

ROYALTY PHARMA

# Tividenofusp alfa synthetic royalty

December 2025

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# Tividenofusp alfa synthetic royalty funding

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## 1

### **Denali's tividenofusp alfa for Hunter syndrome (MPS II)**

Hunter syndrome: genetic orphan lysosomal storage disease that damages multiple organs and tissues, including the brain

Tividenofusp alfa: enzyme replacement therapy enabled by Denali's TransportVehicle platform to cross blood brain barrier

PDUFA date of April 5, 2026 for accelerated approval<sup>(1)</sup>

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## 2

### **First potential FDA-approved therapy for MPS II addressing brain & periphery**

Elaprase (standard of care enzyme replacement therapy) does not address neurological symptoms

Tividenofusp alfa Phase 1/2 results normalized key biomarkers of neurological and peripheral disease<sup>(2)</sup>

Phase 2/3 confirmatory results in 2027 to support global approval<sup>(3)</sup>

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## 3

### **Established market opportunity**

>2,000 patients globally with ~500+ patients in the U.S.<sup>(4)</sup>

Market validated by Takeda's Elaprase (~\$650m global sales)<sup>(5)</sup>

Consensus tividenofusp alfa sales of \$575 million by 2035<sup>(6)</sup>

Expect unlevered IRR in the low double digits to low teens under a range of scenarios

MPS II: Mucopolysaccharidoses Type II; PDUFA: Prescription Drug User Fee Act; IRR: internal rate of return

1. Denali Therapeutics press release, October 13, 2025.

2. Denali Therapeutics press release, February 6, 2025.

3. Stifel Healthcare conference transcript, November 12, 2025.

4. Baird Healthcare conference transcript, September 9, 2025.

5. Takeda Q4 financial results, May 8, 2025.

6. Visible Alpha unadjusted consensus sales, December 1, 2025.

# Acquired synthetic royalty on tividenofusp alfa for Hunter syndrome

## Up to \$275m to acquire a royalty on Denali's tividenofusp alfa

- \$200m payment to Denali on FDA accelerated approval and \$75m on EMA approval if achieved by December 31, 2029
- Entitled to 9.25% royalty on worldwide net sales
- Royalty payments to Royalty Pharma cease upon reaching a multiple of 3.0x, or 2.5x if achieved by first quarter of 2039
- Phase 2/3 COMPASS confirmatory results vs. active comparator expected in 2027 to support global approval<sup>(1)</sup>
- Transaction expected to deliver unlevered IRR in the low double digits to low teens under a range of scenarios

## Tividenofusp alfa consensus sales<sup>(2)</sup> (\$ in millions)



IRR: internal rate of return; FDA: Food and Drug Administration; EMA: European Medicines Agency; MPS II: Mucopolysaccharidoses Type II

1. Phase 2/3 COMPASS study is enrolling patients with MPS II in North America, South America and Europe to support global approval. Participants are randomized 2:1 to receive either tividenofusp alfa or idursulfase, respectively. Cohort A enrolled 42 patients with neuronopathic MPS II and Cohort B is enrolling patients with non-neuronopathic MPS II.

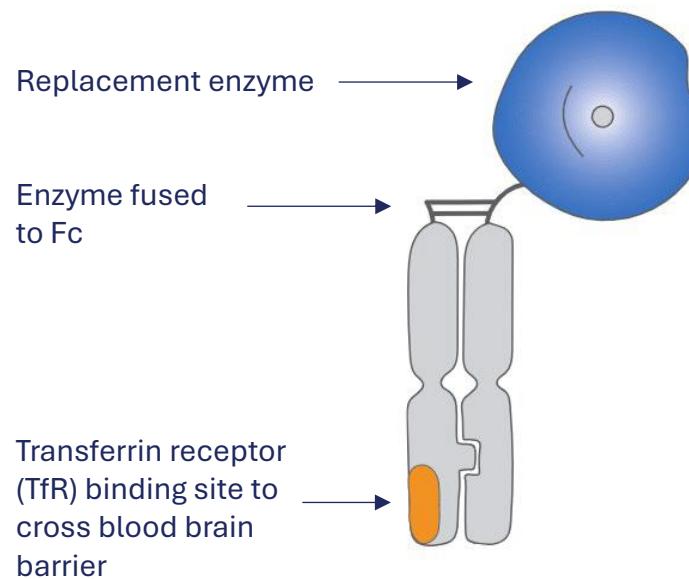
2. Visible Alpha unadjusted consensus sales, December 1, 2025.

# Phase 1/2 clinical results support potential for accelerated approval

Tividenofusp alfa achieved normalization of key brain biomarkers in addition to gains on measures of peripheral disease

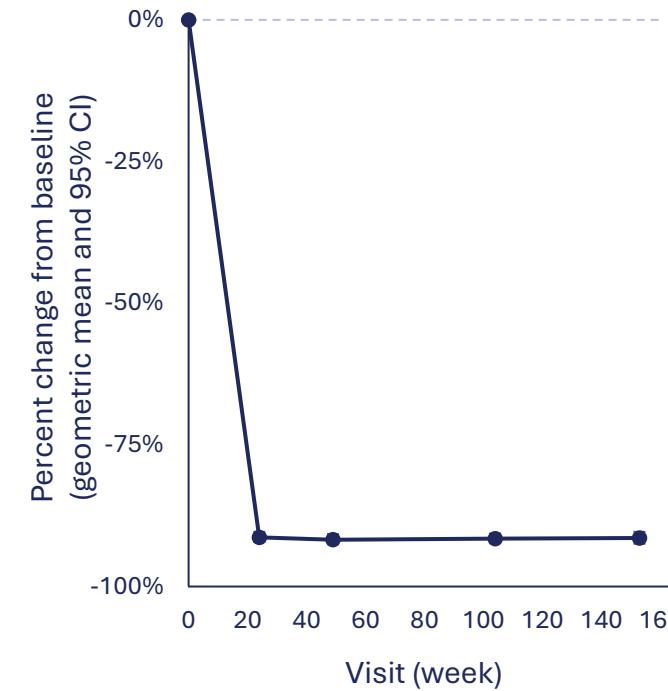
## Denali's TransportVehicle (TV) platform

(Engineered to optimize brain delivery)<sup>(1)</sup>



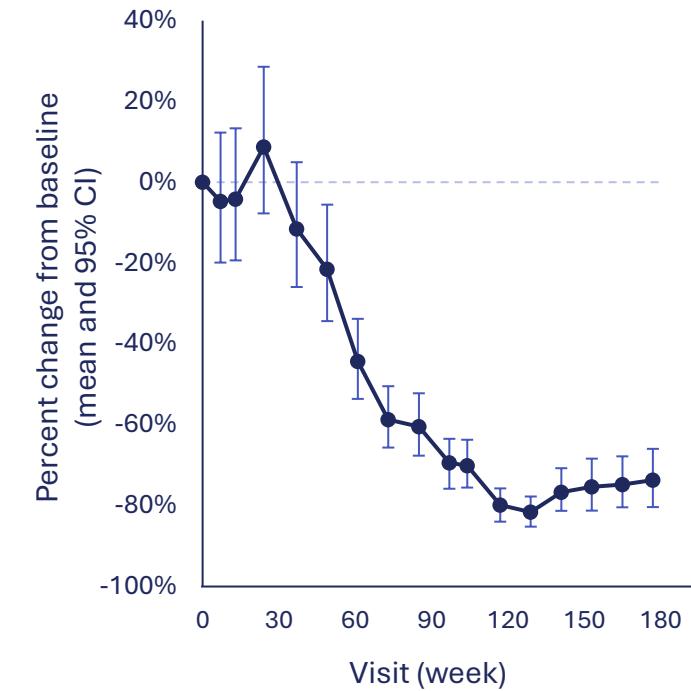
## CSF Heparan Sulfate

(Biomarker of neurological disease)<sup>(1)</sup>



## Serum NfL

(Biomarker of neuronal damage)<sup>(1)</sup>



# Tividenofusp alfa – addressing significant unmet patient need

## Market dynamics

### Ultra rare disease

**>2,000<sup>(1)</sup>**  
(patients globally)

Patients are split ~1/3 in the U.S., EU and RoW<sup>(2)</sup>

### Neurological symptoms

**>2/3<sup>(1)</sup>**  
(of patients have neurological disease)

Cognitive decline starts between 2-4 years old

### Low life expectancy

**~33 yrs<sup>(3)</sup>**  
(median survival)

Neuronopathic patients rarely survive beyond the second decade

### Validated market

**\$650m<sup>(4)</sup>**  
(Elaprase sales)

FY 2024 global sales for Takeda's Elaprase

U.S.: United States; EU: European Union; RoW: Rest of World; CNS: central nervous system

1. Denali Therapeutics corporate presentation, November 2025.

2. Jefferies Global Healthcare Conference transcript, November 18, 2025.

3. Burton, B.K., Jego, V., Mikl, J. et al. Survival in idursulfase-treated and untreated patients with mucopolysaccharidosis type II: data from the Hunter Outcome Survey (HOS). *J Inherit Metab Dis* 40, 867–874 (2017).

4. Takeda FY 2024 financial results, May 8, 2025.