

## **Mallinckrodt** Pharmaceuticals

Investor Briefing 2017 Presentation  
H.P. Acthar<sup>®</sup> Gel (repository corticotropin injection)

Hugh O'Neill  
EVP and President, Autoimmune and Rare Diseases

October 4, 2017



# Stewardship of H.P. Acthar<sup>®</sup> Gel (repository corticotropin injection) has evolved under Mallinckrodt

Present



Future

Clinical and HEOR<sup>1</sup> data emerging from multiple sources

Ongoing release of clinical and HEOR data

Integrated medical plans changing scientific dialogue

Engaged, supportive KOLs<sup>2</sup>

Solidified regulatory approach

Updated regulatory and clinical package

Strategic long-term investments

Brand modernization

Strong clinical-selling emphasis, discipline

Demand driven by strong clinical value

Proactive payer engagement

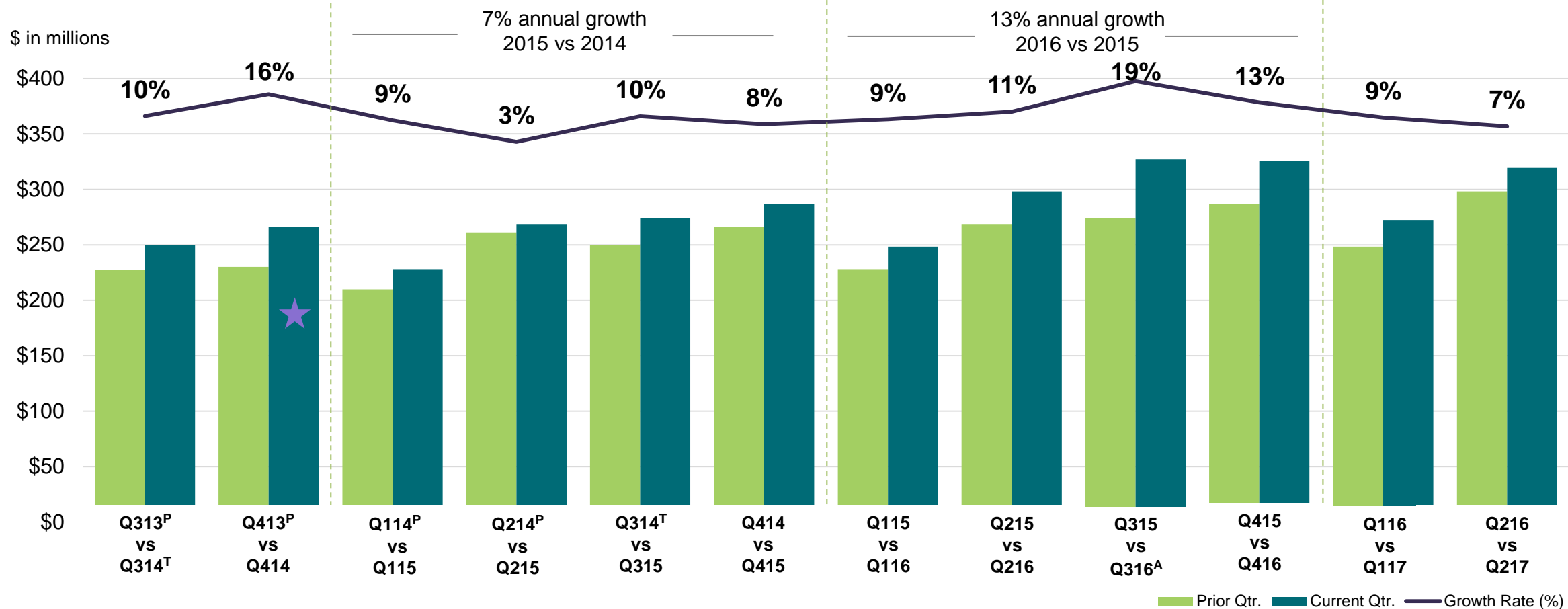
Further stabilization through long-term payer partnerships, focused on access for appropriate patients

Improved patient services model

Seamless patient services model

<sup>1</sup> Health Economics and Outcomes Research  
<sup>2</sup> Key opinion leaders

# H.P. Acthar Gel net sales growth



<sup>A</sup> – Includes an additional selling week due to our 52-53 week fiscal year accounting convention

<sup>T</sup> - Represents period of partial Mallinckrodt ownership, with acquisition of H.P. Acthar Gel on August 14, 2014

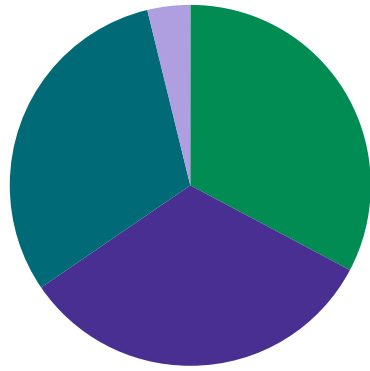
<sup>P</sup> - Proforma amounts utilized for quarters prior to acquisition

★ Represents first full quarter under Mallinckrodt's ownership

Growth rates calculated on an operational basis; excludes foreign currency impact (no Fx impact for H.P. Acthar Gel)

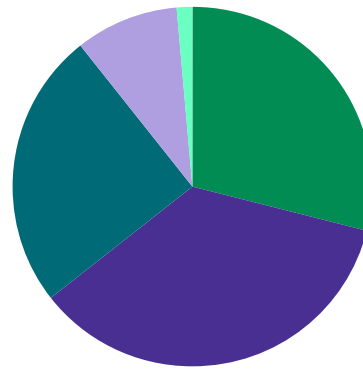
# H.P. Acthar Gel therapeutic area mix has shifted toward rheumatology and pulmonology

2014 Net Sales by TA



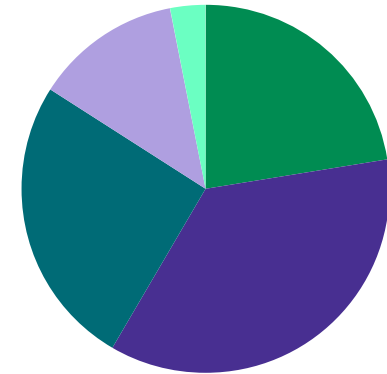
■ Neurology ■ Rheumatology ■ Nephrology ■ Other

2015 Net Sales by TA



■ Neurology ■ Rheumatology ■ Nephrology  
■ Pulmonology ■ Other

2016 Net Sales by TA

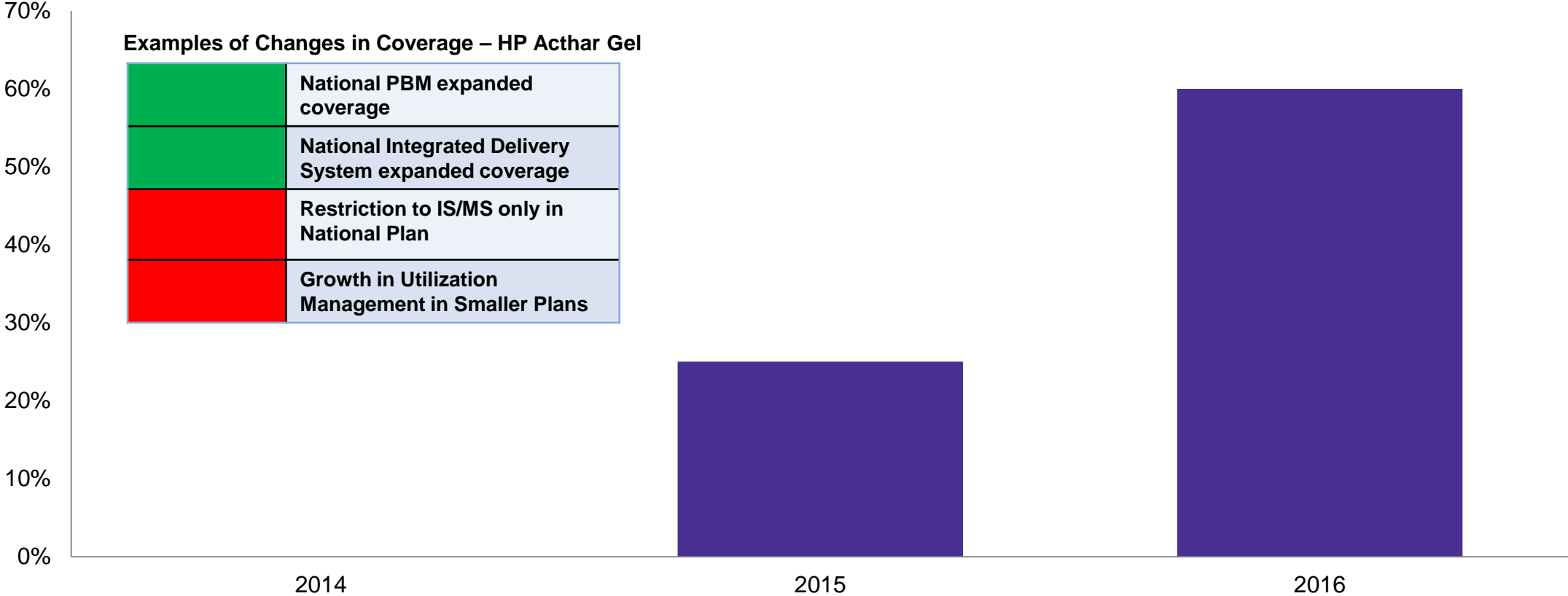


■ Neurology ■ Rheumatology ■ Nephrology  
■ Pulmonology ■ Other

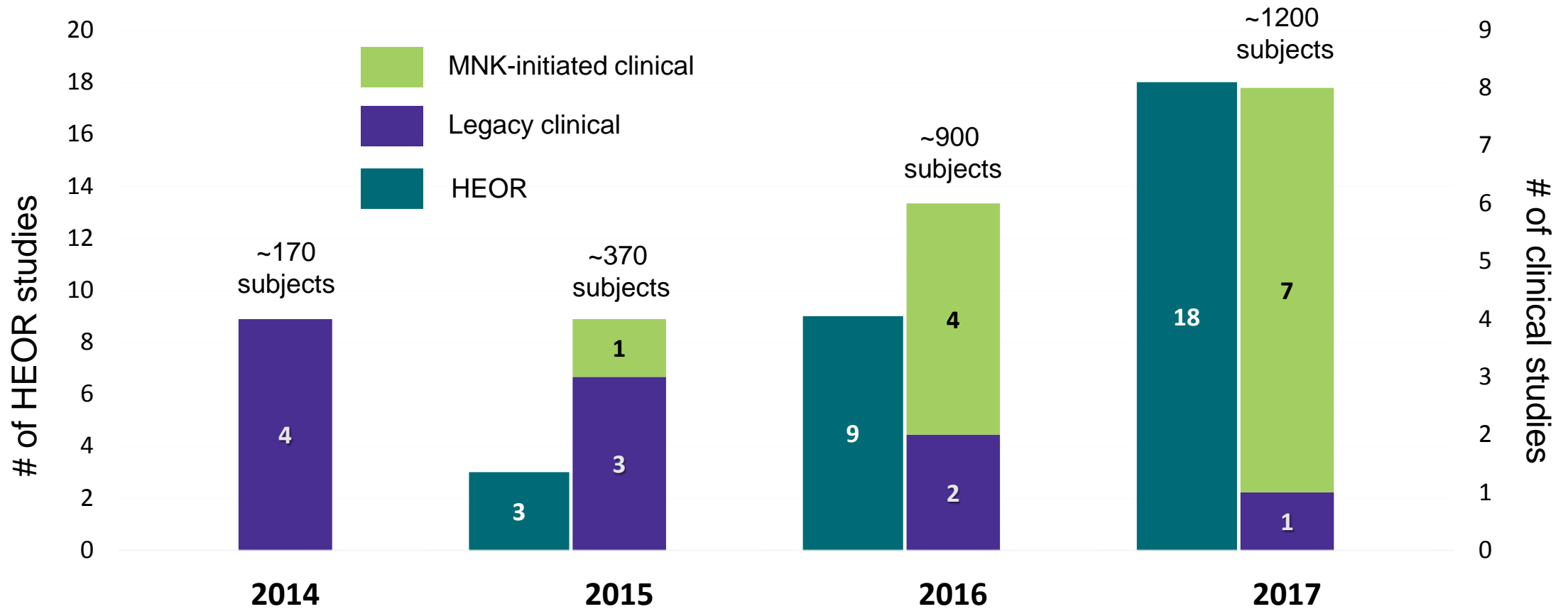
- Full launch of Pulmonology indication (sarcoidosis)
- Expansion of Rheumatology promotion (rheumatoid arthritis)
- Decrease in Multiple Sclerosis indication reliance
- Return to Nephrology growth
- Launch of Ophthalmology indications

# Payer engagement driven by evidence generation and patient focus

## % Commercial Lives Under Contract



# Data generation/dissemination have increased dramatically

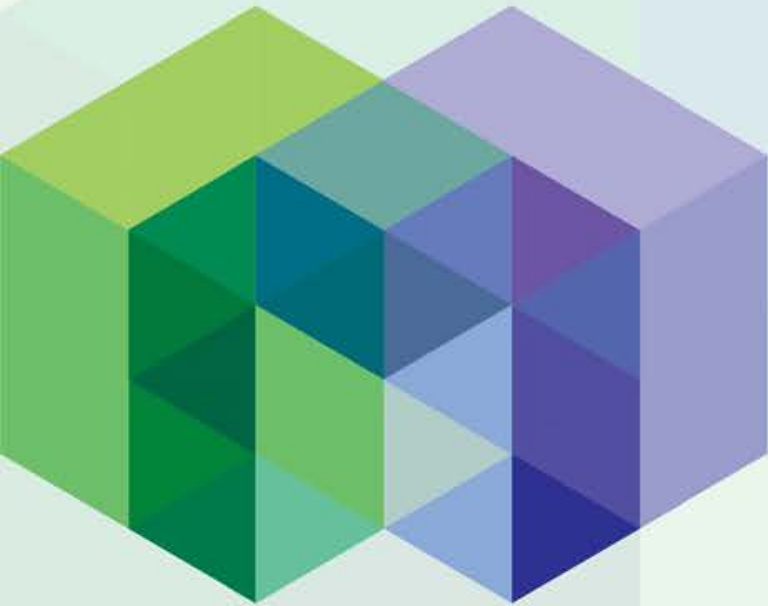


- >110 abstracts and manuscripts published since acquisition
- >40 Investigator-initiated research programs funded by Mallinckrodt

**Mallinckrodt has invested >\$250 million  
in H.P. Acthar Gel since acquisition...**

**...and believes H.P. Acthar Gel  
can fill substantial, unmet medical  
need in significantly underserved  
patient populations.**





**Mallinckrodt Pharmaceuticals**  
H.P. Acthar<sup>®</sup> Gel (repository corticotropin injection)  
Physician Panel

*Participants:*

Raj Ayinla, M.D.  
Amit Govil, M.D.

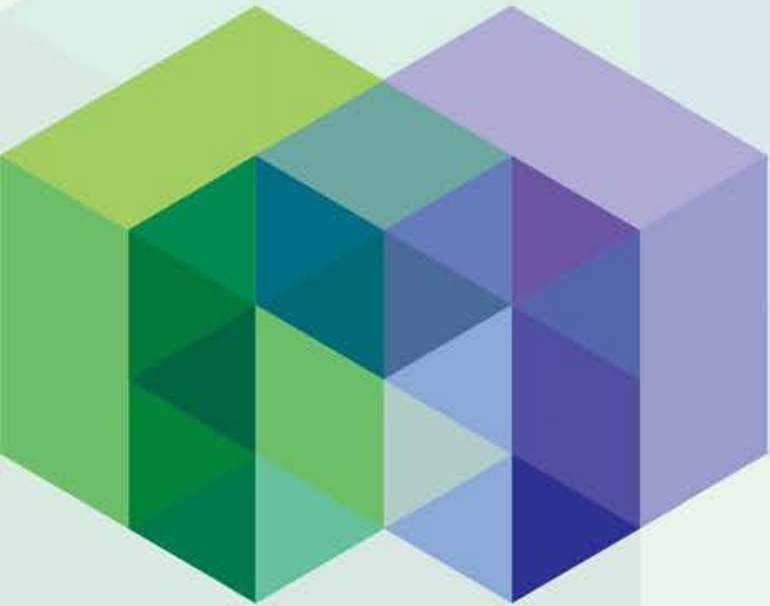
*Moderator:*

Steve Romano, M.D.  
EVP & Chief Scientific Officer

October 4, 2017







## **Mallinckrodt Pharmaceuticals**

Patient Experience

H.P. Acthar<sup>®</sup> Gel (repository corticotropin injection)

October 4, 2017

# H.P. Acthar Gel (repository corticotropin injection) Nephrology Indication and Important Safety Information

## U.S. FOOD AND DRUG ADMINISTRATION-APPROVED NEPHROLOGY INDICATION FOR USE

- ▶ Acthar is a prescription medicine for the reduction of proteinuria in people with nephrotic syndrome of the idiopathic type (unknown origin) without uremia (accumulation of urea in the blood due to malfunctioning kidneys) or that due to lupus erythematosus (lupus).
- ▶ Acthar is injected beneath the skin or into the muscle.

## IMPORTANT SAFETY INFORMATION

- ▶ You should NOT take Acthar before talking to your doctor if you have any of these conditions: **A skin condition called scleroderma, bone density loss, any infections, herpes simplex of the eye, had recent surgery, stomach ulcers or history of stomach ulcers, heart failure, uncontrolled high blood pressure, have been given, or are about to receive, a live or live attenuated vaccine, or have allergies to pig-derived protein. Tell your doctor if you are pregnant or plan on becoming pregnant.**
- ▶ Acthar is injected beneath the skin or into the muscle. It should never be injected into a vein.
- ▶ Acthar can cause side effects similar to those with steroid treatments. It can cause adrenal gland changes which may cause symptoms of Cushing's syndrome.

# H.P. Acthar Gel (repository corticotropin injection) Nephrology

## Indication and Important Safety Information (continued)

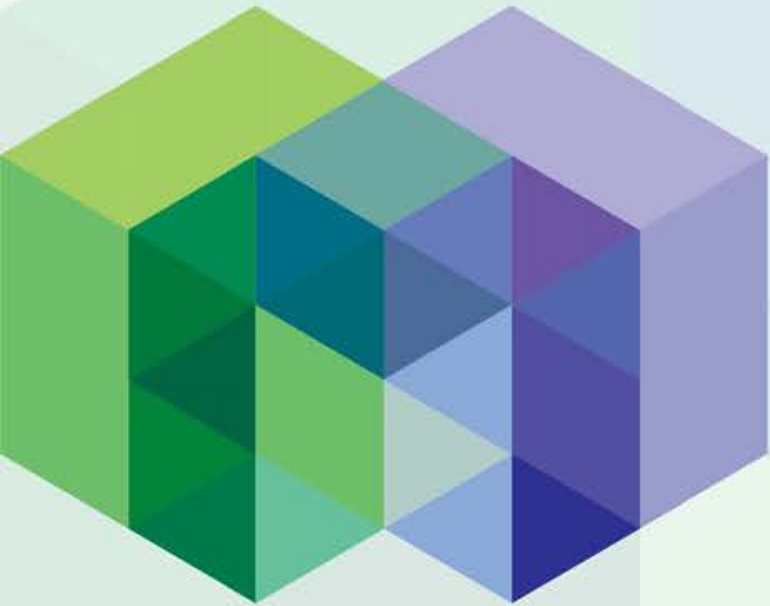
### IMPORTANT SAFETY INFORMATION (continued)

- ▶ **People on steroids or with Cushing's syndrome may experience: increased risk of infections; an increase in upper body fat, rounded "moon" face, bruising easily, or muscle weakness; increased blood pressure, body salt, and fluid; unpredictable response to vaccines; stomach or intestinal problems; changes in mood or behavior; worsening of other medical conditions; eye problems; or allergic reactions. Tell your doctor if you experience any of the above symptoms. Also tell your doctor about any other health problems you have and about all medicines you are taking.**
- ▶ **Taking Acthar may mask symptoms of other diseases and may cause bone density loss at any age.**
- ▶ **The most common side effects include: Fluid retention, changes in blood sugar, increased blood pressure, behavior and mood changes, and changes in appetite and weight.**
- ▶ **Specific side effects in children under 2 years of age include: Increased risk of infections, increased blood pressure, irritability, symptoms of Cushing's syndrome, cardiac hypertrophy (thickening of the heart muscle) and weight gain.**
- ▶ **The above side effects may also be seen in adults and children over 2 years of age.**
- ▶ **These are not all of the possible side effects of Acthar.**

# H.P. Acthar Gel (repository corticotropin injection) Nephrology Indication and Important Safety Information (continued)

## IMPORTANT SAFETY INFORMATION (continued)

- ▶ Tell your doctor about any side effect that bothers you, or that does not go away. Call your doctor or pharmacist for medical advice about side effects. You may report side effects to the FDA. Call 1.800.FDA.1088 or visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch). You may also report side effects by calling 1.800.778.7898.
- ▶ Please see accompanying full [Prescribing Information](#) or visit [www.acthar.com/pdf/Acthar-PI.pdf](http://www.acthar.com/pdf/Acthar-PI.pdf) for additional [Important Safety Information](#).



## **Mallinckrodt Pharmaceuticals**

Patient Experience

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# Thank You

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