YUVIWEL® (navepegritide) FDA Approval

Ascendis Pharma A/S
March 2, 2026

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YUVIWEL® Now FDA-Approved

- The first and only FDA-approved once-weekly therapy for children with achondroplasia[1]
- The only therapy to provide continuous systemic exposure to CNP over the weekly dosing interval
- FDA approval based on three randomized, double-blind, placebo-controlled clinical trials, including the pivotal ApproaCH Trial results[2]
- Granted Rare Pediatric Disease Priority Review Voucher (PRV), which confers priority review to a subsequent drug application that would not otherwise qualify for priority review

Third TransCon® product in a row to receive FDA approval

1. YUVIWEL [package insert]. Princeton, NJ: Ascendis Pharma Growth Disorders A/S. February 2026. FDA granted approval under the FDA's Accelerated Approval Program. Continued approval for this indication, which was based on an improvement in annualized growth velocity (AGV), may be contingent upon verification and description of clinical benefit in confirmatory trial(s).
2. Savarirayan R, McDonnell C, Bacino CA, et al. *JAMA Pediatr* 2026;180(1):18–25. Published online November 17, 2025. doi:10.1001/jamapediatrics.2025.4771.

Select Highlights of U.S. Prescribing Information

INDICATIONS	• YUVIWEL is indicated to increase linear growth in pediatric patients 2 years of age and older with achondroplasia with open epiphyses.
DOSAGE & ADMINISTRATION	• YUVIWEL should be administered subcutaneously once-weekly based on body weight. • Refer to the Full Prescribing Information for complete dosage and administration information.
SAFETY	**Contraindications** • None. **Warnings and Precautions** • Risk of low blood pressure: Transient decreases in blood pressure have been reported with a once-daily CNP analog. • Patients are advised to contact healthcare provider if they experience symptoms of decreased blood pressure while being treated with YUVIWEL. **Adverse Reactions occurring in (≥5%) of patients** • Vomiting, injection-site reaction, pain in extremity, and nausea.

YUVIWEL [package insert]. Princeton, NJ: Ascendis Pharma Growth Disorders A/S. February 2026.

Key Label Takeaways

- Indicated to increase linear growth in pediatric patients 2 years of age and older with achondroplasia with open epiphyses
- Primary endpoint of LS mean treatment difference between YUVIWEL and placebo was estimated from an analysis of covariance (ANCOVA) model[1]
  - AGV of 1.5 cm/year[2] at week 52 for YUVIWEL vs placebo in all children
  - AGV of 1.8 cm/year[2] at week 52 for YUVIWEL vs placebo in children aged ≥5 years
  - AGV was maintained among those who had received 2 years of treatment with YUVIWEL[3]
- Once-weekly dosing results in continuous systemic exposure of CNP over the dosing interval[4]
- Low incidence of injection-site reactions at 0.4 events/child/year observed for YUVIWEL
- Switch guidance: Start once-weekly YUVIWEL on the day after completing the last dose of daily CNP therapy
- No food or fluid intake required when administering YUVIWEL

1. Included treatment, strata (defined by sex and age), baseline age, and baseline achondroplasia-specific height Z-score as covariates. Results from clinical trial of navepegritide consisting of a randomized, double-blind, placebo-controlled 52-week period, followed by a single-arm 52-week OLE period (Trial 1; NCT05598320).
2. Least-squares mean difference in annualized growth velocity.
3. Results from 52-week randomized, double-blind, placebo-controlled Phase 2 dose-finding trial (Trial 2; NCT04085523) where all 57 patients entered the single-arm OLE and continued treatment with navepegritide.
4. Mean apparent elimination half-life of released CNP was 5.3 days.
YUVIWEL [package insert]. Princeton, NJ: Ascendis Pharma Growth Disorders A/S. February 2026.

Validated Algorithm with TransCon Technology: Three Consecutive U.S. FDA Approved Products

Growth Hormone Deficiency[1]
TransCon hGH

Skytrofa® lonapegsomatropin-tcgd

United States[2]
SKYTROFA (lonapegsomatropin-tcgd)
Approved for pediatric and adult GHD

European Union[3] **& Select Other Countries**[4]
SKYTROFA (lonapegsomatropin)
Approved for pediatric GHD

Hypoparathyroidism[5]
TransCon PTH

Yorvipath® palopegteriparatide

United States[6]
YORVIPATH (palopegteriparatide)
Approved for adults with hypopara

European Union[7] **& Select Other Countries**[8]
YORVIPATH (palopegteriparatide)
Approved for adults with chronic hypopara

Achondroplasia[9]
TransCon CNP

ONCE-WEEKLY yuviwel® navepegritide

United States[9]
YUVIWEL (navepegritide)
Approved for children 2 years of age and older with ACH

European Union
MAA validated and under CHMP review

1. SKYTROFA-APPROVED-US-PI_25-SEPT-2025.pdf.
2. SKYTROFA-APPROVED-US-PI_25-SEPT-2025.pdf.
3. SKYTROFA SmPC. Hellerup, Denmark: Ascendis Pharma Endocrinology Division A/S. October 2023.
4. SKYTROFA is also approved in Norway, Iceland, Liechtenstein and Great Britain (covering England, Wales, Scotland).
5. In the U.S., YORVIPATH is indicated for the treatment of hypoparathyroidism in adults. In the EU, the therapeutic indication for YORVIPATH is a parathyroid hormone (PTH) replacement therapy indicated for the treatment of adults with chronic hypoparathyroidism.
6. YORVIPATH [package insert]. Princeton, NJ: Ascendis Pharma Endocrinology, Inc. August 2024.
7. YORVIPATH SmPC. Hellerup, Denmark: Ascendis Pharma Bone Diseases A/S. November 2023.
8. YORVIPATH is also approved in Norway, Iceland and Great Britain (covering England, Wales, Scotland).
9. YUVIWEL [package insert]. Princeton, NJ: Ascendis Pharma Growth Disorders A/S. February 2026.

Vision 2030

Achieve blockbuster status for multiple products and expand our engine for future innovation

Be the Leading Endocrinology Rare Disease Company

- Achieve >€5B for TransCon PTH, TransCon hGH, and TransCon CNP through worldwide commercialization
- Be the leader in Growth Disorders and Hypoparathyroidism, pursuing clinical conditions, innovative LCM, and complementary patient offerings
- Expand pipeline with Endocrinology Rare Disease blockbuster product opportunities

Create Value in Additional Therapeutic Areas through Innovative Business Models

- Obtain accelerated approval in Oncology with registrational trials ongoing
- Pursue TransCon product opportunities in >€5B indications
- Maximize value creation of these product opportunities through collaboration with therapeutic area market leaders

Differentiate with Ascendis Fundamentals

- Outperform industry drug development benchmarks with Ascendis' product innovation algorithm
- Remain independent as a profitable biopharma through lean and flexible ways of working
- Let our values Patients, Science, Passion drive our decisions to success

Ascendis Pharma's 2025 - 2030 strategic roadmap

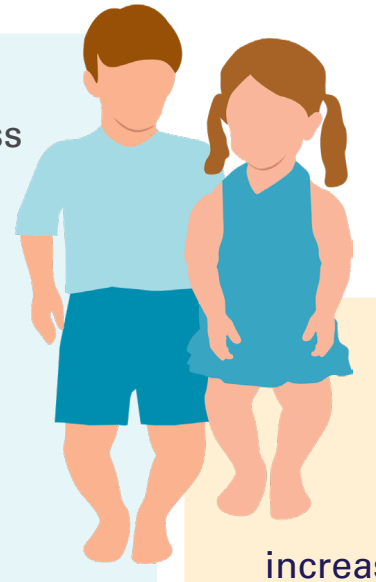
Achondroplasia

A rare condition with unmet medical needs

Medical Complications Over a Lifespan

Medical complications of achondroplasia vary and may include spinal cord compression, sleep disorders, otitis media, hearing loss, abnormal curvature of the spine, spinal stenosis (narrowing), and more.[1-7]

- Leg bowing
- Otitis media
- Hearing loss
- Spinal abnormalities
- Spinal stenosis
- Obesity
- Skeletal dysplasia
- Enlargement of specific brain structures
- Limited elbow extension
- Low muscle tone with weakness
- Impaired muscle strength and stamina
- Upper airway obstruction
- Sleep-disordered breathing
- Restricted hip mobility
- Speech delay
- Misalignment of teeth



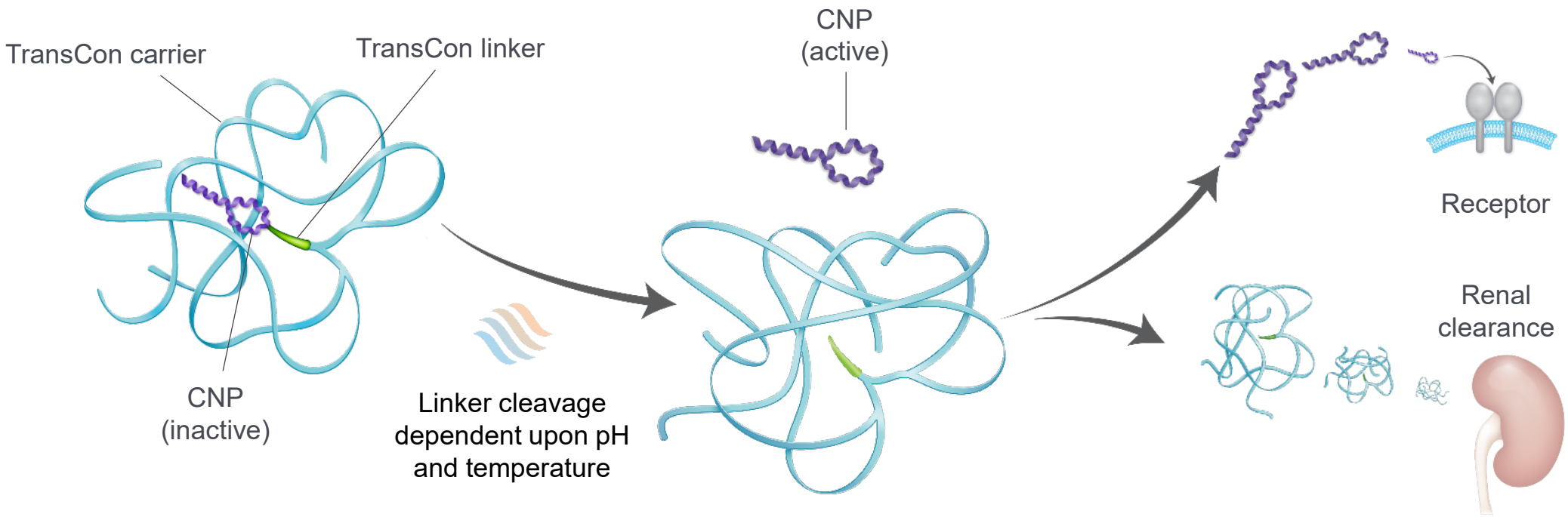
Major treatment goals are to decrease the incidence and severity of achondroplasia-related medical complications, increase height, promote proportional growth, and improve quality of life.[8,9]

1. Ireland PJ, et al. Appl Clin Genet 2014; 7: 117-25. 2. Horton WA, et al. Lancet 2007; 370(9582): 162-72. 3. Sims DT, et al. J Appl Physiol 2018; 124(3): 696-703. 4. de Vries OM, et al. Am J Med Genet A 2021;185(4): 1023-32. 5. Pauli RM. Orphanet J Rare Dis 2019;14(1):1. 6. Dhiman N, et al. Qual Life Res 2017; 26(5): 1337-48. 7. Savarirayan R, et al. Nat Rev Endocrinol 2022; 18(3): 173-89. 8. McGraw SA, et al. Adv Ther 2022; 39(7): 3378-91 9. U.S. FDA. Minutes of a Joint Meeting of the Pediatric Advisory Committee and the Endocrinologic and Metabolic Drugs Advisory Committee. 2018. https://www.fda.gov/media/114640/download.

YUVIWEL

Introducing a new once-weekly treatment option

YUVIWEL Design



YUVIWEL is a prodrug of CNP, administered once weekly and designed to provide continuous exposure to active CNP to tissues throughout the body

Breinholt VM et al. J Pharmacol Exp Ther. 2019;370(3):459-471.

Efficacy at Week 52 in Children with Achondroplasia

Primary endpoint of LS mean treatment difference in AGV between YUVIWEL and placebo was estimated from an analysis of covariance (ANCOVA) model[1]

	YUVIWEL (n = 57)	Placebo (n = 27)	Treatment Difference [95% CI][2]	p-value
Annualized growth velocity (cm/year), All children	5.9	4.4	1.5 [1.0,1.9]	<0.0001
Annualized growth velocity (cm/year), ≥5 years old			1.8	
Change from baseline				
Achondroplasia-specific height Z-score	0.3	0.0	0.3 [0.2, 0.4]	<0.0001
CDC-based height Z-score	0.1	-0.2	0.3 [0.1, 0.5]	NA

1. Included treatment, strata (defined by sex and age), baseline age, and baseline achondroplasia-specific height Z-score as covariates.
2.Treatment differences between YUVIWEL and placebo were estimated from an analysis of covariance (ANCOVA) model that included treatment, strata (defined by sex and age), baseline age, and baseline achondroplasia height Z-score as covariates.

Improvements in AGV and height Z-scores were observed across all predefined subgroups analyzed, including age group, sex, and region

YUVIWEL [package insert]. Princeton, NJ: Ascendis Pharma Growth Disorders A/S. February 2026.

Adverse Reactions from USPI

Table 2: Adverse Reactions Reported in ≥ 5% of Participants Treated with Navepegritide 0.1 mg/kg/week and ≥ 2% Higher Than Placebo During the Placebo-Controlled Period of Trials 1 and 2

Adverse Reaction	NAVEPEGRITIDE 0.1 mg /kg/week N = 68 n (%)	Placebo N = 42 n (%)
Vomiting	14 (21)	6 (14)
Injection-site reaction*	13 (19)	6 (14)
Pain in extremity	8 (12)	3 (7)
Nausea	4 (6)	0

*Includes injection-site swelling, injection-site erythema, injection-site bruising, injection-site reaction, injection-site pruritus, injection-site discoloration, injection-site hemorrhage, injection-site pain, injection-site vesicles, and injection-site edema.

YUVIWEL [package insert]. Princeton, NJ: Ascendis Pharma Growth Disorders A/S. February 2026.
USPI: United States Prescribing Information.

Dosage, Administration, Storage & Handling Highlights

ONCE-WEEKLY yuviwel® navepegritide

- Administer once-weekly by subcutaneous injection, with dosage based on body weight
- Periodically monitor growth and adjust dose according to body weight
- Discontinue when no further growth potential, as indicated by epiphyseal closure
- USPI switch guidance: start once-weekly YUVIWEL on the day after completing the last dose of daily CNP therapy
- No food or fluid intake requirements when administering YUVIWEL noted within the USPI
- YUVIWEL can also be stored at room temperature up to 30°C (86°F) for up to 6 months and can be returned to refrigeration within the 6 months

YUVIWEL [package insert]. Princeton, NJ: Ascendis Pharma Growth Disorders A/S. February 2026.

Launch Perspective

Community-Focused Development and Launch

Ascendis has built deep relationships with the community to design and deliver a highly differentiated treatment.

Development: Engagement since 2017 to gain patient, family, advocacy and HCP perspectives.

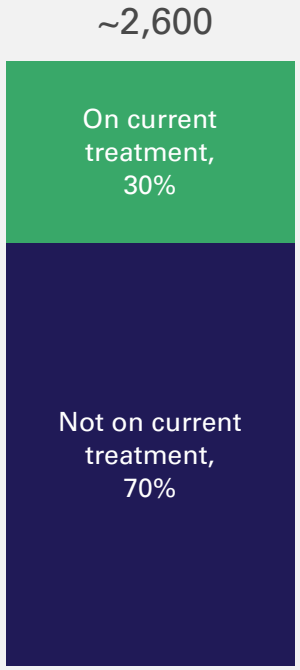
Regulatory: Consultation on outcomes that matter most to community from infancy to adulthood. More clinical trials in process or planned (infant and adult trials).

On Market: Suite of patient services Ascendis Signature Access Program (A.S.A.P.), including support navigating the treatment journey and financial assistance programs for eligible patients.

Novel Approaches: Exploring multiple indications and regimens (e.g., TransCon CNP + TransCon hGH) to expand treatment options and patient reach.

Achondroplasia U.S. Landscape

U.S. Pediatric ACH Market[1]



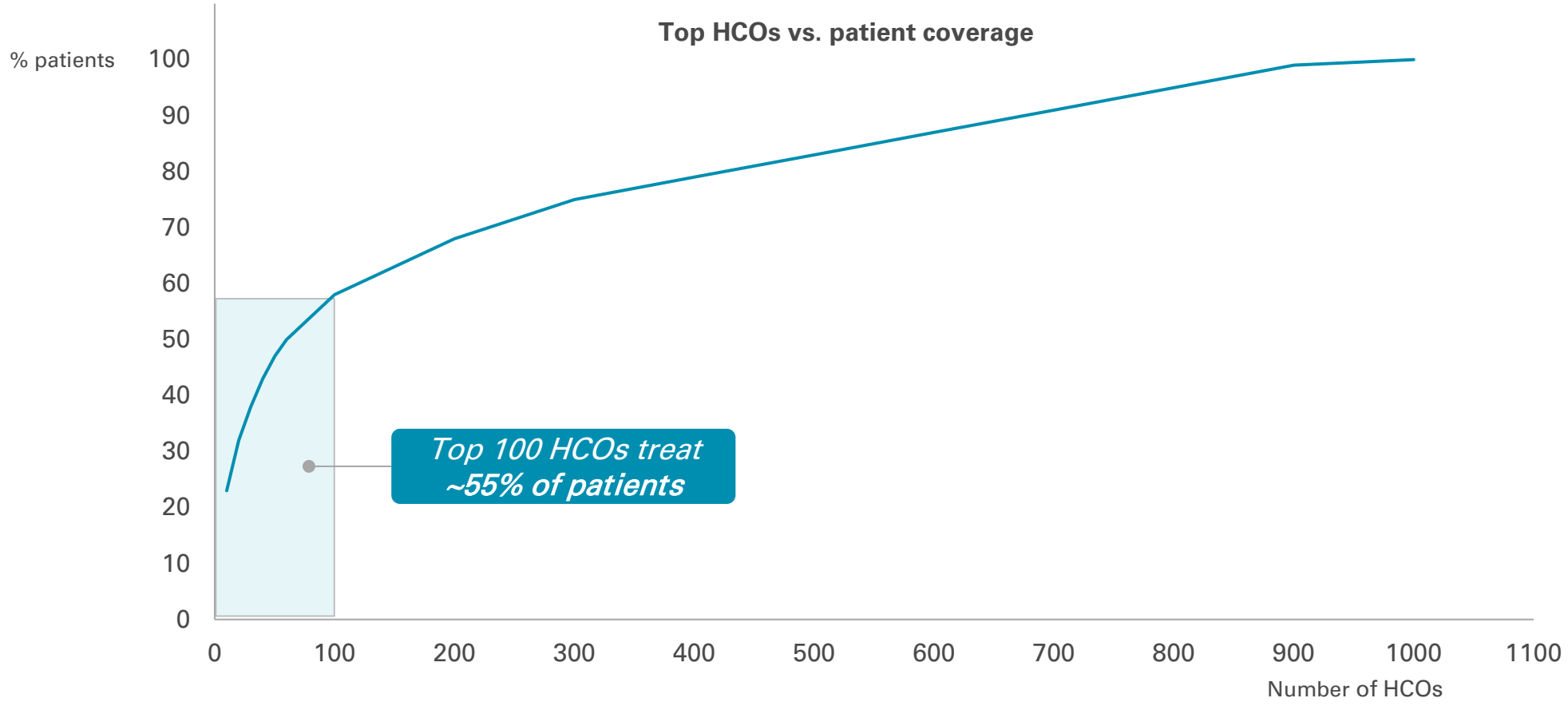
In the U.S. market, those living with achondroplasia have diverse treatment goals:

- Currently on a daily therapy
- Previously tried a daily therapy and have since discontinued due to tolerability, convenience, or perceived lack of benefit
- Naïve to pharmacological treatment

YUVIWEL is expected to grow the therapeutic class with uptake from both treated and untreated patients

1. Children with achondroplasia aged ≤ 18 years. Stevenson et al. (2012). American Journal of Medical Genetics, Part A, 158A(5), 1046–1054.; Waller et al. (2008). American Journal of Medical Genetics Part A, 146A(18), 2385–2389.

Patient Care Concentrated in U.S. Centers of Excellence



Over half of patients are concentrated within 100 skeletal dysplasia clinics

Source: Komodo claims data (range from January 2016 to March 2025); HCOs=healthcare orgs.

Key U.S. Commercial Activities

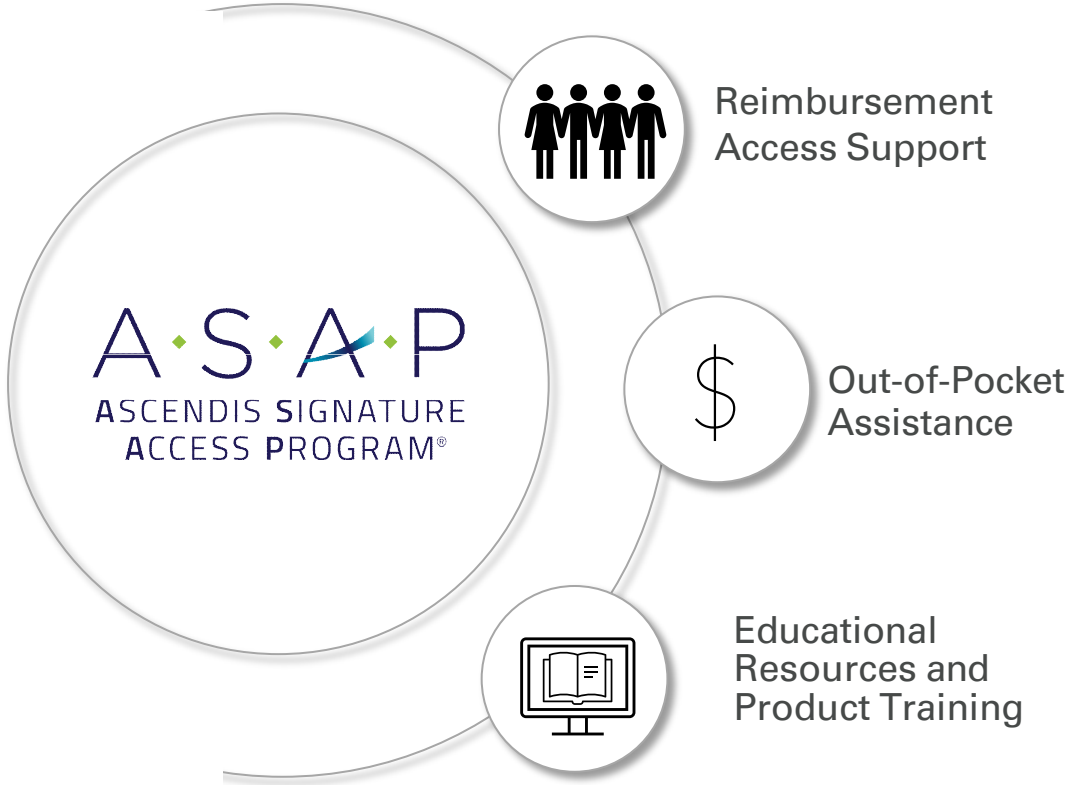
Execute on a focused and high-impact launch strategy

- Engage with Centers of Excellence, thought leaders, and patient advocacy groups to educate key stakeholders on YUVIWEL's clinical value and differentiation
- Invest in multi-channel education and support for caregivers and patients
- Focus on optimizing patient experience and ensuring patient choice
- Leverage established infrastructure and systems, which have supported over 15,000 patients prescribed SKYTROFA

Prepared to support YUVIWEL commercial availability in early part of Q2 2026

Ensuring Affordable and Broad Access in the U.S.

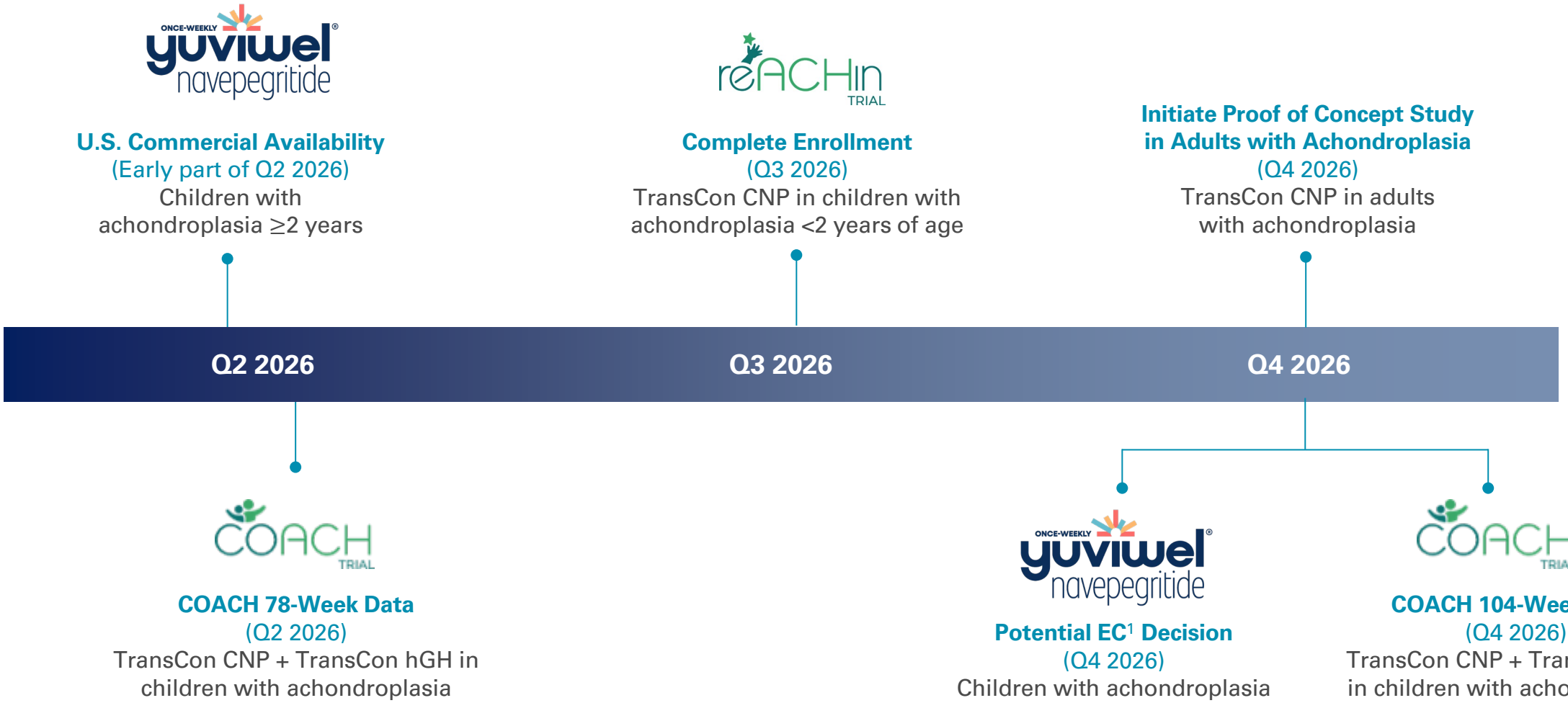
Patient Access



Patient Affordability

- **Commercial:** Eligible commercially insured patients pay as little as $0 a month with a co-pay card
- **Government:** Affordable out-of-pocket or patients will be screened for available assistance programs
- **Uninsured or underinsured:** Patients who require additional assistance will be screened for the Ascendis Patient Assistance Program (PAP)

YUVIWEL – Key Expected 2026 Milestones



[1] EC = European Commission.
Timing is approximate and is subject to change.

Summary & Next Steps

- The first and only FDA-approved once-weekly therapy for children with achondroplasia
- Granted Rare Pediatric Disease PRV
- Product availability anticipated in the early part of the second quarter of 2026
- In European Union, Marketing Authorisation Application (MAA) is under review; decision expected in the fourth quarter of 2026
- Plan to make YUVIWEL available in International Markets through named patient programs using U.S. approval and existing infrastructure
- Extensive ongoing development program with YUVIWEL as a foundational therapy, in combination with SKYTROFA, as well as planned label expansion programs to other indications

Third consecutive TransCon product with blockbuster potential now FDA approved

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Thank you

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