



IVERIC bio Enters into Strategic Manufacturing Relationship with Catalent's Paragon Gene Therapy for Orphan Inherited Retinal Diseases

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NEW YORK & SOMERSET, N.J.--(BUSINESS WIRE)--Jun. 17, 2019-- [IVERIC bio, Inc.](#) (NASDAQ: ISEE) and [Catalent Biologics](#), today announced that they have entered into an agreement for production and manufacturing of GMP-grade adeno-associated virus (AAV) vector for IVERIC bio's gene therapy product candidates, IC-100 for the treatment of rhodopsin-mediated autosomal dominant retinitis pigmentosa (RHO-adRP) and IC-200 for the treatment of BEST1 related retinal diseases. IVERIC bio expects to initiate Phase 1/2 clinical trials for IC-100 in 2020 and IC-200 in the first half of 2021. IVERIC bio has engaged Paragon Gene Therapy, part of Catalent Biologics, to provide materials for preclinical activities and its planned Phase 1/2 clinical trials for both product candidates.

"We fully appreciate the importance of having a world-class manufacturing infrastructure in place as we continue to build and advance our gene therapy pipeline for inherited retinal diseases," stated Glenn P. Sblendorio, Chief Executive Officer and President of IVERIC bio. "Our relationship with Catalent secures access to state-of-the-art manufacturing capabilities and capacity that we believe will enable us to enter into the next phase of gene therapy development with our product candidates IC-100 for RHO-adRP and IC-200 for BEST1 related retinal diseases."

"We are extremely pleased to partner with IVERIC bio as they advance their portfolio of AAV gene therapies for orphan inherited retinal diseases," added Pete Buzy, President of Paragon Gene Therapy. "We look forward to a strong relationship with the goal of achieving IVERIC bio's gene therapy AAV manufacturing milestones for the production of clinical material."

"We believe that AAV gene therapy is the future of drug development for orphan inherited retinal diseases," stated Keith Westby, Chief Operating Officer of IVERIC bio. "When building a gene therapy franchise the selection of an experienced manufacturer is a critical component. We believe Paragon's specialized expertise in AAV vector manufacturing and the addition of their new world-class commercial-scale facility will positively impact the advancement of our gene therapy pipeline. We look forward to collaborating closely with the Paragon team."

About IVERIC bio

IVERIC bio is a biotechnology company with a focus on the discovery and development of novel gene therapy solutions to treat orphan inherited retinal diseases with unmet medical needs. Vision is Our Mission. For more information on the Company's gene therapy and other programs, please visit www.ivericbio.com.

About Catalent

In May 2019, Catalent, Inc. announced that it had completed the \$1.2 billion acquisition of Paragon Bioservices, Inc., a leading viral vector development and manufacturing partner for gene therapies.

Paragon's unique and differentiated scientific, development, and manufacturing capabilities, will fundamentally enhance Catalent's biologics business and end-to-end integrated biopharmaceutical solutions and allow Catalent to capitalize on strong industry tailwinds in the potentially \$40 billion addressable market for gene therapies.

Catalent is the leading global provider of advanced delivery technologies, and development and manufacturing solutions for drugs, biologics, gene therapies, and consumer health products. With over 85 years serving the industry, Catalent has proven expertise in bringing more customer products to market faster, enhancing product performance and ensuring reliable global clinical and commercial product supply. Catalent employs over 11,000 people, including over 1,800 scientists, at more than 30 facilities across five continents, and in fiscal year 2018 generated over \$2.5 billion in annual revenue. Catalent is headquartered in Somerset, New Jersey. For more information, visit www.catalent.com.

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IVERIC bio Forward-looking Statements

Any statements in this press release about IVERIC bio's future expectations, plans and prospects constitute forward-looking statements for purposes of the safe harbor provisions under the Private Securities Litigation Reform Act of 1995. Forward-looking statements include any statements about IVERIC bio's strategy, future operations and future expectations and plans and prospects for IVERIC bio, and any other statements containing the words "anticipate," "believe," "estimate," "expect," "intend," "goal," "may," "might," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions. In this press release, IVERIC bio's forward looking statements include statements about the implementation of its strategic plan, including its transition to a gene therapy focused company, the timing, progress and results of clinical trials and other research and development activities, including manufacturing activities, the potential utility of its product candidates and the potential for its business development strategy, including any potential in-license or acquisition opportunities. Such forward-looking statements involve substantial risks and uncertainties that could cause IVERIC bio's development programs, future results, performance or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, those related to the initiation and the conduct and design of research programs and clinical trials, establishment of manufacturing capabilities, availability of data from these programs, reliance on university collaborators and other third parties, expectations for regulatory matters, need for additional financing and negotiation and consummation of in-license and/or acquisition transactions and other factors discussed in the "Risk Factors" section contained in the quarterly and annual reports that IVERIC bio files with the Securities and Exchange Commission. Any forward-looking statements represent IVERIC bio's views only as of the date of this press release. IVERIC bio anticipates that subsequent events and developments will cause its views to change. While IVERIC bio

may elect to update these forward-looking statements at some point in the future, IVERIC bio specifically disclaims any obligation to do so except as required by law.

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