NEWS RELEASE

November 13, 2024

This press release is being provided for a United States audience as a reference. The original news release was issued by Nippon Shinyaku Co., Ltd., the parent company of NS Pharma on November 13, 2024. Please click here to review: https://www.nippon-shinyaku.co.jp/file/download.php?file_id=7885. The text contains content related to U.S. unapproved drugs and unapproved indications.

Nippon Shinyaku and Atsena Therapeutics enter into an Exclusive Strategic Collaboration for ATSN-101 in the U.S. and Japan

KYOTO, Japan and Durham, North Carolina, USA, November 13, 2024 - Nippon Shinyaku Co., Ltd. (Nippon Shinyaku; Headquarters: Kyoto; President, Toru Nakai) and Atsena Therapeutics, Inc. (Atsena; Headquarters: Durham, North Carolina, USA, Chief Executive Officer (CEO) : Patrick Ritschel) have entered into an exclusive license agreement for the commercialization of ATSN-101 in the territory of the U.S. and for the development and commercialization of ATSN-101 in the territory of Japan for advancing Atsena's first-in-class, investigational gene therapy ATSN-101 for Leber congenital amaurosis caused by biallelic mutations in *GUCY2D* (LCA1).

Under the terms of the licensing agreement, Nippon Shinyaku will receive exclusive commercial rights in the U.S. and Japan, and Atsena will retain commercial rights in the rest of the world. ATSN-101 will be marketed by NS Pharma, Inc. (New Jersey, USA, President: Yukiteru Sugiyama), a wholly owned subsidiary of Nippon Shinyaku in the U.S.

Atsena will receive an upfront payment, additional milestone payments, downstream royalties based on sales and will be reimbursed as it continues development work on ATSN-101, including an anticipated global pivotal trial.

ATSN-101 is a first-in-class, investigational gene therapy for the treatment of LCA1. Atsena has received Rare Pediatric Disease Designation, Regenerative Medicine Advanced Therapy Designation and Orphan Drug Designation from the U.S. Food and Drug Administration (FDA) for ATSN-101. In the event Atsena receives a Rare Pediatric Disease Priority Review Voucher (PRV) in connection with the approval of the Biologic

License Application for ATSN-101, Atsena shall own and retain all rights, title and interest in such PRV.

“ATSN-101 provides a potential, innovative treatment in an area where no approved solutions currently exist,” said Nippon Shinyaku President Toru Nakai. “We are excited by the opportunity of this novel ocular gene therapy and our collaboration with Atsena and its groundbreaking science.”
“This collaboration creates a path to accelerate the development of ATSN-101 and validates Atsena’s pioneering technology and development capabilities. We anticipate this will be the first of many ocular gene therapy treatments from our clinical portfolio to come,” said Patrick Ritschel, CEO of Atsena Therapeutics. “We look forward to working with Nippon Shinyaku as we advance ATSN-101 into a pivotal trial and potential approval to provide an innovative solution to patients and families affected by LCA1 around the world.”

About *GUCY2D*-associated Leber congenital amaurosis (LCA1)
LCA1 is a monogenic eye disease that disrupts the function of the retina. It is caused by mutations in the GUCY2D gene and results in early and severe vision impairment or blindness. LCA1 is one of the most common forms of LCA and there are no approved treatments for it.

About ATSN-101
ATSN-101 is an investigational, subretinal AAV5 gene therapy being evaluated in an ongoing Phase I/II clinical trial for LCA1. At 12 months post-treatment, ATSN-101 has demonstrated durable, clinically meaningful improvements in vision at the high dose and is well-tolerated. Results from this trial were recently published in The Lancet.

About Rare Pediatric Disease Designation
The Rare Pediatric Disease Designation is granted by the FDA for promoting the development of new drugs for rare diseases that occur in the U.S. before the age of 18 and affect fewer than 200,000 people. With this designation, the product will be eligible to receive a Priority Review Voucher upon approval that could be used to advance another program.

About Regenerative Medicine Advanced Therapy Designation
The Regenerative Medicine Advanced Therapy (RMAT) Designation is an FDA-designated system for advanced regenerative medicine therapies targeted at developing serious diseases that have shown certain effect in clinical trials based on the 21st Century Cures Act in the U.S. Companies with RMAT designations are given the opportunity for priority review and accelerated approval for the product.

About Orphan Drug Designation

The Orphan Drug Designation is provided for orphan drugs and biologics intended for the safe and effective treatment, diagnosis or prevention of rare diseases/disorders that affect fewer than 200,000 people in the U.S., or that affect more than 200,000 persons but are not expected to recover the costs of developing and marketing a treatment drug. With orphan designation, the FDA grants a seven-year market exclusivity for the product and provides certain incentives such as tax credits towards the cost of development, upon approval.

About Nippon Shinyaku

Based on Nippon Shinyaku's business philosophy, "Helping people lead healthier, happier lives," we aim to be an organization trusted by the community through creating unique medicines that will bring hope to patients and families suffering from illness.
Please visit our website (https://www.nippon-shinyaku.co.jp/english/) for products or detailed information.

About Atsena Therapeutics

Atsena Therapeutics is a clinical-stage gene therapy company developing best-in-class treatments for the reversal or prevention of blindness from inherited retinal diseases. In an ongoing Phase I/II clinical trial, the company is evaluating ATSN-101 for LCA1, one of the most common causes of blindness in children. In another ongoing clinical trial, the company is evaluating ATSN-201 for X-linked retinoschisis (XLRS), a genetic condition affecting boys and men that is typically diagnosed in childhood. Atsena's pipeline is powered by novel adeno-associated virus (AAV) technology tailored to overcome the hurdles presented by inherited retinal diseases. Founded by pioneers in ocular gene therapy, Atsena is led by an experienced team dedicated to addressing the needs of patients with vision loss. For more information, please visit https://atsenatx.com/.

Nippon Shinyaku contact:

e_mail_kouhou@po.nippon-shinyaku.co.jp

Atsena contacts:

Media: tplohoros@6degreespr.com
Business: info@atsenatx.com