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ASIA EDITION

Isolere Bio launches manufacturing-grade IsoTag™ AAV reagent

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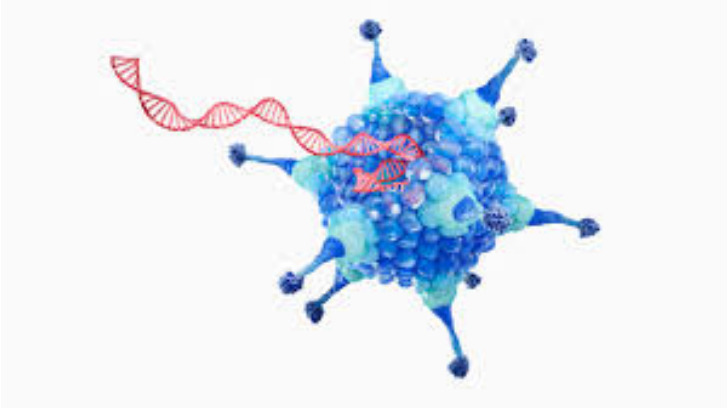
FDA acknowledges drug master file submission as Isolere Bio advances its breakthrough AAV purification technology into clinical manufacturing applications



-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.