



## Ionis presents new data demonstrating long-term disease control with DAWNZERA™ (donidalorsen) at ACAAI 2025 Annual Meeting

November 6, 2025

- DAWNZERA showed durable efficacy, demonstrating 94% overall mean HAE attack rate reduction at one year in OASISplus open-label extension study
- Patients in OASISplus switch study achieved 68% improvement in mean HAE attack rate compared to prior prophylactic therapy one year after switching to DAWNZERA
- Long-term efficacy and safety maintained up to four years in Phase 2 open-label extension

CARLSBAD, Calif.--(BUSINESS WIRE)--Nov. 6, 2025-- [Ionis Pharmaceuticals, Inc.](#) (Nasdaq: IONS) today announced new long-term data for DAWNZERA™ (donidalorsen), the first and only RNA-targeted prophylactic medicine for hereditary angioedema (HAE), to be presented at the 2025 American College of Allergy, Asthma & Immunology (ACAAI) Annual Scientific Meeting in Orlando, Florida. Results demonstrate the long-term durability and safety of DAWNZERA, including new data from patients who were followed for one year in the ongoing OASISplus open-label extension (OLE) and switch cohorts, as well as new four-year results from the Phase 2 OLE study.

DAWNZERA was recently [approved](#) by the U.S. Food and Drug Administration for prophylaxis to prevent attacks of HAE in adult and pediatric patients 12 years of age and older.

“These new long-term data support our belief that DAWNZERA, which is now available to people living with HAE in the U.S., is well-positioned to transform the treatment paradigm for HAE,” said Kenneth Newman, M.D., senior vice president, clinical development, Ionis. “The latest results from across our clinical studies support the strong and durable efficacy and safety profile of DAWNZERA. Presentations at the congress offer patients and physicians valuable insights to support informed treatment decisions, including when transitioning to DAWNZERA from a previous prophylactic therapy.”

The OASISplus OLE cohort enrolled adult and adolescent patients continuing from the Phase 3 OASIS-HAE pivotal trial, who received DAWNZERA every four (Q4W) or every eight weeks (Q8W). At Week 52 in the OLE, DAWNZERA demonstrated a 94% and 95% mean attack reduction from baseline for patients in the Q4W (n=69) and Q8W (n=14) dosing groups, respectively. Nearly all (97%) patients reported well-controlled disease as measured by the Angioedema Control Test (AECT score  $\geq 10$ ) at Week 52 compared to baseline.

OASISplus also included a switch cohort evaluating DAWNZERA Q4W in patients previously treated with lanadelumab, C1-esterase inhibitor or berotralstat. At Week 52, patients who switched to DAWNZERA (n=64) experienced a 68% improvement in monthly HAE attack rate compared to baseline with prior prophylactic therapy, with 90% reporting well-controlled disease as measured by the AECT.

In the Phase 2 OLE study, patients treated with DAWNZERA Q4W showed a 97% mean HAE attack rate reduction over four years. The median attack-free interval was 2.7 years, and 71% of patients were attack-free for more than one year.

Across all studies, DAWNZERA demonstrated a favorable long-term safety and tolerability profile. The majority of treatment-emergent adverse events (TEAEs) were mild or moderate, with no serious TEAEs related to DAWNZERA.

Ionis will present a total of six posters at the congress, which are available on Ionis' [website](#).

### IMPORTANT SAFETY INFORMATION

#### CONTRAINDICATIONS

DAWNZERA is contraindicated in patients with a history of serious hypersensitivity reactions, including anaphylaxis, to donidalorsen or any of the excipients in DAWNZERA.

#### WARNINGS AND PRECAUTIONS

##### Hypersensitivity Reactions

Hypersensitivity reactions, including anaphylaxis, have been reported in patients treated with DAWNZERA. If signs and symptoms of serious hypersensitivity reactions occur, discontinue DAWNZERA and institute appropriate therapy.

#### ADVERSE REACTIONS

Most common adverse reactions (incidence  $\geq$  5%) are injection site reactions, upper respiratory tract infection, urinary tract infection, and abdominal discomfort.

Please see full [Prescribing Information](#) for DAWNZERA.

### About Hereditary Angioedema (HAE)

HAE is a rare and potentially life-threatening genetic condition that involves recurrent attacks of severe swelling (angioedema) in various parts of the body, including the hands, feet, genitals, stomach, face and/or throat. HAE is estimated to affect approximately 7,000 people in the U.S.

### About DAWNZERA™ (donidalorsen)

DAWNZERA™ (donidalorsen) is approved by the U.S. Food and Drug Administration for prophylaxis to prevent attacks of hereditary angioedema (HAE) in adult and pediatric patients 12 years of age and older. DAWNZERA is an RNA-targeted medicine designed to target plasma prekallikrein (PKK), which plays an important role in activating inflammatory mediators associated with acute attacks of HAE. For more information about DAWNZERA, visit [DAWNZERA.com](https://www.dawnzera.com).

### About Ionis Pharmaceuticals, Inc.

For three decades, Ionis has invented medicines that bring better futures to people with serious diseases. Ionis has marketed medicines and a leading pipeline in neurology, cardiometabolic and other areas of high patient need. As the pioneer in RNA-targeted medicines, Ionis continues to drive innovation in RNA therapies in addition to advancing new approaches in gene editing. A deep understanding of disease biology and industry-leading technology propels our work, coupled with a passion and urgency to deliver life-changing advances for patients. To learn more about Ionis, visit [ionis.com](https://www.ionis.com) and follow us on [X \(Twitter\)](#), [LinkedIn](#) and [Instagram](#).

### Forward-looking Statements

This press release includes forward-looking statements regarding Ionis' business and the therapeutic and commercial potential of DAWNZERA, our commercial medicines, additional medicines in development and technologies. Any statement describing Ionis' goals, expectations, financial or other projections, intentions or beliefs is a forward-looking statement and should be considered an at-risk statement. Such statements are subject to certain risks and uncertainties including those inherent in the process of discovering, developing and commercializing medicines that are safe and effective for use as human therapeutics, and in the endeavor of building a business around such medicines. Ionis' forward-looking statements also involve assumptions that, if they never materialize or prove correct, could cause its results to differ materially from those expressed or implied by such forward-looking statements. Although Ionis' forward-looking statements reflect the good faith judgment of its management, these statements are based only on facts and factors currently known by Ionis. Except as required by law, we undertake no obligation to update any forward-looking statements for any reason. As a result, you are cautioned not to rely on these forward-looking statements. These and other risks concerning Ionis' programs are described in additional detail in Ionis' annual report on Form 10-K for the year ended December 31, 2024, and most recent Form 10-Q, which are on file with the Securities and Exchange Commission. Copies of these and other documents are available from the Company. In this press release, unless the context requires otherwise, "Ionis," "Company," "we," "our" and "us" all refer to Ionis Pharmaceuticals and its subsidiaries.

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