# Isarna Therapeutics Announces First Patient Enrolled in International Phase 2a Clinical Study in Ophthalmology Indications Wet AMD and DME

**Munich, Germany, November 30, 2021** – Isarna Therapeutics today announced the enrollment of the first patient in the BETTER Study, a parallel, two-segment Phase 2a clinical study to evaluate Isarna's lead candidate ISTH0036 in patients with wet age-related macular degeneration (wet AMD) and diabetic macular edema (DME). The study aims to enroll as many as 24 patients for each indication and will be led by internationally renowned experts at clinical trial centers in Austria and India with lead investigators Prof. Matthias Bolz and Priv. Doz. Rupert Strauss at the Kepler University in Linz, Austria. The study's objective is to evaluate ISTH0036 in these two indications and gain data that will enable the transition into a Phase2b/3 clinical trial.

"Based on the positive results from our Phase 1 study supporting the safety of ISTH0036 and the encouraging data from preclinical studies in retinal disease, Isarna has committed to exploring ISTH0036 in ophthalmic indications where TGF-β plays a vital role in disease progression and where we see the greatest potential value for patients," said **Prof. Marion Munk, CMO of Isarna Therapeutics**.

The Phase 2a trial will gather data on the reduction of retinal fluid and central macular thickness (CMT) as the primary endpoint and improvement of visual acuity (VA) as a secondary endpoint during a treatment period of seven months, followed by a two-month safety follow-up. The trial aims to explore the prevention of fibrosis and epithelial-mesenchymal transition as a key differentiator to currently approved anti-angiogenic therapies, mostly targeting Vascular Endothelial Growth Factors (VEGF). Furthermore, the durability of the antisense therapy ISTH0036 will be evaluated, which showed target suppression in preclinical models for more than four months. Patients selected for the trials will include both newly diagnosed, treatment naïve patients and those who have already been treated with anti-VEGF therapeutics.

Wet AMD causes reduced vision in the center of the eye and affects as many as 190 million people globally[1]. Macular edema occurs when there is abnormal leakage and accumulation of fluid in the macula from damaged, dysfunctional blood vessels in the retina. A common cause of macular edema is diabetes, which is the leading cause of irreversible blindness in mature adults in the U.S.[2] Both diseases can be treated with a range of anti-VEGF drugs however, these therapeutics are not able to maintain visual acuity as many patients develop fibrosis during the disease progression.

"Fibrosis is a primary concern in long-term retina pathologies and is a key driver of significant vision loss even under optimal gold-standard therapy with anti-VEGF. ISTH0036 could be the first drug that targets and prevents development of fibrosis and therefore may become a unique and promising new therapy for retinal indications," said **Dr. René Rückert, COO of Isarna Therapeutics**.

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1. Bourne RR, Stevens GA, White RA, Smith JL, Flaxman SR, Price H, et al. Causes of vision loss worldwide, 1990-2010: a systematic analysis. Lancet Glob Health. 2013;1:e339–49.
2. Bressler NM. Age-related macular degeneration is the leading cause of blindness. JAMA. 2004 Apr 21;291(15):1900-1. doi: 10.1001/jama.291.15.1900. PMID: 15108691.

Isarna has developed ISTH0036 to target the transforming growth factor-beta (TGF-β), a protein which is chronically elevated in ophthalmic, fibrotic, immunologic, and cancerous diseases. ISTH0036 suppresses TGF-β protein production via well-studied antisense mechanisms.

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## About Isarna

Isarna Therapeutics was built on profound knowledge in antisense oligonucleotide design and therapeutic development of this innovative compound class. Today, Isarna is developing a portfolio of antisense therapies targeting an emerging therapeutic field in human biology: TGF-β signaling. Precise modulation of TGF-β pathways using antisense therapy may result in safer and more effective treatment options for a broad range of indications. Currently, Isarna is focusing on ophthalmology; its lead compound, ISTH0036, has entered Phase 2a clinical development in the blockbuster indications wet AMD and DME. In addition, Isarna has established a portfolio of antisense compounds addressing three important isoforms of TGF-β to treat fibrotic liver disease, such as NASH, and various forms of cancer.


## Contact Isarna

Claus Schalper, CEO
info@isarna-therapeutics.com

## Media Inquiries

Trophic Communications
Gretchen Schweitzer or Desmond James
Phone: +49 151 678 59086
isarna@trophic.de