## EXPANDED INDICATION

**Product availability expected in Q4 2025**

# NOW APPROVED FOR ADULTS WITH GHD

Once-weekly Skytrofa® lonapegsomatropin-tcgd

SKYTROFA® is an hGH indicated for the replacement of endogenous GH in adults with GHD[1]


For illustrative purposes only.

**Discover the features of the SKYTROFA Auto-Injector, designed with your patients in mind**

GH = growth hormone; GHD = growth hormone deficiency; hGH = human growth hormone.

### IMPORTANT SAFETY INFORMATION

### INDICATIONS AND USAGE

SKYTROFA® (lonapegsomatropin-tcgd) injection is a human growth hormone (GH) indicated for the:

- Treatment of pediatric patients aged 1 year and older who weigh at least 11.5 kg and have growth failure due to inadequate secretion of endogenous GH
- Replacement of endogenous GH in adults with growth hormone deficiency (GHD)

### CONTRAINDICATIONS

SKYTROFA is contraindicated in patients with:

- Acute critical illness after open heart surgery, abdominal surgery or multiple accidental trauma, or those with acute respiratory failure due to risk of increased mortality with use of somatropin
- Hypersensitivity to somatropin or any of the excipients in SKYTROFA
- Pediatric patients with closed epiphyses
- Active malignancy
- Active proliferative or severe non-proliferative diabetic retinopathy
- Pediatric patients with Prader-Willi syndrome who are severely obese, have a history of upper airway obstruction or sleep apnea, or have severe respiratory impairment due to the risk of sudden death

**Please see Important Safety Information throughout and click here for full Prescribing Information for SKYTROFA.**

## Key features

# SKYTROFA is the ONLY GH that offers your adult patients all of these features:

Once-weekly Skytrofa® lonapegsomatropin-tcgd

Predictable release of the same somatropin as that used in daily somatropin injections[2-4]*

Auto-injector designed to deliver the full dose and minimize the potential for wasted medication[1]

Room temperature storage for up to 6 months[1,3,4†]

A preservative-free formulation[1,3,4]

**Starting dose tailored by age and oral estrogen intake.**
It is recommended that adult patients start on one of the following weekly dosage strengths: 0.7 mg, 1.4 mg, or 2.1 mg.[1‡]

GH = growth hormone.

*SKYTROFA is a prodrug that releases active somatropin with the same molecular weight and amino acid sequence as endogenous GH.[1,2]

† SKYTROFA cartridges can be stored at 36°F to 46°F (2°C to 8°C) in the outer carton to protect from light until the expiration date. The SKYTROFA outer carton containing blistered cartridges may be stored at room temperature (up to 86°F [30°C]) for up to 6 months and can be returned to refrigeration within the 6 months. Do not use SKYTROFA beyond the expiration date or 6 months after the date it was first removed from refrigeration (whichever is earlier).[1]

‡ 0.7 mg once weekly for adults aged older than 60 years, with no oral estrogen intake; 1.4 mg once weekly for adults aged 30 to 60 years, with no oral estrogen intake; 2.1 mg once weekly for adults aged younger than 30 years or adults of any age intaking oral estrogen.[1]

### IMPORTANT SAFETY INFORMATION (continued)
### WARNINGS AND PRECAUTIONS

- **Increased Mortality in Patients with Acute Critical Illness:** Increased mortality has been reported after treatment with somatropin in patients with acute critical illness due to complications following open-heart surgery, abdominal surgery, multiple accidental trauma, and in patients with acute respiratory failure
- **Severe Hypersensitivity:** Serious systemic hypersensitivity reactions including anaphylaxis and angioedema have been reported with post-marketing use of somatropin products, including SKYTROFA. Inform patients and/or caregivers that such reactions are possible and that prompt medical attention should be sought if an allergic reaction occurs
- **Increased Risk of Neoplasms:** There is an increased risk of malignancy progression with somatropin treatment in patients with active malignancy. Any preexisting malignancy should be inactive, and its treatment complete prior to instituting SKYTROFA. In childhood cancer survivors treated with radiation to the brain/head for their first neoplasm who developed subsequent GHD and were treated with somatropin, an increased risk of a second neoplasm has been reported. Children with certain rare genetic causes of short stature have an increased risk of developing malignancies and should be carefully monitored for development of neoplasms. Monitor patients with a history of GHD secondary to an intracranial neoplasm for progression/recurrence of the tumor. Monitor patients carefully for development of neoplasms and/or increased growth/potential malignant changes of preexisting nevi. Advise patients/caregivers to report changes in the appearance of preexisting nevi
- **Glucose Intolerance and Diabetes Mellitus:** Treatment with somatropin may decrease insulin sensitivity, particularly at higher doses. Previously undiagnosed impaired glucose tolerance and overt type 2 diabetes mellitus may be unmasked. Monitor glucose levels in all patients, especially those with risk factors for type 2 diabetes mellitus, such as obesity or a family history of type 2 diabetes mellitus. When initiating SKYTROFA, monitor patients with preexisting type 1 or type 2 diabetes mellitus or impaired glucose tolerance closely, and adjust the doses of antihyperglycemic drugs as needed

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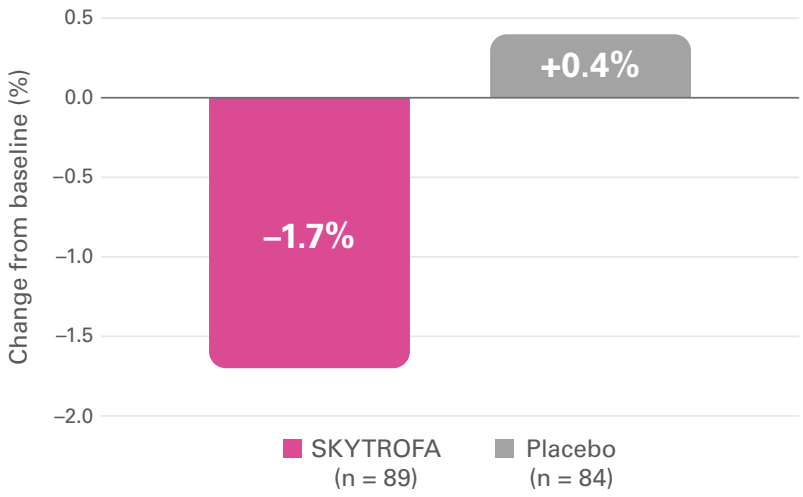
**In a trial of adults with GHD (N = 259), SKYTROFA resulted in:**

Pivotal foreSIGHt TRIAL

Once-weekly Skytrofa® lonapegsomatropin-tcgd

# Significant improvement in trunk percent fat compared with placebo[1]

## Primary endpoint: change from baseline in trunk percent fat at week 38[1]




Mean treatment difference was –2.0% (95% CI: –2.9 to –1.1; $P < 0.0001$)[1]

**Study design:** foresiGHt was a 38-week multicenter, randomized, parallel-group, placebo-controlled (double-blind), phase 3 study conducted in 259 adults with GHD. The study enrolled patients aged 23 to 81 years who were GH treatment-naïve or had not received GH treatment during the prior 12 months. Doses were titrated over 12 weeks to reach the target maintenance dose by subgroup based on age and oral estrogen intake, with a fixed maintenance dose for the remaining 26 weeks of treatment. The primary efficacy endpoint was change from baseline in trunk percent fat compared with placebo, as measured by DXA, at week 38.[1,5]

CI = confidence interval; DXA = dual-energy X-ray absorptiometry; GH = growth hormone; GHD = growth hormone deficiency.

**IMPORTANT SAFETY INFORMATION (continued)**
**WARNINGS AND PRECAUTIONS (continued)**

- **Intracranial Hypertension:** Intracranial hypertension (IH) with papilledema, visual changes, headache, nausea, and/or vomiting has been reported in a small number of patients treated with somatropin. Symptoms usually occurred within 8 weeks of the initiation of somatropin and resolved rapidly after cessation of therapy/reduction of the dose. Perform fundoscopic examination prior to initiation of treatment and periodically thereafter. If papilledema is observed, stop the treatment. If somatropin-induced IH is confirmed, restart SKYTROFA treatment at a lower dose after IH-associated signs and symptoms have resolved
- **Fluid Retention:** May occur during somatropin therapy. Clinical manifestations of fluid retention (eg, edema, arthralgia, myalgia, nerve compression syndromes including carpal tunnel syndrome/paresthesia) are usually transient and dose dependent
- **Hypoadrenalism:** Patients receiving somatropin therapy who have or are at risk for pituitary hormone deficiency(s) may be at risk for reduced serum cortisol levels and/or unmasking of central (secondary) hypoadrenalism. Patients treated with glucocorticoid replacement for previously diagnosed hypoadrenalism may require an increase in their maintenance/stress doses following initiation of SKYTROFA therapy. Monitor patients with known hypoadrenalism for reduced serum cortisol levels and/or need for glucocorticoid dose increases
- **Hypothyroidism:** Undiagnosed/untreated hypothyroidism may prevent an optimal response to SKYTROFA. Monitor thyroid function periodically as hypothyroidism may occur or worsen after initiation of SKYTROFA

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# Established safety profile

Once-weekly Skytrofa® lonapegsomatropin-tcgd

**AEs occurring in ≥ 5% of SKYTROFA-treated adults and more frequently than in placebo-treated adults (38 weeks of treatment)[1]**

| AEs | SKYTROFA (n = 89) n (%) | Placebo (n = 84) n (%) |
|---|---|---|
| Edema* | 7 (8%) | 1 (1%) |
| Central (secondary) hypothyroidism† | 6 (7%) | 1 (1%) |

AEs that are medically related were grouped to a single preferred term.

*Edema in the SKYTROFA treatment group included edema peripheral (6) and peripheral swelling (1).

†Central (secondary) hypothyroidism in the SKYTROFA treatment group included thyroxine free decreased (3), central hypothyroidism (2), thyroxine decreased (1), blood thyroid-stimulating hormone decreased (1), tri-iodothyronine free decreased (1). Preexisting central hypothyroidism in 5 of 6 SKYTROFA-treated patients.

- More SKYTROFA-treated patients shifted from normal or low baseline levels to elevated alkaline phosphatase levels at the end of the trial compared with the placebo group (14% versus 6%)[1]
- Low incidence of serious AEs in patients treated with SKYTROFA and placebo (4.5% and 1.2%, respectively)[5]

AE = adverse event.

**IMPORTANT SAFETY INFORMATION (continued)**

**WARNINGS AND PRECAUTIONS (continued)**

- **Slipped Capital Femoral Epiphysis in Pediatric Patients:** Slipped capital femoral epiphysis may occur more frequently in patients undergoing rapid growth and may lead to osteonecrosis. Evaluate pediatric patients receiving SKYTROFA with the onset of a limp or complaints of persistent hip or knee pain for slipped capital femoral epiphysis and osteonecrosis, and manage accordingly
- **Progression of Preexisting Scoliosis in Pediatric Patients:** Monitor patients with a history of scoliosis for disease progression
- **Pancreatitis:** Cases of pancreatitis have been reported in pediatric patients receiving somatropin. The risk may be greater in pediatric patients than in adults. Consider pancreatitis in patients with persistent severe abdominal pain
- **Lipoatrophy:** Lipoatrophy may result when somatropin is administered at the same site over a long period of time. Rotate injection sites to reduce this risk
- **Sudden Death in Pediatric Patients With Prader-Willi Syndrome:** There have been reports of fatalities after initiating therapy with somatropin in pediatric patients with Prader-Willi syndrome who had one or more of the following risk factors: severe obesity, history of upper airway obstruction or sleep apnea, or unidentified respiratory infection. Male patients with one or more of these factors may be at greater risk than female patients. SKYTROFA is not indicated for the treatment of pediatric patients who have growth failure due to genetically confirmed Prader-Willi syndrome
- **Laboratory Tests:** Serum levels of alkaline phosphatase and phosphate may increase after SKYTROFA therapy. Serum levels of parathyroid hormone may increase after somatropin treatment. If a patient is found to have abnormal laboratory tests, monitor as appropriate

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# Consider SKYTROFA for your adult patients with GHD

Once-weekly
**Skytrofa®**
lonapegsomatropin-tcgd

The SKYTROFA Auto-Injector is designed with your patients' needs in mind[1,6]

- No dose dialing
- No split doses
- No exposed needle during injections


For illustrative purposes only.

Be the first to know when SKYTROFA is available for your adult patients with GHD

**SCAN BELOW TO CONNECT WITH US**

GHD = growth hormone deficiency.

**IMPORTANT SAFETY INFORMATION (continued)**

**ADVERSE REACTIONS**

- Pediatric patients with GHD: the most common adverse reactions (≥ 5%) in patients treated with SKYTROFA and more frequently than in those treated with daily somatropin were viral infection, pyrexia, cough, nausea and vomiting, hemorrhage, diarrhea, abdominal pain, and arthralgia and arthritis
- Adult patients with GHD: the most common adverse reaction (≥ 5%) in patients treated with SKYTROFA and more frequently than in those treated with placebo were edema and central (secondary) hypothyroidism

**DRUG INTERACTIONS**

- **Glucocorticoids:** Patients treated with glucocorticoid replacement for hypoadrenalism may require an increase in their maintenance or stress doses following initiation of SKYTROFA
- **Pharmacologic Glucocorticoid Therapy and Supraphysiologic Glucocorticoid Treatment:** Adjust glucocorticoid dosing in pediatric patients to avoid both hypoadrenalism and an inhibitory effect on growth
- **Cytochrome P450-Metabolized Drugs:** SKYTROFA may alter the clearance. Monitor carefully if used with SKYTROFA
- **Oral Estrogen:** Patients receiving oral estrogen replacement may require higher SKYTROFA dosages
- **Insulin and/or Other Antihyperglycemic Agents:** Dose adjustment of insulin and/or antihyperglycemic agent may be required for patients with diabetes mellitus

**You are encouraged to report side effects to FDA at (800) FDA-1088 or www.fda.gov/medwatch. You may also report side effects to Ascendis Pharma at 1-844-442-7236.**

**Please see Important Safety Information throughout and click here for full Prescribing Information for SKYTROFA.**

**References: 1.** SKYTROFA. Prescribing information. Ascendis Pharma, Inc.; 2025. **2.** Thornton PS, Maniatis AK, Aghajanova E, et al. Weekly lonapegsomatropin in treatment-naïve children with growth hormone deficiency: the phase 3 heiGHt trial. *J Clin Endocrinol Metab.* 2021;106(11):3184-3195. doi:10.1210/clinem/dgab529 **3.** SOGROYA. Prescribing information. Novo Nordisk Inc.; 2025. **4.** NGENLA. Prescribing information. Pfizer Inc.; 2023. **5.** Gilis-Januszewska A, Biller BMK, Doknic M, et al. Results of the foresiGHt trial support the efficacy and safety of once-weekly lonapegsomatropin in adults with growth hormone deficiency (GHD). Abstract/poster presented at: Joint Congress of European Society for Paediatric Endocrinology and European Society of Endocrinology; May 10-13, 2025; Copenhagen, Denmark. **6.** SKYTROFA. Instructions for use. Ascendis Pharma, Inc.; 2025.

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