Charles River and Navega Therapeutics Announce Comprehensive Gene Therapy Manufacturing Collaboration

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Next-generation AAV gene therapy to target debilitating pain disorders

WILMINGTON, Mass.--(BUSINESS WIRE)--Mar. 14, 2024-- Charles River Laboratories International, Inc. (NYSE: CRL) and Navega Therapeutics, Inc., a biotechnology company developing epigenetic gene therapies, today announced an AAV9 production program agreement. As part of Charles River's Cell and Gene Therapy (CGT) Accelerator Program (CAP), Navega will have access to established contract development and manufacturing (CDMO) capabilities and advisory services to produce an adeno-associated virus (AAV)-based gene therapy, NT-Z001, for Phase I clinical trials.

Developing a Non-Opioid Treatment for Chronic Pain

Navega is pursuing an approach for treatment of chronic pain associated with rare diseases such as small fiber neuropathy and primary erythromelalgia by harnessing the precision of its AI-enabled zinc-finger epigenome regulation platform. Navega's epigenetic therapy addresses a gain-of-function mutation in the Nav 1.7 gene, linked to inherited erythromelalgia, small fiber neuropathy and other chronic, debilitating pain disorders. With over 17 million Americans living with high-impact chronic pain, Navega's non-opioid gene therapy for chronic pain may also be used in other intractable pain indications, including neuropathic and inflammatory pain.

Plasmid and Viral Vector CDMO Solutions

To bring NT-Z001 to clinic, Navega will leverage Charles River's off-the-shelf plasmid products, custom plasmid capabilities, and Good Manufacturing Practice (GMP)-grade AAV production.

Simplifying complex supply chains, without compromising on quality, Charles River provides phase-appropriate solutions to meet the growing global demand for plasmid DNA, viral vector, and cell therapy services. Through several acquisitions, capacity expansions, and the establishment of manufacturing platforms including eXpDNA ™ (plasmid), nAAVigation ™ (AAV), and Lentivation ™ (lentiviral vector) to expedite and standardize supply, Charles River's CGT portfolio has been significantly enhanced. Combined with the company's legacy testing services, Charles River offers an industry-leading "concept to cure" solution for advanced therapies, helping developers to navigate the path to clinic and beyond.

New for the 2024 Charles River Cell & Gene Therapy Summit, the Company Pitches session showcases the "who, what, why, and how," highlighting technologies, milestones, path to clinic, and patient outcomes. Join Ana Moreno, CEO, Navega Therapeutics on March 19 in San Francisco – see the full agenda and save your seat: https://bit.ly/3SW3VOV

Approved Quotes

- "The collaboration with Navega will tap into our premier gene therapy CDMO capabilities and robust AAV offerings. We are thrilled that our expertise will help bring Navega's gene therapy closer to patients suffering with chronic pain." - Kerstin Dolph, Corporate Senior Vice President, Biologics Solutions, Charles River
- "The selection of Charles River as our CDMO resulted from the additional benefits of its CGT Accelerator Program, including manufacturing prioritization for Nav 1.7, introduction to key industry players, scientific advisory and consulting services, plus co-marketing efforts. We are delighted to have been selected from a pool of talented applicants." - Ana Moreno, PhD, Chief Executive Officer, Navega Therapeutics, Inc.

About Charles River

Charles River provides essential products and services to help pharmaceutical and biotechnology companies, government agencies and leading academic institutions around the globe accelerate their research and drug development efforts. Our dedicated employees are focused on providing clients with exactly what they need to improve and expedite the discovery, early-stage development and safe manufacture of new therapies for the patients who need them. To learn more about our unique portfolio and breadth of services, visit www.criver.com.

About Navega Therapeutics Inc.

Navega is a preclinical stage company developing epigenetic-regulation gene therapies to tackle common and complex diseases via a proprietary AI-enabled zinc finger platform. Due to the involvement of NaV1.7 in multiple chronic pain states, Navega is harnessing the power of the epigenome to modify its expression and treat multiple chronic pain indications, including chemotherapy-induced peripheral neuropathy. Other indications in Navega's pipeline include neurological and ophthalmic diseases.

To learn more visit https://navegatx.com/.

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