

# UROVANT SCIENCES

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J.P.Morgan

**UROVANT**  
SCIENCES

# Forward-Looking Statements

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This presentation contains forward-looking statements, including without limitation, statements related to: our plans to file for approval of vibegron with the FDA, and the timing of such filing and the likelihood of FDA approval; our ability to successfully develop Vibegron in the United States and other major markets, including meeting clinical endpoints and adequacy of clinical trial results; our ability to commence and complete new clinical trials, including for URO-902, as planned and on expected timelines; the commercial potential for Vibegron, including market size, reimbursement status, potential expanded indications and product differentiation relative to competitors; and the expected duration of patent protection. Forward-looking statements can be identified by "anticipate," "believe," "can," "continue," "could," "estimate," "expect," "intend," "likely," "may," "might," "objective," "ongoing," "plan," "potential," "predict," "project," "should," "to be," "will," "would," or the negative or plural of these words or other similar expressions or variations, although not all forward-looking statements contain these identifying words. Urovant cannot assure you that the events and circumstances reflected in the forward-looking statements will be achieved or occur and actual results could differ materially from those expressed or implied by these forward-looking statements. Forward-looking statements are subject to a number of risks, uncertainties, assumptions and other factors known and unknown that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by the forward-looking statements.

Urovant believes it has a reasonable basis for the statements contained in this document, which are based on information available to Urovant as of the date hereof, however, such information may be inaccurate or complete. In preparing these materials, including the models and projections contained herein, Urovant has relied upon and assumed, without independent verification, the accuracy and completeness of information available from public sources. Without limiting the generality of the foregoing, no audit or review has been undertaken by an independent third party of the financial assumptions, data, results, calculations and forecasts contained, presented or referred to in this document. Any assumptions, analyses, projections or predictions are Urovant's and Urovant's alone. You should conduct your own independent investigation and assessment as to the validity of the information contained in this document and the economic, financial, regulatory, legal, taxation, stamp duty and accounting implications of that information.

These risks and uncertainties include, but are not limited to, those identified herein, and other risks and uncertainties in the section titled "Risk Factors" set forth in Urovant's Form 10-Q, which was filed with the Securities and Exchange Commission ("SEC") on November 7, 2019, as well as any other future filings with the SEC available at [www.sec.gov](http://www.sec.gov).

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# UROVANT

## Investment Highlights



### **Vibegron: NDA submitted December 2019**

- Positive EMPOWUR Phase 3 results announced in March 2019
- Approval projected in December 2020



### **Blockbuster potential for vibegron**

- OAB category has created multiple blockbuster products
- Currently marketed  $\beta$ 3 agonist sales in the Americas for FY2019 estimated to be \$773 million (estimated 18% y/y)
- Vibegron has the potential to become a highly differentiated  $\beta$ 3 agonist with opportunity for significant market share across OAB therapies<sup>1</sup>



### **Multiple large-market clinical programs under development**

- Potential for vibegron to be the first product approved for OAB in men with benign prostatic hyperplasia, a 2 million patient opportunity
- Potential for vibegron to address significant unmet need in the 7+ million patients with pain associated with irritable bowel syndrome (IBS)
- Potential for URO-902 to be first gene therapy approved for OAB



### **Sumitomo Dainippon relationship provides Urovant with access to capital and commercial infrastructure**








### **Management team with demonstrated track record of success**

**Vision: Make Urovant A Leading Urology Specialty Company**

# Sumitomo Dainippon Pharma-Roivant Alliance

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-  Roivant Sciences and Sumitomo Dainippon Pharma have consummated a transaction to create a broad strategic alliance
-  Urovant entered into a \$300 million, low-interest, interest-only, five-year term loan facility with Sumitomo Dainippon Pharma; no repayments due until the end of the term
-  Sumitomo Dainippon Pharma expects to continue to support Urovant through profitability
-  Sumitomo Dainippon Pharma to provide Urovant with access to its U.S. commercial infrastructure, including drug distribution, operations and managed care support
-  Sumitomo Dainippon Pharma has entered into an investor rights agreement with Urovant providing for several protections for minority shareholders

# Late-Stage Urology Pipeline

DRUG CANDIDATE	INDICATION	PHASE 1	PHASE 2	PHASE 3	UPCOMING MILESTONE
Vibegron	Overactive Bladder (OAB)				FDA acceptance of vibegron NDA Q1 2020
	OAB in Men with BPH				Completion of part 2 2021
	IBS-Associated Pain				Phase 2a top-line data 2H 2020
URO-902	OAB				Complete phase 2a cohort 1 enrollment 2H 2020

***Focused business development activities to support our vision of being a leading urology company***

*Initial Target Areas: OAB (spectrum of care), bladder cancer, urology rare diseases and other urological conditions predominately treated by urologists*

# Large Market

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- ✔ More than **30 million** Americans over 40 years old suffer from bothersome symptoms of OAB<sup>1</sup>
- ✔ **~14 million** patients discuss symptoms with a physician<sup>2</sup>
- ✔ **~3.3 million** patients on prescription therapy<sup>3</sup>
- ✔ **~18 million** prescriptions written per year in the US<sup>4</sup>

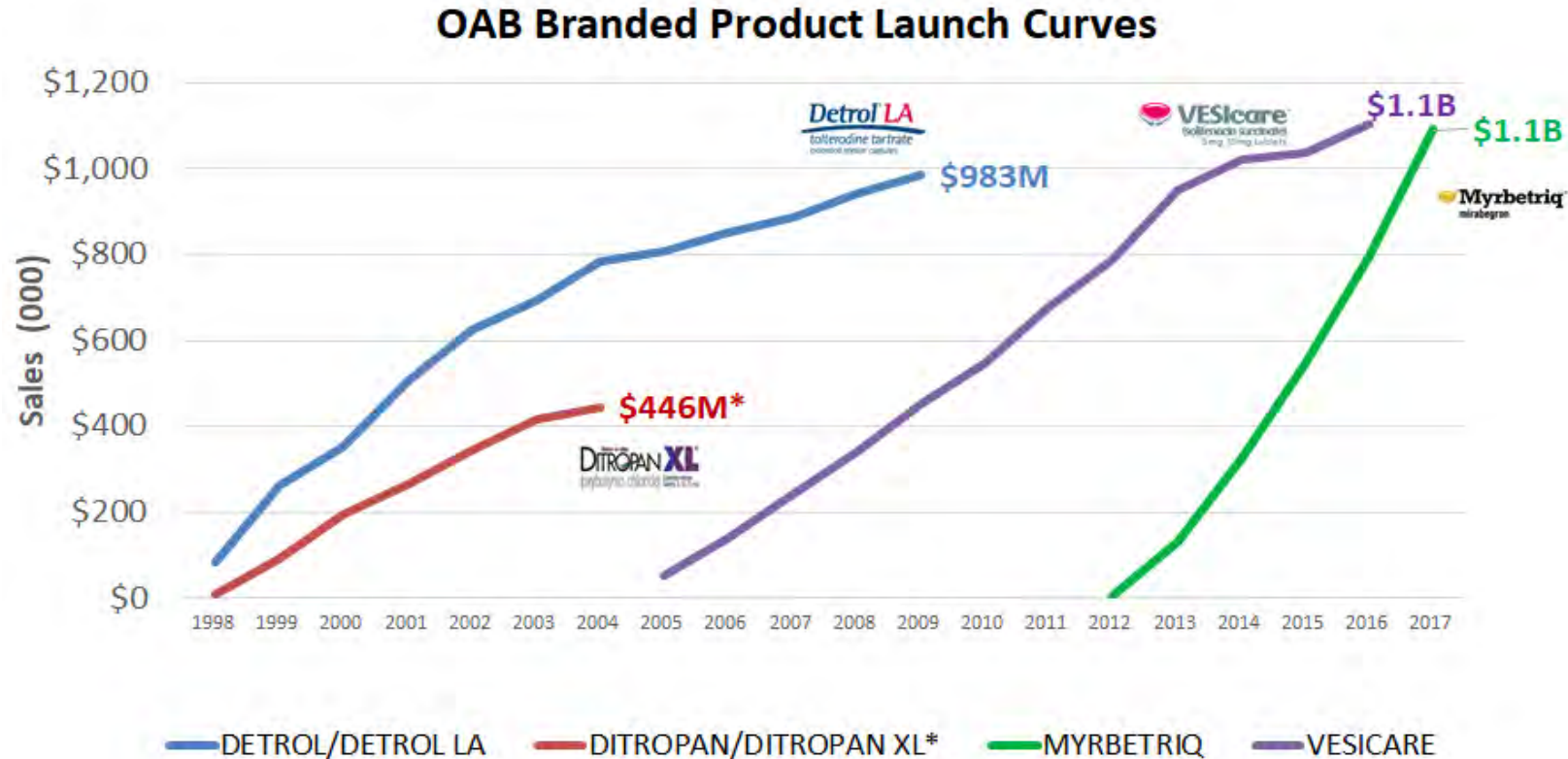
1. Coyne et al., EpiLUTS 2007

2. Benner et al., J Urol, 2009

3. BIQVIA (IMS) New to Brand Data 2016-2017

4. IQVIA (IMS) NPA MAT 12-month Rx data ending Dec 2018

# Blockbuster OAB Launches Every Seven Years



**Strong Wholesale Revenues for New OAB Entrants (with Incremental Differentiation)**

1 IQVIA Launch Edition; data for DETROL/DETROL LA and DITROPAN/DITROPAN XL combined  
 \* DITROPAN/DITROPAN LA based on XL peak, as Ditropan peak data unavailable; sales based on WAC of respective years



# VIBGRON CLINICAL DATA AND DEVELOPMENT



# Extensive Clinical Development Program Market

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- ✓ In-licensed from Merck in February 2017
- ✓ Three successful large, placebo-controlled studies completed in over 4,000 patients achieving all primary and secondary endpoints
- ✓ Robust clinical pharmacology package (21 studies complete)
- ✓ Long-term toxicity and carcinogenicity studies complete

**Potential to address the limitations of both anticholinergics and mirabegron and become a highly differentiated  $\beta_3$  agonist<sup>1</sup>**

1. Subject to approval by the FDA, including FDA approval of the inclusion of urgency data, rapid onset of action data and a single convenient once-daily dose in the label

# Potential Points of Differentiation<sup>1</sup>

	Vibegron <sup>2</sup>	Mirabegron	ACH
Highly selective for human $\beta 3$ receptor <sup>3</sup>	✓	✗	n/a
Rapid onset of efficacy by 2 weeks	✓	✗	✗
Potential efficacy claim for urgency <sup>4</sup>	✓	✗	✗
Potential broader efficacy claims	✓	✗	✗
No CYP2D6 drug-drug interactions	✓	✗	Some
No QTc signal	✓	✗	✗
Single convenient crushable dose <sup>5</sup>	✓	✗	✗
No known dementia risk <sup>6</sup>	✓	✓	✗

1. Based on product labels, publicly available literature, and data on file  
 2. Based on clinical trials to date. Vibegron is in Phase 3 clinical development for OAB and has not been approved by the FDA or any other regulatory authority. All potential points of differentiation are subject to verification through further clinical development of vibegron and the review of the FDA  
 3. Based on in vitro data  
 4. Subject to approval by the FDA, including FDA approval of the inclusion of urgency data  
 5. Assuming successful result in planned relative bioavailability study or FDA acceptance of in vitro data  
 6. Gray et al. JAMA Intern Med. 2015

# EMPOWUR Results: Vibegron Demonstrated Strong Efficacy Across All OAB Endpoints

## Week 12 LS Mean Change from Baseline (Placebo-Adjusted)

Endpoint	Vibegron	n	p-value
<b>UUI Episodes<sup>2</sup></b>	<b>-0.6</b>	<b>383</b>	<b>&lt;0.0001</b>
<b>Micturitions<sup>2</sup></b>	<b>-0.5</b>	<b>492</b>	<b>&lt;0.001</b>
Urgency Episodes <sup>3</sup>	-0.7	492	0.0020
Total Incontinence Episodes <sup>3</sup>	-0.7	383	<0.0001
Volume Voided (ml) <sup>3</sup>	21.2	490	<0.0001
OAB-q Coping Score <sup>3</sup>	3.6	512	0.0038

Tolterodine <sup>1</sup>	n	p-value
-0.4	286	0.0123
-0.3	378	0.0988
-0.4	378	0.0648
-0.5	286	0.0074
13.3	375	<0.001
3.1	401	0.0212

1. Tolterodine was an active control, comparisons vs placebo

2. Co-primary endpoint

3. Key Secondary Endpoint

LS=Least Squares

# Rapid Onset and Sustained Benefit in Phase 3 Trial

## Change in Average Daily UUI Episodes

### 3003 Study

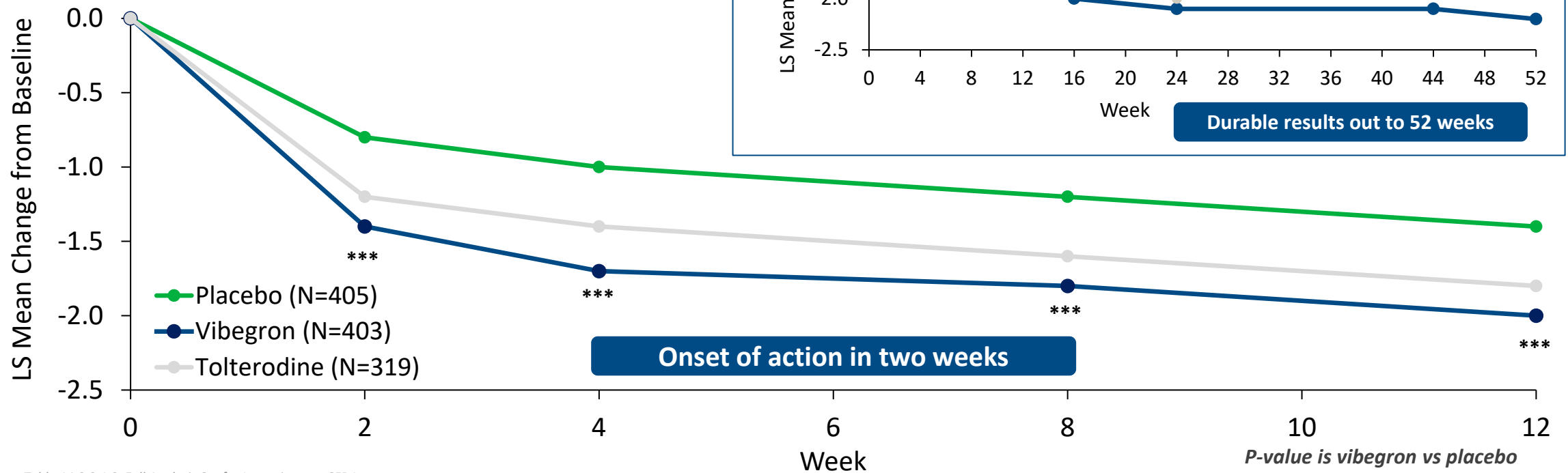
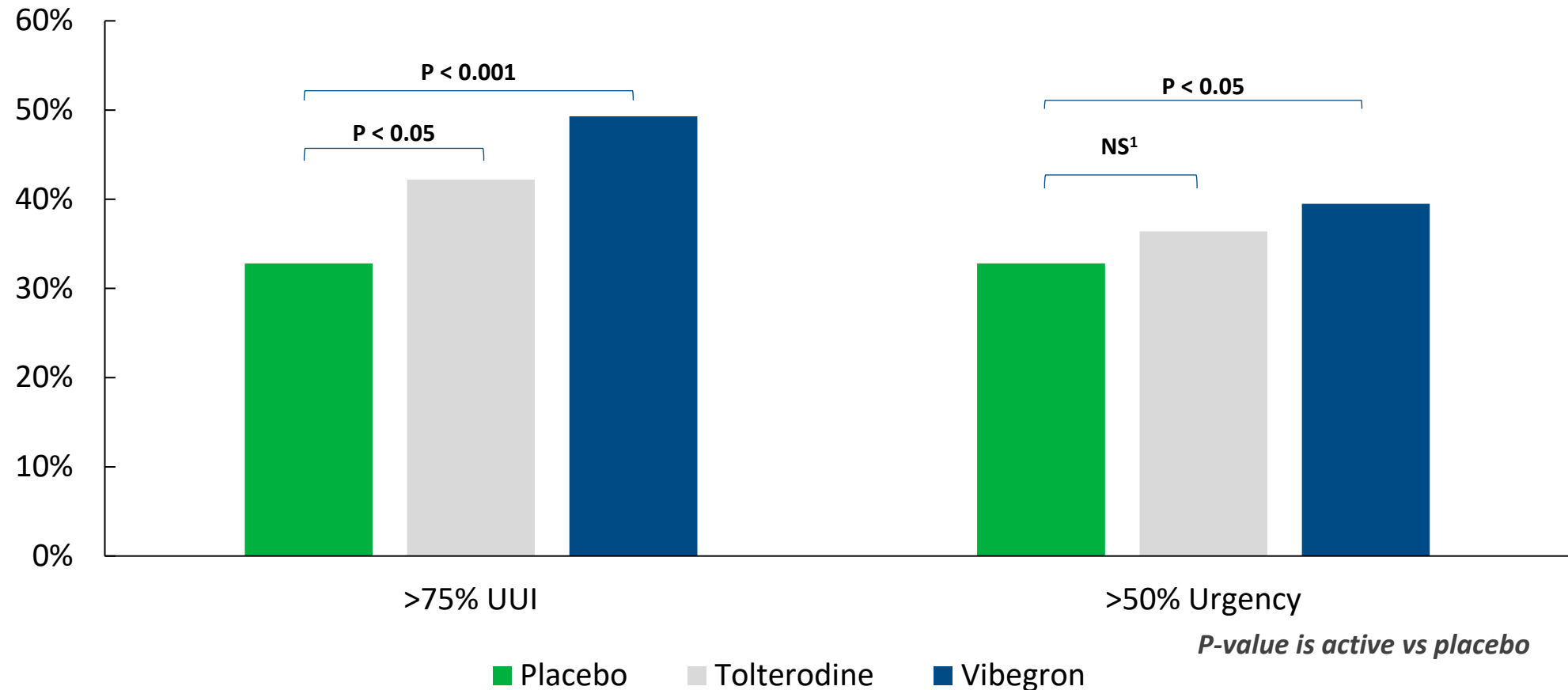


Table 14.2.2.1.2, Full Analysis Set for Incontinence, CFB Least squares mean  
Covariates included in the mixed model for repeated measures are study visit, sex, region, baseline number of UUI, and treatment by study visit interaction.

# >50% of Patients Achieved a 75% Reduction in UUI Episodes at Week 12



1. P-values for the difference in proportions between active and placebo were calculated using the Cochran-Mantel-Haenszel risk difference estimate stratified by OAB Type (Wet vs Dry) and Sex (Female vs Male), with weights proposed by Greenland and Robins. MI has been used to impute values missing for any reason at the weeks analyzed. Adjusted proportions are presented.  
Table 14.2.4.1.1 Full Analysis Set for Incontinence. 75% Reduction in UUI from Baseline at Week 12  
Table 14.2.5.1.1 Full Analysis Set for Incontinence 100% Reduction in UUI from Baseline at Week 12  
Table 14.2.6.1.1 Full Analysis Set 50% Reduction in Urgency from Baseline at Week 12

# Most Common Adverse Events Consistent with Placebo

(>2% and > Placebo)

AE term n (%)	Placebo N=540	Vibegron N=545	Tolterodine N=430
Headache	13 (2.4)	22 (4.0)	11 (2.6)
Nasopharyngitis	9 (1.7)	15 (2.8)	11 (2.6)
Diarrhea	6 (1.1)	12 (2.2)	9 (2.1)
Nausea	6 (1.1)	12 (2.2)	5 (1.2)

Table 14.3.1.15, Safety Analysis Set. Represents number of patients.

Vibegron has not demonstrated a QTc signal at any dose, including the highest tested dose of 400 mg

Successful ambulatory blood pressure study with no statistically significant increase in daytime ambulatory systolic blood pressure, including no increase above the pre-specified limit of 3.5 mmHg

# Single Convenient Crushable Dose

- ✓ Single convenient 75mg dose, no titration required
- ✓ Completed pharmacokinetic study on food effect and the crushed tablet. Results support proposed labeling for administration of vibegron with / without food and as a crushed tablet in soft food

Survey: Importance of VIBEGRON dosing attributes	HCPs (N=150)
<b>DOSING</b>	
<b>PRODUCT X can be crushed if needed</b>	<b>145</b>
<b>PRODUCT X - Once a day 75 mg immediate release tablet</b>	<b>129</b>
<b>No titration</b>	<b>120</b>

Scores of 100 = average  
Scores 120+ highlighted as significantly above average

Physician Quant Survey, Apr 2018

**HCP market research suggests no titration and crushability as strong potential benefits of vibegron**

Study parameters: Physicians & NP/PAs who have specialties in Urology or OB/GYN, in practice at least 5 years, spend at least 50% of time in direct patient care at an individual or group practice and currently treat at least 50 OAB patients. 150 HCP total sample comprised of 50 UROs, 50 PCPs, 25 OB/GYNs, and 25 NP/PAs.

HCP questions – If I were to use PRODUCT X (based on this information) to treat my patients with overactive bladder, I would feel:

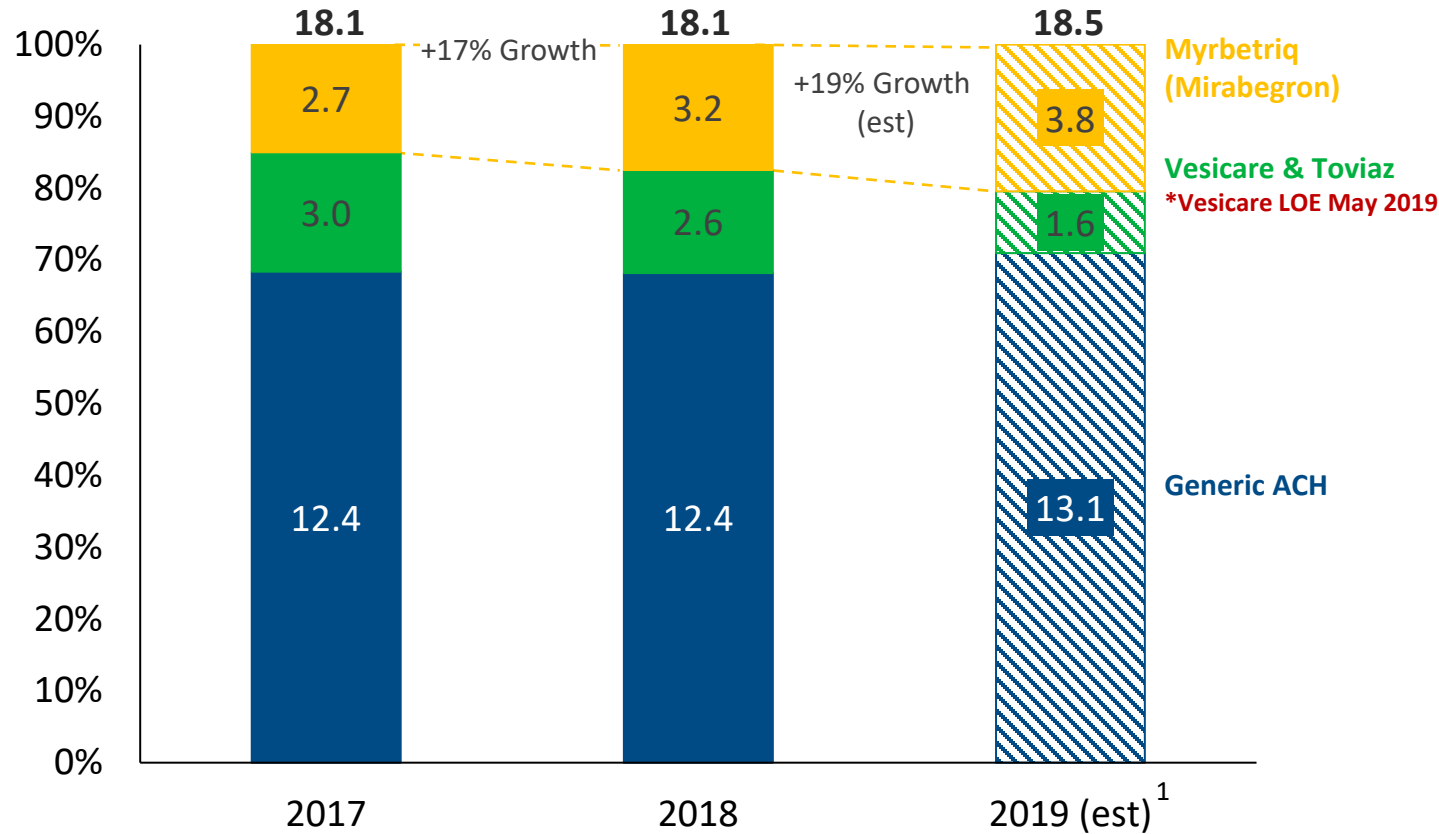


# OAB MARKET



# Mirabegron, a $\beta 3$ Agonist, Gaining Market Share in U.S.

2019  $\beta 3$  total prescription share estimated at ~20%



- ~19%+  $\beta 3$  TRx estimated growth in 2019 vs. market growth of 2%<sup>1</sup>
- FY2019  $\beta 3$  agonist net sales in the Americas estimated to be \$773 million (+18% y/y)<sup>2</sup>

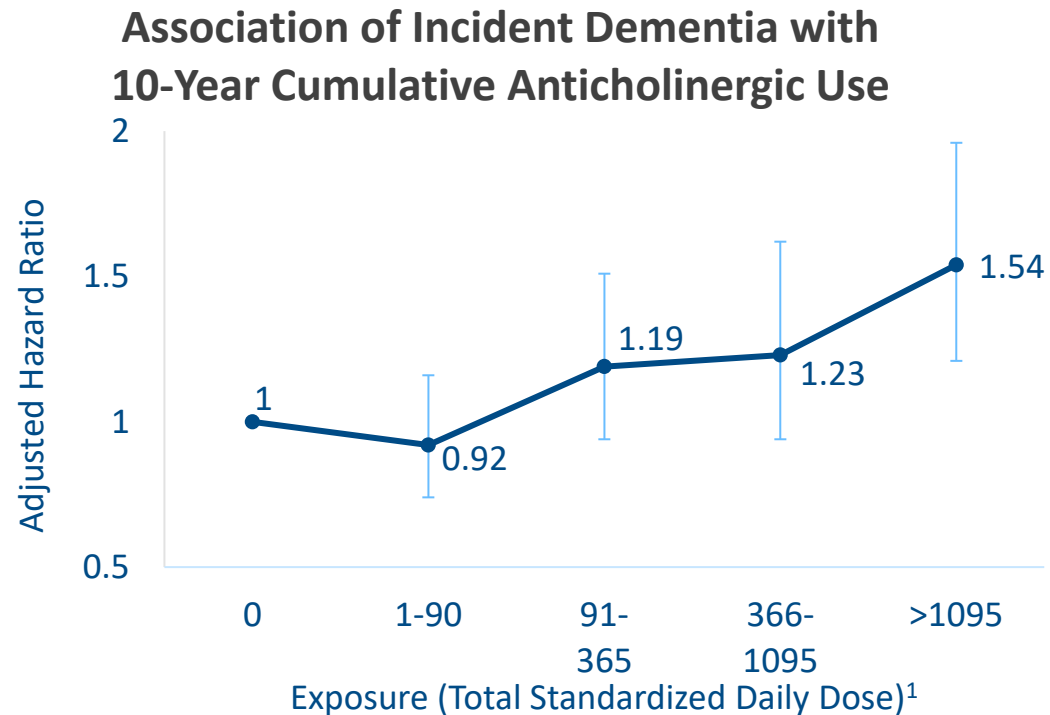
We estimate each percentage point of US OAB market share is worth ~\$70 million<sup>3</sup>

1. IQVIA (IMS) NPA Oct 2019 and company estimates  
 2. Astellas reported projected net sales of mirabegron in the Americas of \$773 million for the 2019 fiscal year ending March 31, 2019  
 3. Based on mirabegron's wholesale acquisition cost of \$384.28 per month (PriceRx, Jan 2019) and the over 18 million oral OAB prescriptions in the United States in 2018

# Anticholinergic Use Associated with Cognitive Impairment and Dementia

“Higher cumulative anticholinergic use is associated with an increased risk for dementia. Efforts to increase awareness among health care professionals and older adults about this potential medication-related risk are important to minimize anticholinergic use over time.”

Gray et al., JAMA Intern Med. 2015



## The evidence continues to grow:

- Prospective analysis of **>3,400 participants** aged  $\geq 65$  shows 10-year cumulative dose-response relationship for increased risk of both dementia and Alzheimer’s disease ( $p < 0.001$ )<sup>1</sup>
- Retrospective analyses of **40,000 patients across >30 studies** establish a **cognitive impairment** relationship<sup>2</sup>
- Case-control study of more than **58,000 patients** found there were **statistically significant associations of dementia risk** with exposure to anticholinergics after adjusting for confounding variables<sup>3</sup>

1. Gray et al., JAMA Intern Med. 2015. Cumulative exposure as a multiple of the minimum effective daily dose. For oxybutynin, the minimum effective daily dose is 5 mg, but the most commonly prescribed dose is 10 mg/day. Each exposure category included over 2,600 person-years of follow-up time.

2. Data on file.

3. Coupland et al., JAMA Intern Med. 2019. Anticholinergic drug exposure and the risks of dementia. A nested case-control study.



# VIBEGRON COMMERCIAL STRATEGY

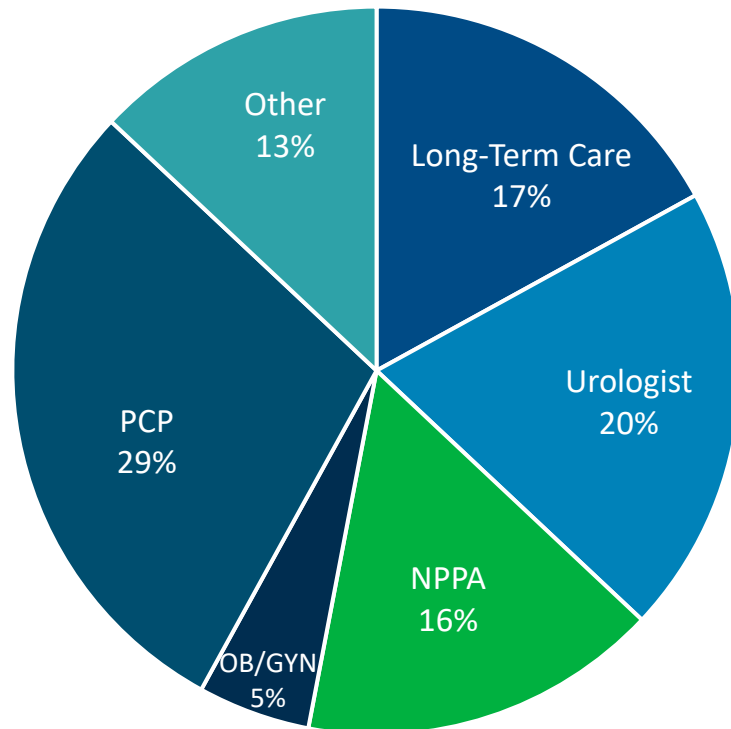
# Key Elements of Commercial Strategy

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- ✔ Deploy a fully scaled sales force effort in Urology and Long-Term Care
- ✔ Start with a targeted effort with high prescribing PCPs
- ✔ Ensure broad payor coverage
- ✔ Exploring co-promote options for broader PCP effort at launch

# Urologists, LTC, High Prescribing PCPs Account for >50% of OAB Prescriptions

OAB Rx 2018 Volume by Specialty<sup>1</sup>



Urologists, LTC, and High Prescribing PCPs account for >50% of all OAB Rx



Urologists prescribe 30% of all  $\beta$ 3s



Urologists and other specialties can be managed with approximately 100 FTEs



LTC segment can be managed with approximately 50 FTEs

**Urologists most productive OAB writers and more likely to prescribe branded drugs**

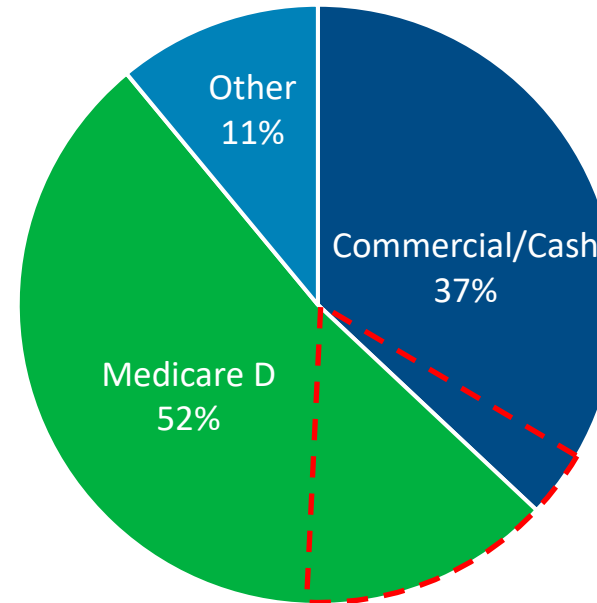
1. IQVIA (IMS) NPA data ending Dec 2018.

# Payor Coverage

## Current Landscape

- ✓ 95% of commercial plans and 100% of Medicare plans cover Myrbetriq<sup>1</sup>
- ✓ Branded agents continue to have pricing elasticity

## OAB Market: TRx by Payor Type<sup>2</sup>



Long-term care, at an estimated 18%<sup>3</sup>, is a significant portion of OAB prescriptions

**Oral OAB category is not highly managed by payors<sup>4</sup>**

1. 1998-2019 Managed Markets Insights and Technology

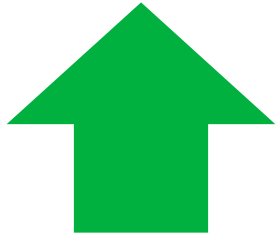
2. IMS PayerTrak Dec 2018

3. IQVIA (IMS) NPA data ending Dec 2018.

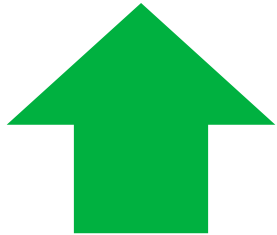
4. Based on two third-party market research studies, commissioned by Urovant in 2018, to assess how Vibegron would be covered, if approved. One research firm interviewed a panel which represented payors covering over 80 million U.S. commercial and Medicare Part D lives. The second research firm interviewed a panel which represented payors covering over 161 million U.S. commercial and Medicare Part D lives.

# Significant Market Expansion Opportunities

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Increase  $\beta$ 3 agonists market share vs ACHs



Increase 2<sup>nd</sup> line OAB therapy utilization



Increase therapy persistence from current levels

**Dissatisfaction with existing therapies creates multibillion-dollar expansion opportunities**

1. IQVIA year ending Oct 2019 NPA
2. 2016 IQVIA Rx/DX Patient Longitudinal Analyses. Assumes all scripts are 30-day supplies, 100% patient compliance



# GROWTH OPPORTUNITIES



# OAB in Men with BPH and IBS-Associated Pain Represent Lifecycle Opportunities with Significant Market Potential

## OAB in Men with BPH

**40 million**

Men aged 50 – 80  
years old with BPH

**>4 million**

Treated BPH patients in the U.S.

**> 2 million**

U.S. BPH patients  
with co-morbid OAB

## IBS-Associated Pain

**30-40 million**

Patients with IBS

**9-10 million**

Patient consult with MD

**> 7-9 million**

Addressable US patient  
Market

IBS population based upon: 1. Rosen et al., Eur Urol 2003. BPH prevalence applied to 2016 population; 2. IMS Health NPA Market Dynamics (2014); 3. Eapen et al., Res Rep Urol. 2016; 4. IQVIA (IMS) NDTI projected BPH patient visits by specialty; 5. Gallegos et al. Pharmacotherapy 2008.

IBS-Associated pain population based upon: 1. IQVIA (IMS) NSP 12-month branded sales ending December 2018; 2. Celtek et al. Gastroenterology 2007; 3. Kelleher et al. Neurogastroenterol Motil 2008; 4. Lovell and Ford. Clin Gastroenterol Hepatol 2012; 5. Canavan. Clinical Epidemiology 2014; 6. Drossman. J Clin Gastroenterol 2009.

# Gene Therapy Overview

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## Market Overview

- ✓ Third-line OAB treatments (e.g. BOTOX and neuromodulation) generate estimated annual sales in excess of \$700 million in the US<sup>1</sup>
- ✓ Potential to address an unmet need for OAB patients who have failed oral pharmacological therapies and are concerned with potential urinary retention after BOTOX or any “toxin” effect or surgical intervention
- ✓ Currently, there are no FDA-approved gene therapy treatments for OAB

## Clinical Summary

- ✓ DNA gene therapy using a plasmid vector
- ✓ Studied in two Phase 1 clinical trials in the US in a total of 22 women with OAB
- ✓ Phase 1b clinical trial (n=13) showed dose-dependent reductions in micturitions, urgency episodes and UUI episodes, achieving statistical significance ( $p < 0.05$ ) in the high dose cohort (24,000 $\mu$ g)

1. Urovant estimates based on third-party market research and Cogentix and Allergan filing



# MILESTONES AND INVESTMENT HIGHLIGHTS

# Urovant Sciences Milestones

**2019**

- Top-line results of the Phase 3 vibegron trial in OAB (March)*
- Begin enrollment of Part 1 of the Phase 3 vibegron trial in OAB & BPH*
- Vibegron long-term extension study results*
- Begin enrollment of Part 2 of the Phase 3 vibegron trial in OAB & BPH*
- Begin enrollment of Phase 2 URO-902 trial*
- Submit NDA for vibegron in OAB*

**2020**

- FDA acceptance of vibegron NDA*
- Top-line results of vibegron trial in IBS-associated pain*
- Complete enrollment of Cohort 1 and begin enrollment of part 2 of URO-902 trial*
- FDA approval of vibegron in OAB*

**2021**

- Commercial launch of vibegron*
- Start pediatric clinical program of vibegron for OAB*
- Top-line results of vibegron trial in OAB and BPH*
- Top-line results of URO-902 trial*

# UROVANT

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