# UROVANT SCIENCES

## H.C. Wainwright & Co.
## 22nd Annual Global Investment Conference

September 15, 2020

# Forward-Looking Statements

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.

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# Company Overview

## Vision

Become a leading urology specialty company

## Mission

Advance urologic care through bold innovation

## Values

Integrity, compassion, bold innovation and collaboration

### About Urovant Sciences

- Global late-stage biopharmaceutical company
- Headquartered in Irvine, California with an office in Durham, North Carolina
- 127 employees

### Focus

- Developing and commercializing innovative therapies for urologic conditions

### Pipeline

- Lead product candidate, vibegron, an oral, once-daily small molecule beta-3 agonist being evaluated for overactive bladder (OAB). PDUFA date, December 26, 2020
- Vibegron is also being evaluated for OAB in men with benign prostatic hyperplasia (OAB+BPH) and abdominal pain associated with irritable bowel syndrome (IBS)
- Second product candidate, URO-902, a novel gene therapy being developed for patients with OAB who have failed oral pharmacologic therapy

### Ownership

- Sumitomo Dainippon Pharma owns ~73% of Urovant's outstanding shares

### Cash Position

- As of June 30, 2020 – $63 million

# Executive Leadership Team

**James Robinson**
President and CEO

Alkermes · astellas · Schering-Plough

**Cornelia Haag-Molkenteller, MD, PhD**
Chief Medical Officer

Allergan · SCHWARZ PHARMA · Hoechst

**Ajay Bansal**
Chief Financial Officer

NEKTAR · VIEWRAY · McKinsey & Company

**Bryan Smith**
General Counsel

Allergan · GIBSON DUNN

**Walt Johnston**
SVP, Commercial

astellas · Pfizer

**Kenton Steward**
SVP, Market Access

Alkermes · astellas · TR

**Nori Ebersole**
Chief Human Resources Officer

PAUL HASTINGS · Allergan

**Christine Ocampo**
Chief Accounting Officer

NOVUS Therapeutics · AVANIR pharmaceuticals · EY

# UROVANT

# Investment Highlights

## Vibegron: NDA accepted March 2020

- Positive EMPOWUR Phase 3 results announced in March 2019
- PDUFA date December 26, 2020

## Blockbuster potential for vibegron

- OAB category has created multiple blockbuster products
- U.S. FY2019 β3 agonist sales were $821 million (estimated 13% y/y)
- Vibegron has the potential to become a highly differentiated β3 agonist with opportunity for significant market share across OAB therapies[1]

## Multiple large-market clinical programs under development

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

## Management team with demonstrated track record of success

- Deep category experience

**Vision: Become A Leading Urology Specialty Company**

1. Subject to the 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

# Urovant Pipeline

| DRUG CANDIDATE | INDICATION | PHASE 1 | PHASE 2 | PHASE 3 | UPCOMING MILESTONE |
|---|---|---|---|---|---|
| vibegron | Overactive Bladder (OAB) |  | | | PDUFA date December 26, 2020 |
| | OAB in Men with BPH |  | | | Phase 3 top-line data 2H 2021 |
| | IBS-Associated Pain |  | | | Phase 2a top-line data November 2020 |
| URO-902 | OAB |  | | | Phase 2a cohort 1 DSMB meeting December 2020 / early 2021 |

**Development and Acquisition of Differentiated Treatments Supports Vision of Becoming a Leading Urology Company**

# VIBEGRON CLINICAL DATA AND DEVELOPMENT

# Extensive Clinical Development Program

- In-licensed from Merck in February 2017
- Three successful, 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 current treatments and become a highly differentiated $\beta_3$ agonist[1]**

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

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

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

| Endpoint | Vibegron | n | p-value | Tolterodine[1] | n | p-value |
|---|---|---|---|---|---|---|
| **UUI Episodes[2]** | **-0.6** | **383** | **<0.0001** | -0.4 | 286 | 0.0123 |
| **Micturitions[2]** | **-0.5** | **492** | **<0.001** | -0.3 | 378 | 0.0988 |
| Urgency Episodes[3] | -0.7 | 492 | 0.0020 | -0.4 | 378 | 0.0648 |
| Total Incontinence Episodes[3] | -0.7 | 383 | <0.0001 | -0.5 | 286 | 0.0074 |
| Volume Voided (ml)[3] | 21.2 | 490 | <0.0001 | 13.3 | 375 | <0.001 |
| OAB-q Coping Score[3] | 3.6 | 512 | 0.0038 | 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 Efficacy Over 52 Weeks in Phase 3 Trial

## Change in Average Daily UUI Episodes

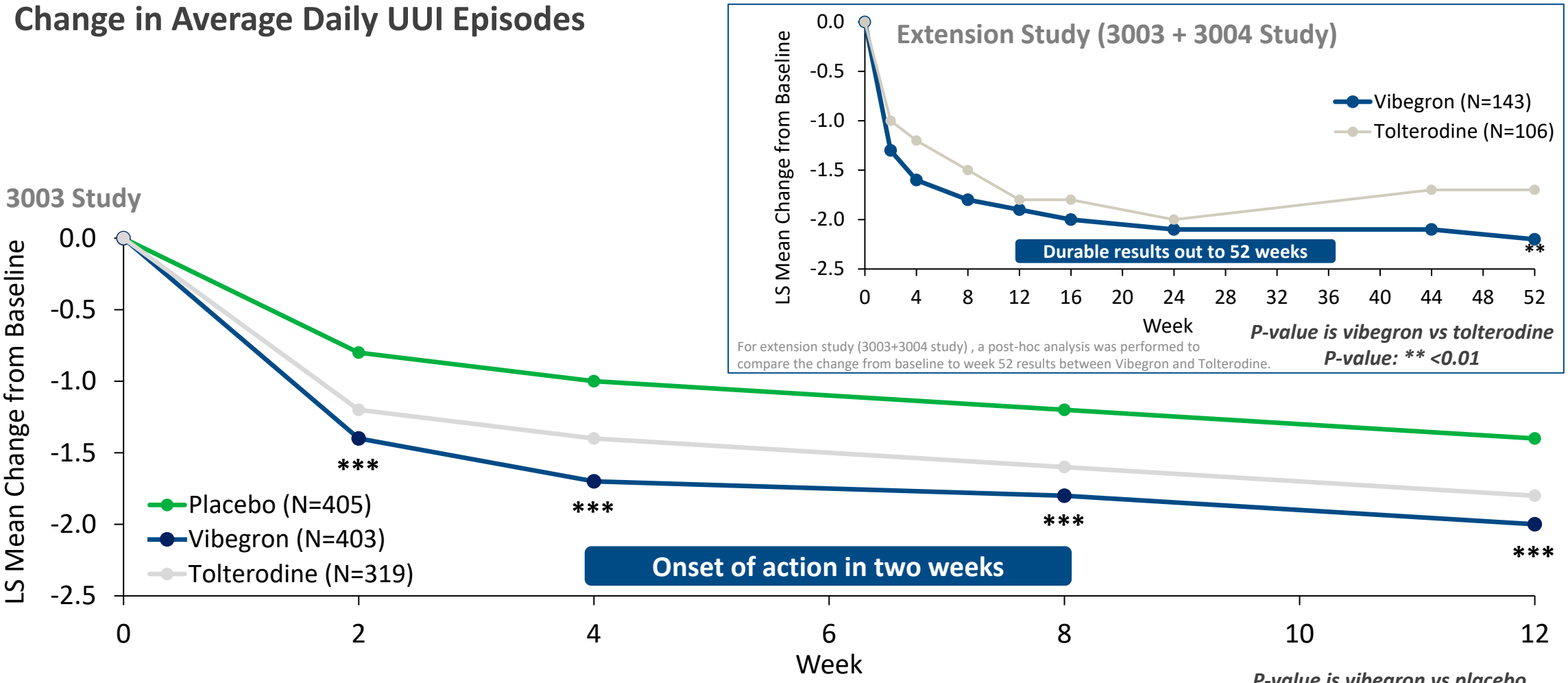
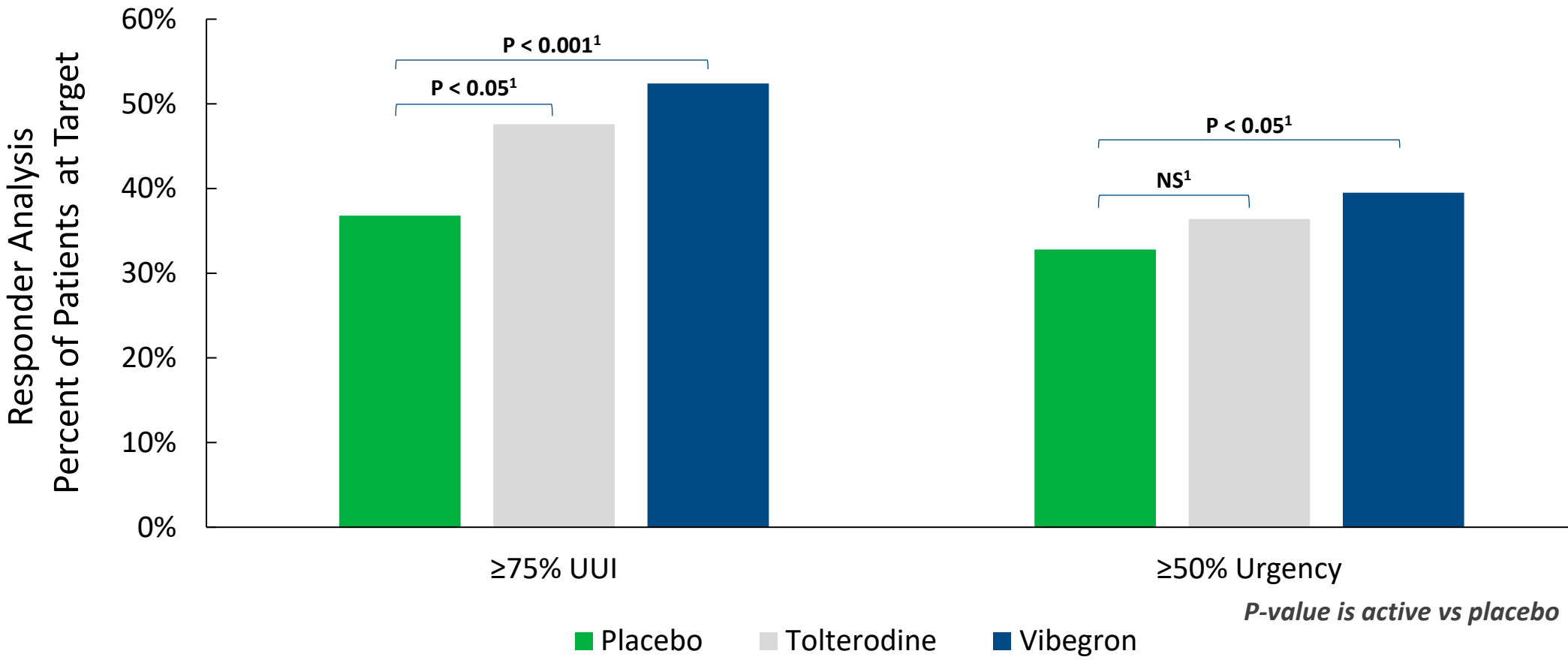



Table 14.2.2.1.2, Full Analysis Set for Incontinence, CFB Least squares mean
Covariates included in the mixed model for repeated measures are study visit, sex, region, baseline number of UUI, and treatment by study visit interaction

# >50% of Patients Achieved ≥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 14.2.6.1.1 Full Analysis Set 50% Reduction in Urgency from Baseline at Week 12

# Vibegron was Well Tolerated

## Most Common Adverse Events in Range of 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) |
| Hypertension | 9 (1.7) | 9 (1.7) | 11 (2.6) |
| Blood pressure increased | 5 (0.9) | 4 (0.7) | 8 (1.9) |

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

Completed 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

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

# Vibegron: Significant Potential For Category-Defining Differentiation[1] in OAB

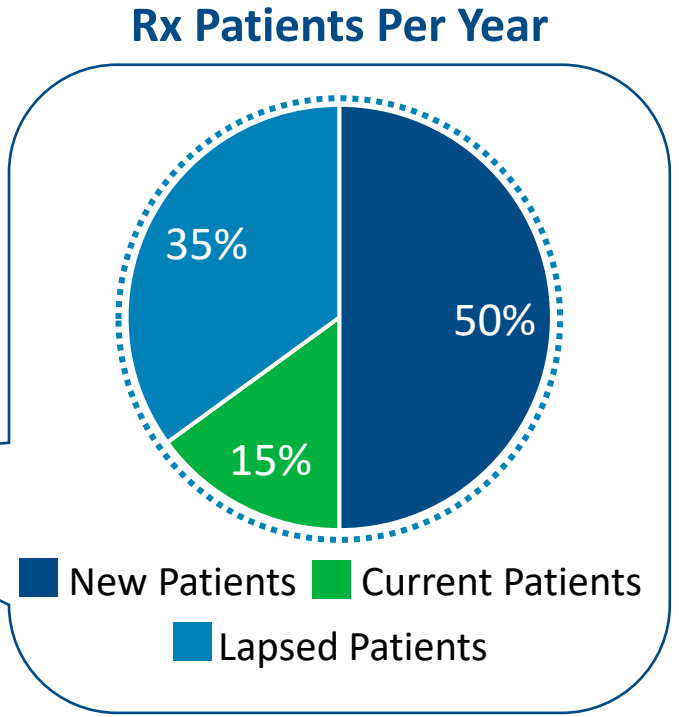
| | vibegron[2] | mirabegron | ACh |
|---|---|---|---|
| Rapid onset of efficacy (2 weeks) | ✓ | ✗ | ✗ |
| Potential efficacy claim for urgency[3] | ✓ | ✗ | ✗ |
| Potential broader efficacy claims | ✓ | ✗ | ✗ |
| No CYP2D6 drug-drug interactions | ✓ | ✗ | Some |
| No QTc signal | ✓ | ✗ | ✗ |
| Single convenient crushable dose[4] | ✓ | ✗ | ✗ |
| No known dementia risk[5] | ✓ | ✓ | ✗ |

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. Subject to approval by the FDA, including FDA approval of the inclusion of urgency data
4. Successful relative bioavailability study, inclusion in the label pending FDA approval
5. Gray et al. JAMA Intern Med. 2015

# OAB MARKET AND VIBEGRON COMMERCIAL STRATEGY

# Large Market

- More than **30 million** Americans over 40 years old suffer from bothersome symptoms of OAB[1]
- **~14 million** patients discuss symptoms with a physician[2]
- **~3.5 million** patients on prescription therapy[3]
- **~18.5 million** prescriptions written per year in the US[4]
- Over **19%** TRx growth in FY 2019 β3 market vs 2% total market[5]




1. Coyne et al., EpiLUTS 2007
2. Benner et al., J Urol, 2009
3. NDTI Audit from May 2014 to April 2020
4. NPA Extended Insights Audit from May 2017 to April 2020
5. IQVIA Launch Edition October 2012 through March 2020

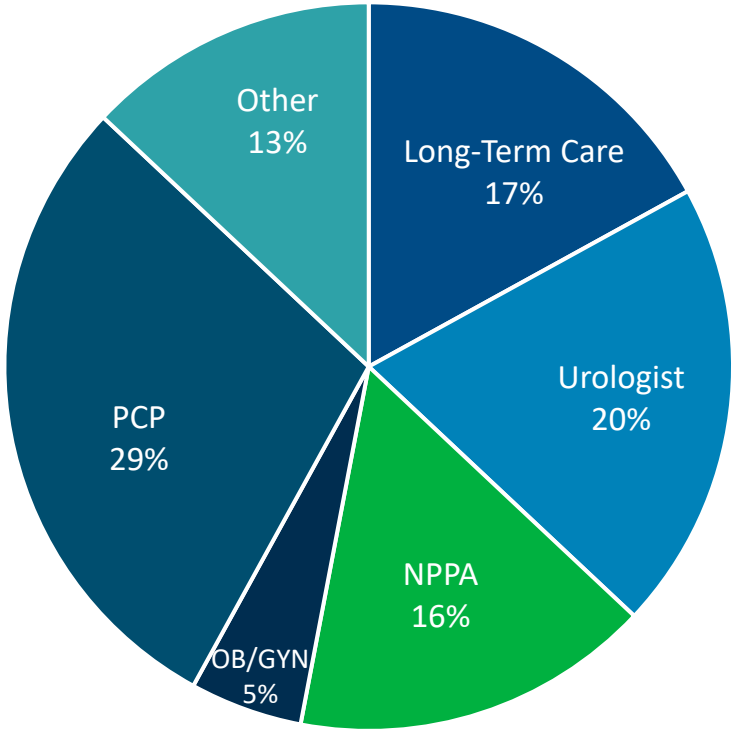
# Goal: Establish Vibegron as the OAB Brand of Choice

## Key Elements of Commercial Strategy

- Deploy a fully scaled, best-in-class sales force in Urology and Long-Term Care
- Start with a targeted effort with high prescribing PCPs
- Ensure broad payor coverage
- Activate patients to request vibegron
- Explore co-promote options for broader PCP effort at launch

# Deploying 160 Sales Reps to Cover Urologists, LTC, High Prescribing PCPs

OAB Rx 2018 Volume by Specialty[1]



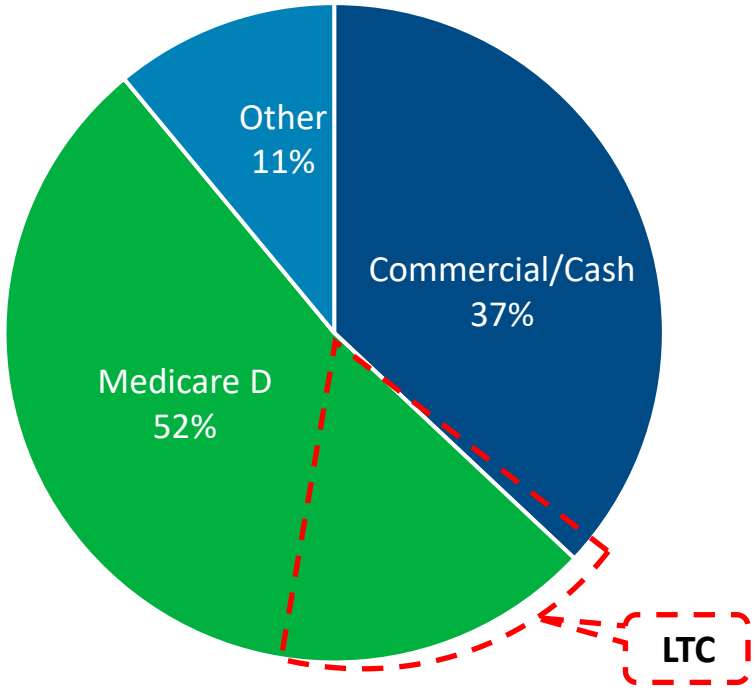

- Urologists, LTC, and High Prescribing PCPs account for >50% of all OAB prescriptions
- Urologists prescribe 30% of all β3s
- Urologists, other specialties, and high prescribing PCPs can be managed with approximately 100 – 120 FTEs
- LTC segment can be managed with approximately 30 – 50 FTEs

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

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

# Experienced Market Access Team Engaging with Payors to Ensure Broad Coverage

TRx by Payor Type[1]

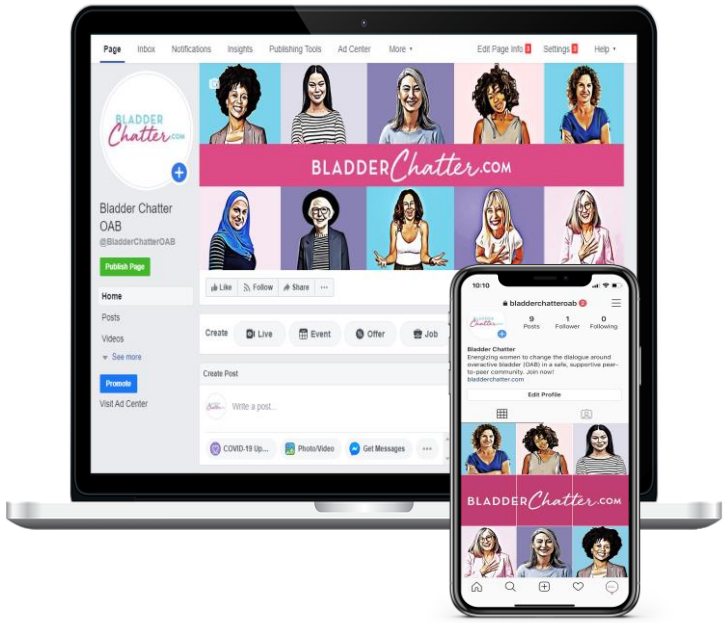



- Established market access team with deep experience in Urology; engaging with key national, regional and long-term care payers
  - Over 120 years of combined OAB experience
- Launched payor preapproval information exchange
- Positive payor feedback on vibegron profile

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

# Activating Patients:  From Awareness to Activation

- Unbranded education awareness programs launched July
- Bladderchatter.com, designed to start a new conversation about OAB
- Over 70k visits to bladderchatter.com to-date
- Deploy multi-channel marketing campaign upon approval
- Maximize activation through digital and social media presence



# GROWTH OPPORTUNITIES

# OAB+BPH: URO-901-3005 Phase 3

COURAGE

## OAB in Men with BPH

**40 million**
Men aged 50 – 80 years old with BPH

**>4 million**
Treated BPH patients in the U.S.

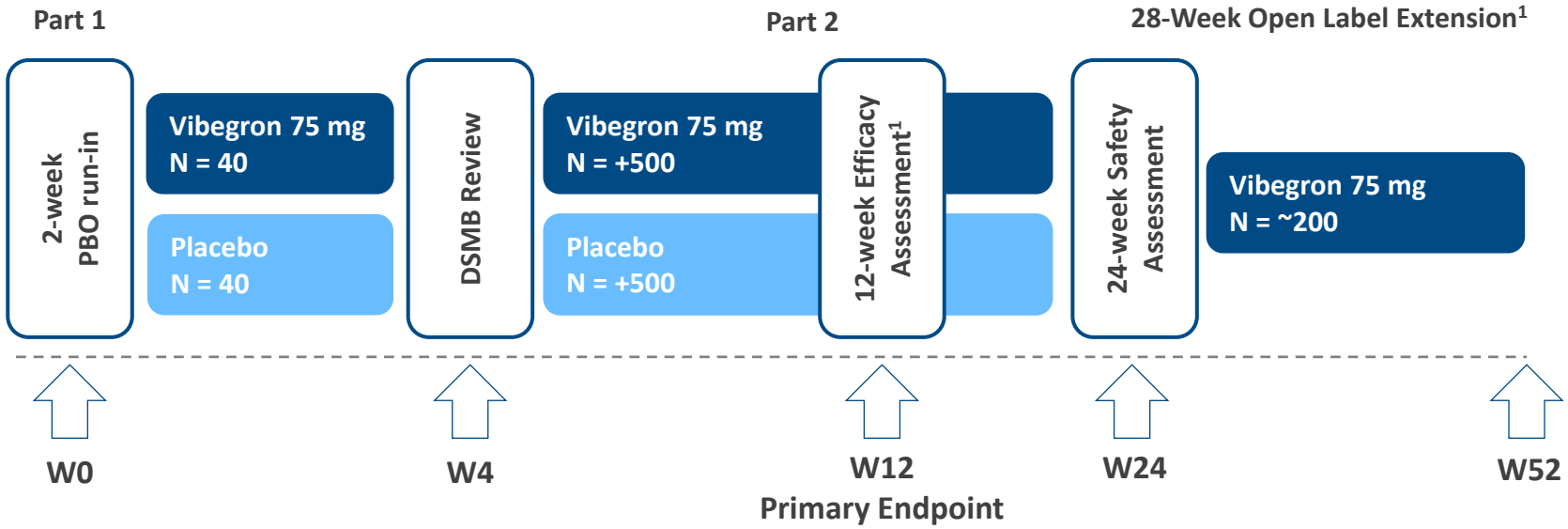
**> 2 million**
U.S. BPH patients with co-morbid OAB

**POPULATION**
- Men with OAB and BPH

**DURATION**
- 12-week primary efficacy treatment period; 24-week efficacy and safety period plus 6-month extension

**KEY ENDPOINTS**
- **Co-primary endpoints:** Change from baseline in daily micturitions (urination) and urgency
- **Key secondary endpoint:** Nocturia (excessive nighttime urination)

**Initiated March 2019; P3 Top Line Data 2H 2021**




OAB+BPH 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: URO-901-2001 Phase 2a

## IBS-Associated Pain

**30-40 million**
Patients with IBS

**9-10 million**
Patients consult with MD

**> 7-9 million**
Addressable U.S. Patient market

**POPULATION**

- Women with IBS with predominantly diarrhea (IBS-D) or mixed episodes of diarrhea and constipation (IBS-M)

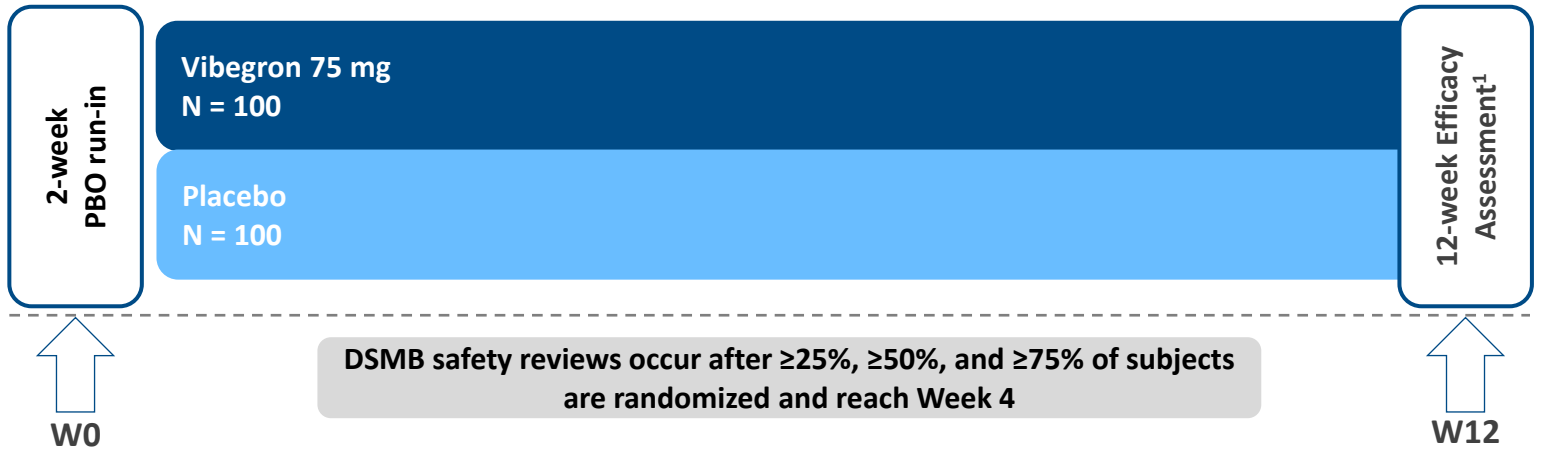
**DURATION**

- 12-week primary efficacy treatment period; total observation period 14 weeks (includes 2-week safety follow-up)

**KEY ENDPOINTS**

- **Primary endpoint:** Proportion achieving ≥30% decrease in worst abdominal pain compared to the weekly baseline average
- **Key secondary endpoints**: Global improvement scale, safety, and a lack of negative effects of stool frequency or consistency

**Initiated December 2018; P2 Top Line Data November 2020**




IBS-Associated pain population based upon: 1. IQVIA (IMS) NSP 12-month braded sales ending December 2018; 2. Cellek 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.
1. Numbers of patients reflect planned enrollment

# Gene Therapy Overview: URO-902

## Market Overview

- Third-line OAB treatments (e.g. BOTOX and neuromodulation) generate >$700M in US annually[1]
- 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 (24,000µg)

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

# Urovant Sciences Milestones

**2019**

- ✓ *Top-line results of the Phase 3 vibegron trial in OAB (March)*
- ✓ *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*
- ✓ *Preparing for the successful launch of vibegron*
- ✓ *Further build out commercial leadership team*
- ☐ *Top-line results of vibegron trial in IBS-associated pain, November 2020*
- ☐ *URO-902 Phase 2a cohort 1 DSMB meeting December 2020 / early 2021*
- ☐ *PDUFA for vibegron in OAB*

**2021**

- ☐ *Potential 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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