Taysha Gene Therapies Bolsters Manufacturing Capacity Through Partnership with Catalent

Partnership to support Taysha's broad gene therapy pipeline

Development and manufacturing partnership will support future preclinical and clinical supply for several gene therapy programs, including CLN1 and Rett syndrome

DALLAS & SOMERSET, N.J.--(BUSINESS WIRE)--Nov. 5, 2020-- Taysha Gene Therapies Inc. (Nasdaq: TSHA), a patient-centric gene therapy company focused on developing and commercializing adeno-associated virus (AAV)-based gene therapies for the treatment of monogenic diseases of the central nervous system in both rare and large patient populations, and Catalent, the leading global provider of advanced delivery technologies, development, and manufacturing solutions for drugs, biologics, cell and gene therapies, and consumer health products, today announced a partnership to support the development and manufacturing of Taysha's gene therapies at Catalent's Maryland-based gene therapy facilities.

"Through this partnership, we will be able to enhance our existing manufacturing capabilities to support Taysha's broad gene therapy pipeline," said RA Session, II, President, Founder and CEO of Taysha. "We are focused on ensuring that we can provide access to potentially curative gene therapies for thousands of patients by establishing this robust infrastructure early."

Taysha has an established partnership with UT Southwestern Medical Center that allows it to access the institution's CGMP-compliant manufacturing suite, which has a capacity of over 500 liters as well as additional 100-liter toxicology material capacity. In addition, Taysha intends to establish its own commercial-scale, CGMP manufacturing facility to meet future demand for its gene therapy product candidates. This new partnership with Catalent intends to rapidly expand Taysha's manufacturing capacity and will support future manufacturing needs for several of Taysha's gene therapy programs, including treatments for CLN1 and Rett syndrome.

"Given Taysha's large and growing pipeline of gene therapies, we wanted to plan for potential increased manufacturing needs above the GMP facility at UT Southwestern and our own planned manufacturing facility," said Fred Porter, Ph.D., Chief Technical Officer for Taysha. "We believe that this partnership is critical to our strategy for future clinical and commercial supply of our gene therapy product candidates."

"Catalent is committed to gene therapy partnerships at all stages of development and manufacturing," commented Manja Boerman, Ph.D., President, Catalent Cell & Gene Therapy. "With our experience in process and analytical development and deep expertise in adeno-associated viral vectors, combined with our growing footprint, we are able to help companies manufacture patient material and reach the clinic faster."

Catalent has five gene therapy facilities in Maryland that provide clinical- through commercial-scale services, and house multiple CGMP manufacturing suites, including fill/finish, central services and testing laboratories, warehousing, and supply chain capabilities.

About Taysha Gene Therapies

Taysha Gene Therapies (Nasdaq: TSHA) is on a mission to eradicate monogenic CNS disease. With a singular focus on developing curative medicines, Taysha aims to rapidly translate its treatments from bench to bedside. It has combined its team's proven experience in gene therapy drug development and commercialization with the world-class UT Southwestern Gene Therapy Program to build an extensive, AAV gene therapy pipeline focused on both rare and large-market indications. Together, Taysha leverages its fully integrated platform—an engine for potential new cures—with a goal of dramatically improving patients' lives. More information is available at www.tayshagtx.com.

About Catalent Cell & Gene Therapy

With deep experience in viral vector scale-up and production, Catalent Cell & Gene Therapy is a full-service partner for adeno-associated virus (AAV) and lentiviral vectors and CAR-T immunotherapies. When it acquired MaSTherCell, Catalent added expertise in autologous and allogeneic cell therapy development and manufacturing to position it as a premier technology, development and manufacturing partner for innovators across the entire field of advanced biotherapeutics. Catalent has a global cell and gene therapy network of dedicated, large-scale clinical and commercial manufacturing facilities, and fill-finish and packaging capabilities located in both the U.S. and Europe. An experienced partner, Catalent Cell & Gene Therapy has worked with industry leaders across 70+ clinical and commercial programs.

Taysha Gene Therapies Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "anticipates," "believes," "expects," "intends," "projects," and "future" or similar expressions are intended to identify forward-looking statements. Forward-looking statements include statements concerning or implying the potential of our product candidates and our plans to establish a commercial-scale manufacturing facility. Forward-looking statements are based on management's current expectations and are subject to various risks and uncertainties that could cause actual results to differ materially and adversely from those expressed or implied by such forward-looking statements. Accordingly, these forward-looking statements do not constitute guarantees of future performance, and you are cautioned not to place undue reliance on these forward-looking statements. Risks regarding our business are described in detail in our Securities and Exchange Commission filings, including in our prospectus dated September 23, 2020, as filed with the Securities and Exchange Commission ("SEC") on September 24, 2020, pursuant to Rule 424(b) under the Securities Act of 1933, as amended, which is available on the SEC's website at www.sec.gov. Additional information will be made available in other filings that we make from time to time with the SEC. Such risks may be amplified by the impacts of the COVID-19 pandemic. These forward-looking statements speak only as of the date hereof, and we disclaim any obligation to update these statements except as may be required by law.

View source version on businesswire.com: https://www.businesswire.com/news/home/20201105005348/en/

Company Contact:
Niren Shah, PharmD, MBA
Taysha Gene Therapies
Nshah@tayshagtx.com

Media Contact:
Carolyn Hawley
Canale Communications
carolyn.hawley@canalecomm.com

Catalent:
Company Contact:
Chris Halling
Catalent
+44 (0)7580 041073
chris.halling@catalent.com

Media Contact:
Richard Kerns
Northern Exposure PR
+44 (0) 161 728 5880
richard@nepr.agency

Source: Taysha Gene Therapies Inc.