

Isolere Bio by Donaldson Passes Most Significant Milestone To-Date, Announces Availability of Manufacturing-Grade IsoTag™ AAV Reagent

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RESEARCH TRIANGLE PARK, N.C.--(BUSINESS WIRE)-- **Isolere Bio by Donaldson**, an innovative bioprocessing technology provider, proudly announces the availability of its manufacturing-grade IsoTag™ AAV reagent for the purification of Adeno-associated Virus (AAV) vectors. As indicated **during the launch of the research-grade reagent** in October 2024, this final advancement in product grade now includes production with validated processes and the availability of a full suite of documentation, including a Regulatory Support File (RSF), validation guide and full design history upon customer request. Additionally, the U.S. Food and Drug Administration (FDA) has acknowledged its receipt of the recently submitted Drug Master File (DMF) for the IsoTag™ AAV reagent, which will support and streamline clinical manufacturing using the reagent.

IsoTag AAV reagent is based on liquid-liquid phase separation technology, originally performed at the Chilkoti biomedical engineering lab at Duke University, dating back to the early 2000s. Spun out of the Chilkoti Lab, Isolere Bio by Donaldson began select collaborations utilizing IsoTag™ AAV reagent under Material Transfer Agreements (MTAs) in 2021, made the product commercially available in 2023 and announced the availability of its research-grade IsoTag AAV reagent last fall. This first-of-its-kind reagent combines the best of both affinity- and size- based separations using a recombinant protein with engineered affinity and unique liquid-phase separation capabilities.

“The availability of this manufacturing-grade IsoTag AAV reagent marks the culmination of years of work. It follows the Isolere Bio journey from small startup in an incubator to now being part of a growing portfolio of solutions within Donaldson Life Sciences,” said Kelli Luginbuhl, general manager of Isolere Bio. “This product has required tremendous perseverance and cross-functional collaboration from our internal team, along with inspiring partners that have been willing to assist in the testing and evaluation of a novel technology. It is humbling to think that IsoTag™ AAV reagent, once an idea, is now a product that can be used to address bottlenecks in our partners’ GMP manufacturing, streamline their purification processes and ultimately bring AAV-based gene therapies to patients in

need.”

Isolere Bio by Donaldson is championing this novel technology to support their stated mission of bringing life-changing therapies to patients around the globe more quickly and more affordably.

The Isolere Bio by Donaldson team will be on site at ASGCT in New Orleans, Louisiana from May 13 to 17. You can connect with the team by visiting booth 1848. On Thursday, May 15 Jennifer Haley, associate director of applications development will present an oral presentation entitled Neutral pH Elution of AAV using Affinity Liquid Phase Separation (ALPS) in Centrifugation and Tangential Flow Filtration (TFF) Formats for Flexible Downstream Processing at 2:15pm in NOLA Theater C. That same day, Isolere Bio by Donaldson scientist Sydney Bear will present a poster on Combining Fixed Bed Bioreactor and Liquid-Phase Affinity Purification Technologies for Next-Generation, Low-Cost Lentiviral Manufacturing from 5:00pm to 7:30pm in Poster Hall I2. To connect with the team, use the ASGCT app.

For more information and/or to obtain a quote, please reach out to Ashley Wilson, business development manager, at ashley.wilson@donaldson.com or visit www.isolerebio.com. To stay up to date on our product journey, follow us on LinkedIn at <https://www.linkedin.com/company/isolere-bio>.

About Isolere Bio

Isolere Bio by Donaldson is an innovator in biopharmaceutical purification technologies, specializing in streamlined solutions for complex biologics. The company works diligently to enhance the efficiency, purity, and cost-effectiveness of biopharmaceutical processes by leveraging cutting-edge materials into next generation solutions. Each product is designed with scalability and sustainability in mind to enable customers to rapidly and reliably commercialize life-saving therapies.

Incorporated in 2017, Isolere Bio became part of Donaldson Company (NYSE: DCI) in early 2023.

For more information, visit isolerebio.com.

About Donaldson Life Sciences – Bioprocessing

Long a pioneer in filtration solutions, Donaldson Company (NYSE: DCI) continues to expand into the Life Sciences sector. The **Bioprocessing division** is concentrated on developing solutions from R&D to commercialization for multi-modality drug manufacturers. The division was built via acquisitions of **Isolere Bio** for multi-modality reagents; **Purilogs** for bioprocessing membranes; and **Solaris Biotech** and **Univercells Technologies** for innovative production technologies. These teams are driven to continuously innovate, evolve, and deliver Smarter

Bioprocessing solutions that help developers improve global health.

For more information, visit donaldsonlifesciences.com.

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