

Waters Launches XBridge Premier GTx BEH SEC Columns for Gene Therapy Applications

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News Summary:

- Reduces the cost of gene therapies by using 3-10x less sample than other methodsⁱ while generating faster results and more drug substance information.
- XBridge Premier GTx BEH SEC columns and a new multi-attribute quantification method doubles analytical speed, quadruples sensitivity, and increases resolution of target analytes by up to 50%.ⁱⁱ
- The combination of size exclusion chromatography (SEC) and Wyatt Multi-Angle Light Scattering (MALS) generates key quality and process attributes in characterizing adeno-associated viral (AAVs) vectored gene therapies.

MILFORD, Mass., Aug. 1, 2023 /PRNewswire/ -- Waters Corporation (NYSE:WAT) introduced the first in a new line of size exclusion chromatography (SEC) columns aimed at improving the analysis while lowering the cost of gene therapies, specifically adeno-associated viral (AAV) vectors. The new Waters™ **XBridge™ Premier GTx BEH™ SEC columns** doubles the speed of measuring the potency and safety of AAVs. Combining the columns with light scattering technologies from its **Wyatt Technology** portfolio deepens the level of information acquired from a single experiment and optimizes the manufacturing of these novel gene delivery vehicles.

Waters' new chromatography columns are aimed at improving the analysis while lowering the cost of gene therapies

"We are witnessing a revolution in medicine thanks to gene therapies like AAVs," said Erin Chambers, Vice President, Consumables and Lab Automation, Waters Corporation. "A small quantity of a gene therapy, such as one of the best-selling eye treatments, can retail for more than \$400,000 per eyeⁱⁱⁱ. This makes it imperative that process and formulation development tests measure

multiple attributes of the drug at once while consuming as little of it as possible. It's why Waters' low adsorption, high-efficiency XBridge Premier GTx BEH SEC columns are such a good choice for process development, formulation studies, regulatory filing support, along with ongoing process monitoring as well as quality control."

Avid Bioservices (Tustin, California) received early access to the XBridge Premier GTx columns. "The XBridge Premier GTx BEH SEC columns significantly widened the dynamic range of our SEC platform method for AAV aggregate analysis," says Kilian Witzel, Senior Scientist, Analytical Development Viral Vectors, Avid Bioservices, Inc. "It is now possible to analyze AAV aggregates from small amounts of sample with an HPLC method that is up to five times faster than conventional SEC methods for this application. This will help us expedite study timelines and reduce overall costs."

AAVs are modified viruses made in bioreactors by living cells and are the number one vehicle for carrying therapeutic genes into human cells. Waters scientists have developed a fast and efficient multi-attribute quantification method of characterizing AAVs that features the following Waters products:

- ACQUITY™ Premier UPLC™ Systems or Arc™ Premier HPLC Systems
- XBridge Premier GTx BEH SEC 450Å 2.5 µm columns
- Arc Premier 2489 UV/Visible detector or 2998 photodiode array detector
- Wyatt™ DAWN™ multi-angle light scattering detector
- Wyatt Optilab™ differential refractive index detector

XBridge Premier GTx BEH SEC columns are now available worldwide from Waters.

Additional Resources

- Learn more about [Waters Gene Therapeutics Columns](#)
- Watch the webinar [Fast, But Sure AAV Aggregate Analysis with Platform SEC Methods](#)
- Download the app note [Improved Size-Exclusion Chromatography of AAVs with XBridge Premier GTx BEH SEC 450Å SEC 2.5 µm Columns](#)
- Follow and connect with Waters via [LinkedIn](#), [Twitter](#), and [Facebook](#)

About Waters Corporation (www.waters.com)

Waters Corporation (NYSE:WAT), a global leader in analytical instruments and software, has pioneered chromatography, mass spectrometry, and thermal analysis innovations serving the life, materials, and food sciences for over 60 years. With approximately 8,000 employees worldwide, Waters operates directly in 35 countries, including 14 manufacturing facilities, and with products available in more than 100 countries.

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i According to beta customer AAV sample analysis and the optimization of lower volume 2.5 µm particle SEC column technology that can produce >3x more concentrated peaks versus an industry standard 7.8 x 300 5 µm particle SEC column.

ii As compared to industry-standard, UV-based HPLC methods employing 5 µm silica particles in stainless steel columns limited to measuring aggregation and titer.

iii [Life Sciences Intelligence](#), May 24, 2023: "The Top 5 Most Expensive FDA-approved Gene Therapies"

iv Method captures the following AAV information: aggregate vs. monomer content, titer, encapsidation ratio, nucleic acid vs. monomer ratio, concentration, absolute molar mass and size, and radii.

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