Case Review:
Management of a Patient With Acromegaly

INDICATION AND USAGE
Sandostatin® LAR Depot (octreotide acetate for injectable suspension) is indicated for long-term maintenance therapy in acromegalic patients who have had inadequate response to surgery and/or radiotherapy or for whom surgery and/or radiotherapy is not an option in patients in whom initial treatment with immediate release Sandostatin® (octreotide acetate) Injection has been shown to be effective and tolerated. The goal of treatment in acromegaly is to reduce GH and IGF-1 levels to normal.

HIGHLIGHTS OF IMPORTANT SAFETY INFORMATION
• Treatment with Sandostatin LAR Depot may affect gallbladder function, glucose metabolism, thyroid and cardiac function, and nutritional absorption. Periodic monitoring is recommended.

Please see additional Important Safety Information on slides 17 and 18.
Please see full Prescribing Information.
Objectives

• Review symptoms of acromegaly and tests used for diagnosis
• Recognize the role of Sandostatin® LAR Depot (octreotide acetate for injectable suspension) as one available treatment option
• Know the treatment course
• Follow the case of a patient with acromegaly from diagnosis through treatment with Sandostatin LAR Depot

Note: Studies conducted with Sandostatin LAR Depot evaluated the effects on growth hormone (GH) and insulin-like growth factor 1 (IGF-1) levels, but not on the symptoms of acromegaly.

Please see the Indication on slide 16 and Important Safety Information on slides 17 and 18.
Case Study Representative of Uncontrolled Acromegaly: Celia

Initial Presentation

- Female, 44 years of age
- Began to experience pain in joints during exercise
- Reports that she has headaches and feels fatigued
- After she noticed her hands and feet growing, Celia made appointment with her doctor

Reference
Case Study: Diagnostic Investigations for Celia

• The diagnosis of acromegaly depends on clinical and laboratory findings
• GH and IGF-1 testing and pituitary magnetic resonance imaging (MRI) are complementary tools to assist physicians in making a diagnosis
• Celia undergoes:
  – Laboratory testing for elevations in GH and IGF-1
  – MRI to confirm presence of pituitary adenoma
  – Visual field testing to assess possible optic chiasmal compression
  – Evaluation for hyperprolactinemia, hypopituitarism, and diabetes
• Celia is eager to finally get an accurate diagnosis

Reference
Case Study: Diagnosing Celia

Laboratory results confirm acromegaly¹
- IGF-1 710 ng/mL (reference range: 37-266 ng/mL)
- GH 9.5 ng/mL by oral glucose tolerance test [OGTT] (GH <1 ng/mL is considered normal)²

Imaging results²
- MRI revealed a large sellar mass with extension into the optic chiasm and invasion of the left cavernous sinus

Further evaluations²
- Her visual field examination revealed vision field defect (ie, quadrantanopsia)
- Serum prolactin 35 ng/mL
- Pituitary assessment revealed hypopituitarism

References

Please see Important Safety Information on slides 17 and 18.
Please see full Prescribing Information.
Treatment Recommendations for Celia

Surgery followed by medical therapy

- Surgical removal of tumor
- Medical therapy with Sandostatin® LAR Depot

Reference
Case Study: Treating Celia

- Celia underwent endonasal transsphenoidal resection of the tumor
- Surgery is recommended as the primary treatment for all patients with microadenomas and for all patients who have macroadenomas with associated mass effects

Reference
Case Study: Treating Celia (cont)

Postoperative results: persistent symptoms
- Reports persistent headaches, sweating, arthralgias, and fatigue, particularly in the morning
  - Sandostatin LAR® Depot is approved for the control of GH and IGF-1
- OGTT and laboratory assays reveal elevated GH (1.4 ng/mL) and IGF-1 (480 ng/mL; reference range 37-266 ng/mL)
- MRI scan reveals an unresectable residual tumor in the left cavernous sinus
- Visual fields are normal

Reference

Please see Important Safety Information on slides 17 and 18. Please see full Prescribing Information.
Treatment With Sandostatin LAR® Depot

- Celia’s physician prescribes subcutaneous Sandostatin® (octreotide acetate) Immediate-release Injection for 2 weeks followed by Sandostatin LAR® Depot (octreotide acetate for injectable suspension)
  - 20 mg intramuscularly (IM) intragluteally every 4 weeks

**INDICATION**
Sandostatin® LAR Depot (octreotide acetate for injectable suspension) is indicated for long-term maintenance therapy in acromegalic patients who have had inadequate response to surgery and/or radiotherapy or for whom surgery and/or radiotherapy is not an option in patients in whom initial treatment with immediate release Sandostatin® (octreotide acetate) Injection has been shown to be effective and tolerated. The goal of treatment in acromegaly is to reduce GH and IGF-1 levels to normal.

Reference
Sandostatin LAR Depot [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corp; 2011.

Please see Important Safety Information on slides 17 and 18. Please see full Prescribing Information.
Highlights of Important Safety Information

- **Warnings and Precautions**: Treatment with Sandostatin® LAR Depot may affect gallbladder function, glucose metabolism, thyroid and cardiac function, and nutritional absorption (periodic monitoring is recommended). Cardiac function: use with caution in at-risk patients.

- **Drug Interactions**: The following drugs require monitoring and possible dose adjustment when used with Sandostatin LAR Depot: cyclosporine, insulin, oral hypoglycemic agents, beta-blockers, and bromocriptine.

- **Adverse Reactions**: The most common adverse reactions occurring in ≥20% of patients are: diarrhea, cholelithiasis, abdominal pain, and flatulence.

Reference
Sandostatin LAR Depot [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corp; 2011.

Please see Important Safety Information on slides 17 and 18.
Please see full Prescribing Information.
Case Study: Side Effects of Treatment

Celia experiences mild to moderate side effects, primarily during the first month of treatment with Sandostatin® LAR Depot.

<table>
<thead>
<tr>
<th>Diarrhea</th>
<th>Abdominal pain</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nausea</td>
<td></td>
</tr>
</tbody>
</table>

Reference
Sandostatin LAR Depot [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corp; 2011.

Please see Important Safety Information on slides 17 and 18. Please see full Prescribing Information.
Case Study: Follow-up for Treatment

Celia is on a stable dose of Sandostatin® LAR Depot to keep her GH and IGF-1 levels controlled.

She is monitored for:

<table>
<thead>
<tr>
<th>GH and IGF-1</th>
<th>Vitamin B&lt;sub&gt;12&lt;/sub&gt; levels</th>
<th>Thyroid function</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gallbladder abnormalities</td>
<td>Cardiac function</td>
<td>Blood glucose levels</td>
</tr>
</tbody>
</table>

Reference
Sandostatin LAR Depot [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corp; 2011.

Please see Important Safety Information on slides 17 and 18.
Please see full Prescribing Information.
Case Study: Development of Gallstones

• Celia develops gallstones after being on Sandostatin® LAR Depot for 12 months

• Her gallstones are asymptomatic

• Sandostatin® LAR Depot is continued, but she is monitored with ultrasounds more frequently

Reference
Sandostatin LAR Depot [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corp; 2011.

Please see Important Safety Information on slides 17 and 18. Please see full Prescribing Information.
Case Study: Helping Celia Beyond Therapy

• Celia’s nurse cultivated an open nurse-patient relationship through active listening and consistent follow-up
• Celia’s nurse helped her understand the rarity of her condition and the importance of staying positive
• Celia was encouraged to identify with others by joining a local support group in the community or seeking online sources of support for patients with acromegaly
Summary

• Celia was diagnosed with acromegaly, underwent transsphenoidal surgery, and was further treated with Sandostatin® LAR Depot

• Patients with acromegaly can present with a variety of signs and symptoms

• The primary treatment strategy for acromegaly is surgical intervention, but medical therapy with Sandostatin® LAR Depot may be indicated for some patients

• Nurse interaction can help patients cope with and understand acromegaly
Sandostatin® LAR Depot Indication

Sandostatin® LAR Depot (octreotide acetate for injectable suspension) is indicated for patients in whom initial treatment with immediate release Sandostatin® (octreotide acetate) Injection has been shown to be effective and tolerated for:

• Long-term maintenance therapy in acromegalic patients who have had inadequate response to surgery and/or radiotherapy or for whom surgery and/or radiotherapy is not an option (the goal of treatment in acromegaly is to reduce GH and IGF-1 levels to normal).

Reference
Sandostatin LAR Depot [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corp; 2011.

Please see Important Safety Information on slides 17 and 18.
Please see full Prescribing Information.
Sandostatin® LAR Depot
Important Safety Information

**Warnings and Precautions:**

- Gallbladder abnormalities may occur: Patients should be monitored periodically.
- Glucose Metabolism: Hypoglycemia or hyperglycemia may occur. Blood glucose levels should be monitored when Sandostatin LAR Depot treatment is initiated or when the dose is altered. Antidiabetic treatment should be adjusted accordingly.
- Thyroid Function: Hypothyroidism may occur. Baseline and periodic assessment of thyroid function (TSH, total and/or free T4) is recommended.
- Cardiac Function: Bradycardia, arrhythmia, conduction abnormalities, and other EKG changes may occur. The relationship of these events to octreotide acetate is not established because many of these patients have underlying cardiac disease. Use with caution in at-risk patients.
- Nutrition: Octreotide may alter absorption of dietary fats. Monitoring of vitamin B₁₂ levels is recommended during therapy with Sandostatin LAR Depot. Patients on total parenteral nutrition (TPN) and octreotide should have periodic monitoring of zinc levels.

**Reference**

Sandostatin LAR Depot [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corp; 2011.

Please see additional Important Safety Information on slide 18.
Please see full Prescribing Information.
Important Safety Information (cont)

• **Drug Interactions:** The following drugs require monitoring and possible dose adjustment when used with Sandostatin LAR Depot: cyclosporine, insulin, oral hypoglycemic agents, beta-blockers, and bromocriptine. Octreotide has been associated with alterations in nutrient absorption, so it may have an effect on absorption of orally administered drugs. Drugs mainly metabolized by CYP3A4 and which have a low therapeutic index should be used with caution.

• **Adverse Reactions:** The most common adverse reactions occurring in patients receiving Sandostatin LAR Depot were biliary abnormalities (52%), diarrhea (36-48%), cholelithiasis (13-38%), abdominal pain or discomfort (11-29%), flatulence (26%), influenza-like symptoms (20%), constipation (19%), headache (15%), anemia (15%), hyperglycemia (15%), injection site pain (2-14%), hypertension (13%), dizziness (12%), fatigue (11%), nausea (10%), vomiting (7%), hypothyroidism (2%), hypoglycemia (2%), and goiter (2%).

Reference
Sandostatin LAR Depot [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corp; 2011.

Please see additional Important Safety Information on slide 17.
Please see full Prescribing Information.