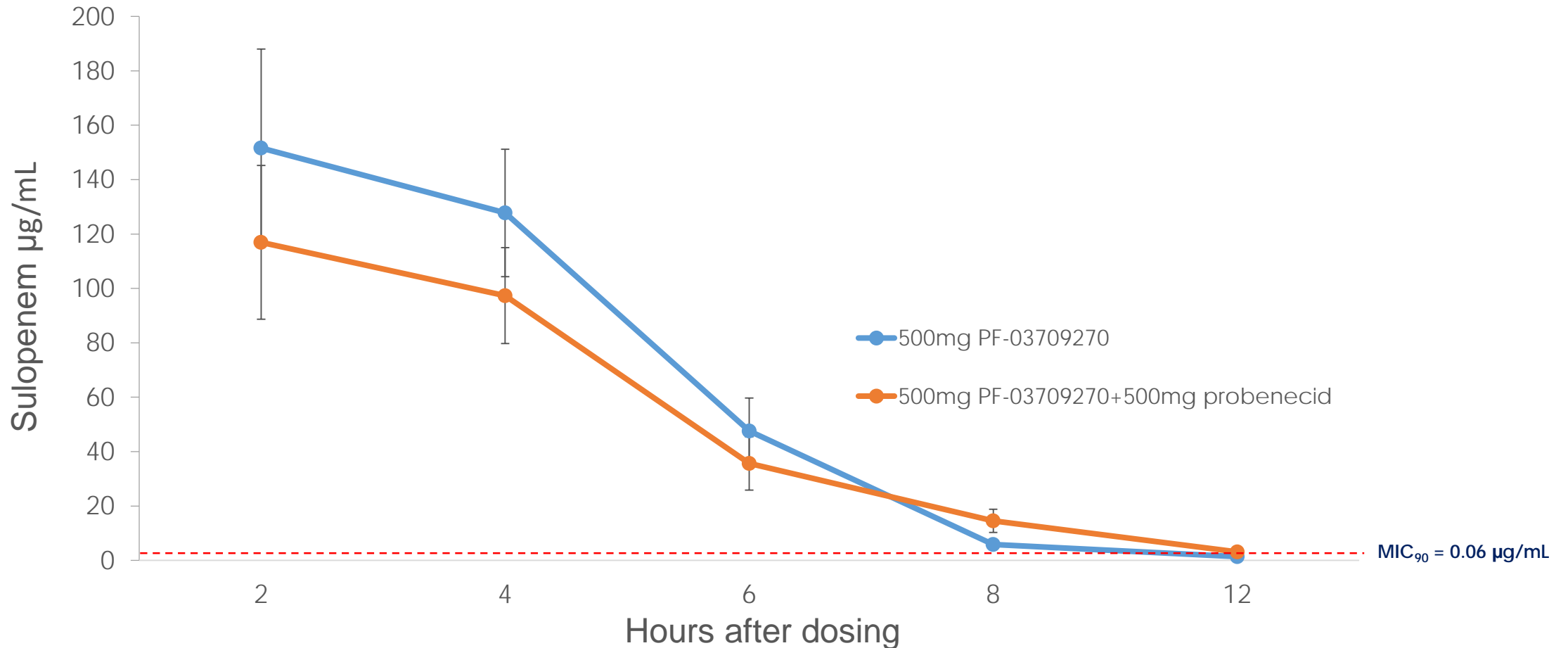
Uropathogens associated with uncomplicated urinary tract infection

Antibiotic Class	Enterobacteriaceae				
	All N=5,395	<i>E. coli</i> N=4,081	<i>K. pneumoniae</i> N=733	<i>P. mirabilis</i> N=284	Other N=297
	% S	% S	% S	% S	%S
Quinolones	77	73	93	81	94
Nitrofurantoin	84	97	42	47	53
Trimethoprim - Sulfamethoxazole	72	67	87	84	92
β-lactams	75	74	84	87	34

Outpatient urine cultures 2015-2017 ; Iterum Therapeutics, Becton Dickinson Insights

# Urine Concentration Data Supports Oral Sulopenem to Treat UTIs

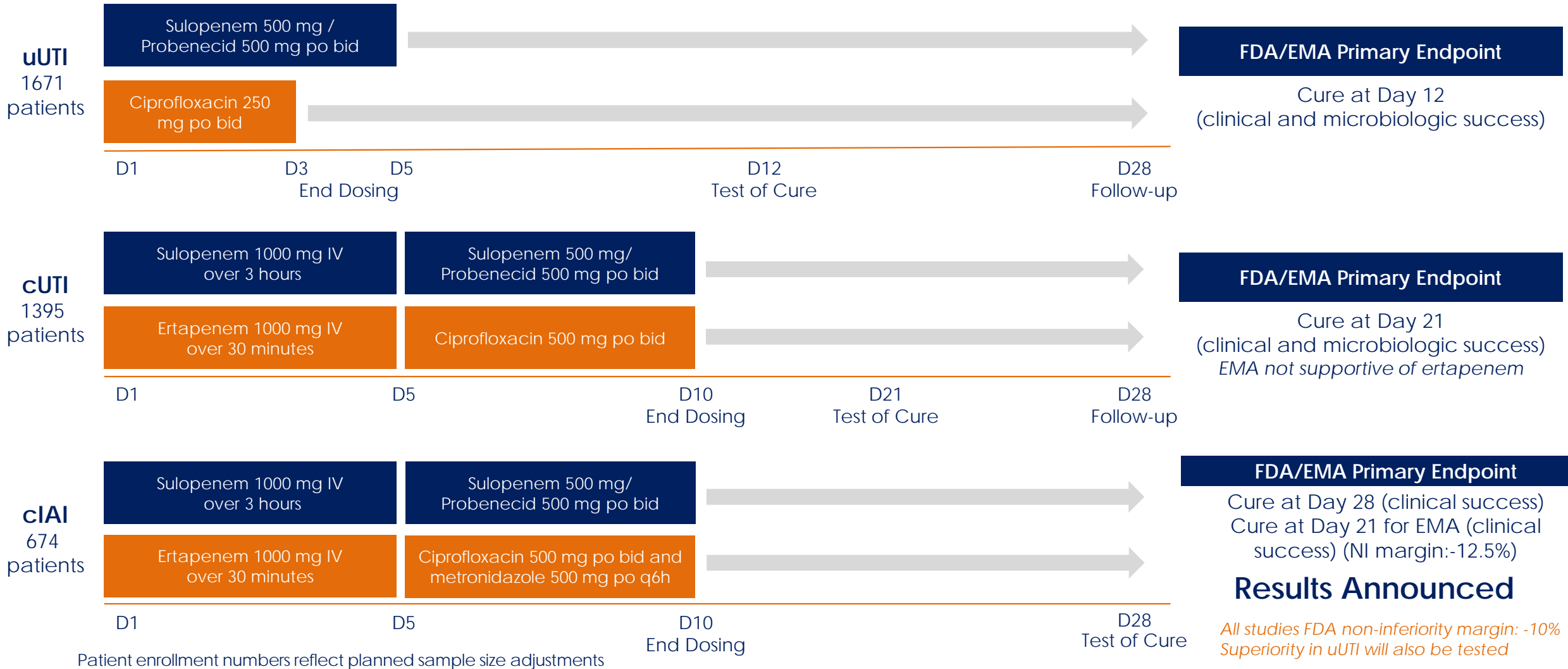
Peak urine concentrations are almost 2,000-fold higher than the MIC<sub>90</sub>, and a single dose will exceed the MIC<sub>90</sub> for the entire bid dosing interval





# Phase 3 Studies Have Completed Enrollment

Anticipate announcing top-line results around the end of Q1 2020



# Complicated Intra-abdominal Infections

## Summary of Phase 3 Results

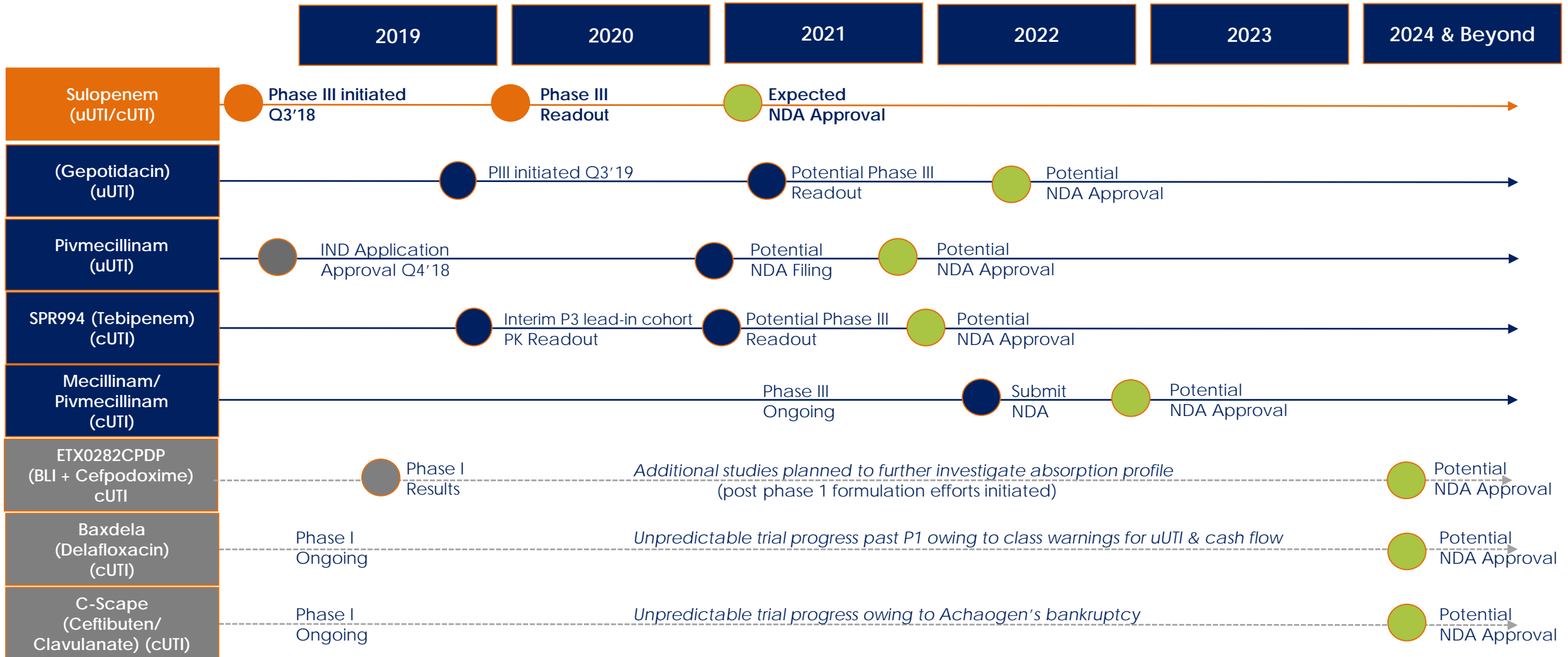
- The primary endpoint narrowly misses the target -10% in the primary micro-MITT population at the Test of Cure visit
  - In key sub-populations, the lower limit of the difference in outcomes is within -10%
  - In three prespecified sensitivity analyses of the primary endpoint, the lower limit is within -10%
- Outcome by key target pathogen was similar between regimens
- Both regimens were well tolerated
  - More SAEs, unrelated to treatment, were seen on the sulopenem regimen
    - Imbalance in patients with “other complicated intra-abdominal infections” with an intraoperative intra-abdominal abscess
  - Overall adverse events were similar between regimens

Primary Endpoint, Clinical Cure at Test of Cure			
Population	Sulopenem	Ertapenem	Difference (95%CI)
Micro-MITT	213/249 (85.5%)	240/266 (90.2%)	-4.7 (-10.3, 1.0)
ITT	292/338 (86.4%)	300/336 (89.3%)	-2.9 (-7.8, 2.0)
MITT	292/335 (87.2%)	298/331 (90.0%)	-2.9 (-7.7, 2.0)
Microbiologic	265/283 (93.6%)	265/277 (95.7%)	-2.0 (-5.7, 1.7)
Clinical	196/212 (92.5%)	212/222 (95.5%)	-3.0 (-7.5, 1.4)

Clinical Outcome by Baseline Pathogen		
	Sulopenem	Ertapenem
<i>Escherichia coli</i>	154/165 (93.3%)	166/174 (95.4%)
<i>Klebsiella pneumoniae</i>	37/40 (92.5%)	26/29 (89.7%)
<i>Proteus mirabilis</i>	6/7 (85.7%)	6/6 (100%)
<i>Bacteroides sp.</i>	90/96 (93.8%)	98/105 (93.3%)

# Snapshot: 5-year Oral UTI Development Pipeline

Expected timing for FDA approval provides valuable first mover advantage for sulopenem



Source: Competitor Investor Presentations, Corporate Press Releases, Analyst Reports, Iterum Estimates

# Sulopenem Launch Planning Underway

Foundational activities in motion preparing the market for success



## Advocacy Development

Collaborating with physician, pharmacist and patient organizations to fight growing resistance problem



**KOL Support**

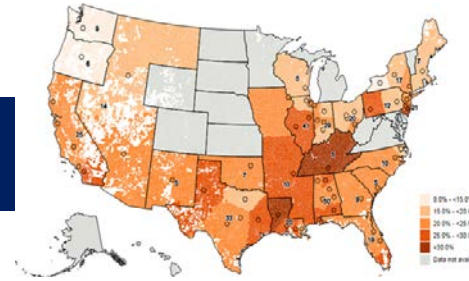


## Payer Reimbursement

Engaging with health plans and PBMs covering >250M US commercial and Medicare lives



**Formulary Access**



## Sales Force Targeting

Mapping areas of greatest need through identification of bacterial resistance at the zip code level



**Early Adoption**



## “Resistance” Campaign

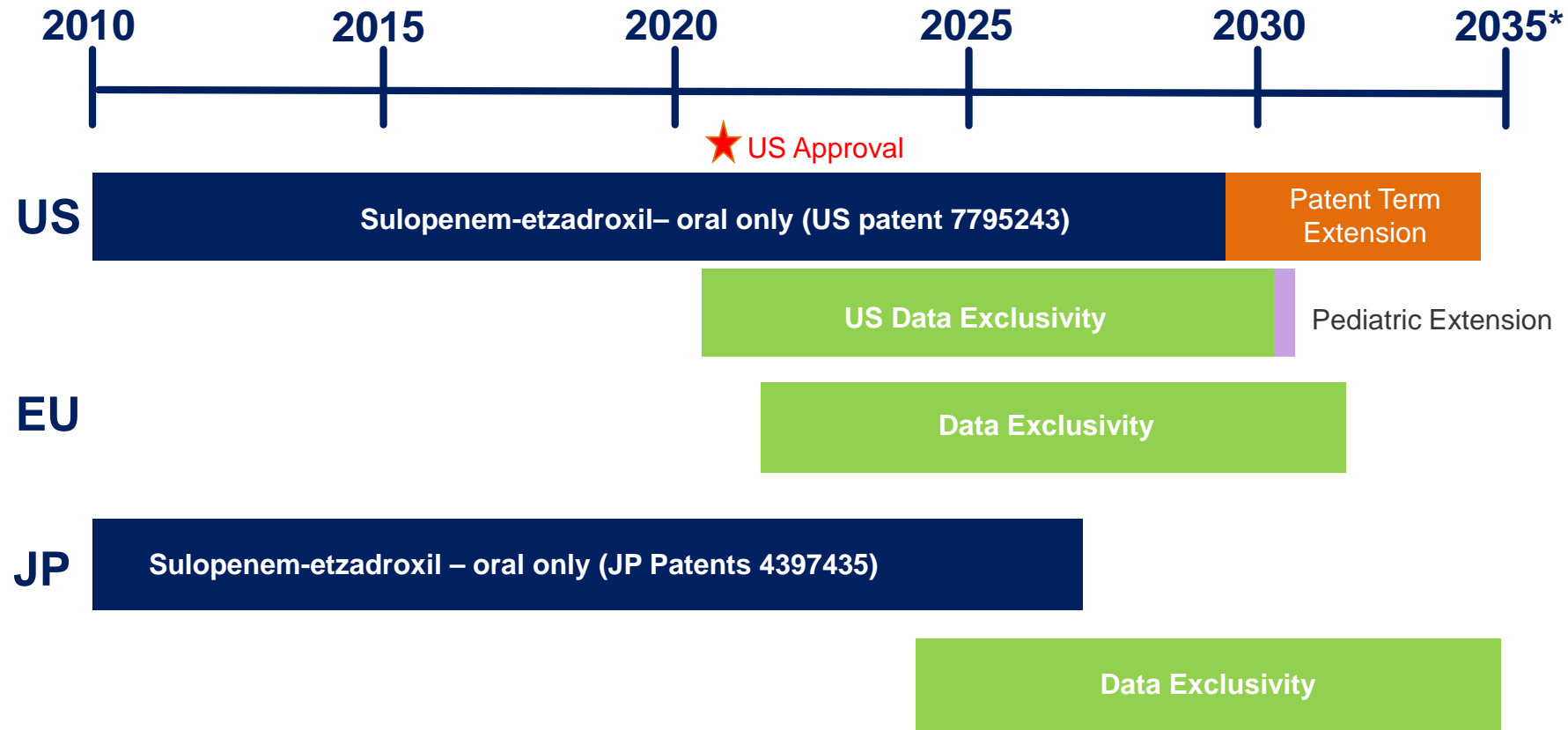
Educating HCPs on geographic-specific bacterial resistance rates and ramifications of treatment failure



**Physician Awareness**

# Long Runway to Capture Value

Sulopenem patents and regulatory exclusivity provide extensive length of protection



10 Years of data exclusivity from time of market approval in EU & Japan; \* Newly filed non-provisional global patents could further extend protection into 2039

# Financial Overview

Key Metric	September 2019
Cash, cash equivalents and short-term investments (millions)	\$28.9*
Gross debt obligation (millions)	\$15.0*
Ordinary shares outstanding (millions)	14.9

\* Raised \$51.6M in January 2020 from the private placement of 6.5% exchangeable senior subordinated notes due 2025 and limited recourse royalty-linked senior subordinated notes

# Multiple Near-term Milestones

Remaining two Phase 3 trials projected to read out in near term

Potential Milestone	Expected Timing
<b>uUTI:</b> Initiate Pivotal Phase 3 Trial	3Q18 ✓
<b>cUTI:</b> Initiate Pivotal Phase 3 Trial	3Q18 ✓
<b>cIAI:</b> Initiate Pivotal Phase 3 Trial	3Q18 ✓
<b>cIAI:</b> Topline Phase 3 Results	4Q19 ✓
<b>cUTI:</b> Topline Phase 3 Results	~end 1Q20
<b>uUTI:</b> Topline Phase 3 Results	~end 1Q20
File NDAs	Mid-20
File MAA in Europe	2H20
Potential FDA Approval	1H21

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