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Avid Bioservices Selected as Commercial Manufacturer for Critical Enzyme Replacement Therapy by Enzyvant, a Subsidiary of Roivant Sciences

TUSTIN, Calif., Feb. 21, 2018 (GLOBE NEWSWIRE) -- Avid Bioservices, Inc. (NASDAQ:CDMO) (NASDAQ:CDMOP), a company working to improve patient lives by providing high quality biologics manufacturing services to biotechnology and pharmaceutical companies, today announced that Enzyvant, a subsidiary of Roivant Sciences, has selected Avid as the commercial drug substance manufacturer for RVT-801, its recombinant human acid ceramidase enzyme replacement therapy being developed as a potential treatment for Farber disease. Successful technology transfer and clinical manufacturing have been underway since mid-2017 and Avid will complete process characterization and optimization followed by process validation in support of Enzyvant's ongoing development and regulatory activities for RVT-801, which include the initiation of a first-in-human clinical study.

RVT-801 will be manufactured in Avid Bioservices' Myford facility, which is designed with cutting-edge, single-use equipment to accommodate a fully disposable biomanufacturing process. A wide range of innovative features are incorporated into this new facility including monolithic modular clean rooms, dedicated support utilities for each key processing area, and the industry's most advanced single-use production systems and flexible solutions. Uni-directional process flows separate personnel and materials and provide assurance that the design meets the most stringent regulatory requirements for commercial biologics API manufacturing.

"We are delighted to add Enzyvant to the growing list of companies that recognize Avid Bioservices' ability to move critically important therapeutic products very rapidly into commercial manufacture," said Roger Lias, Ph.D., president and chief executive officer of Avid Bioservices. "We take great pride in our more than 12-year track record of successfully manufacturing and releasing commercial biologic products for the US, EU and numerous other important international markets."

Alex Tracy, Ph.D., vice president of pharmaceutical development and manufacturing for Roivant Sciences, added, "We presented Avid with very ambitious timelines for RVT-801 manufacturing work and we were extremely impressed with the ability of their team to work creatively with us to design and deliver a program that meets our needs and contributes significant value. We look forward to advancing the development of RVT-801 as a potential therapeutic for Farber's disease."

In winning this manufacturing project, Avid Bioservices was selected by Enzyvant from a large field of internationally recognized contract development and manufacturing organizations.

About Farber Disease
Farber disease is a rare lysosomal storage disease caused by mutations in the *ASAH1* gene, resulting in deficiency of the lysosomal enzyme acid ceramidase. This deficiency leads to the accumulation of the pro-inflammatory sphingolipid ceramide, and a macrophage-driven inflammatory process causing the development of typical clinical symptoms.

Farber patients typically present with the cardinal symptoms of:

- Joint contractures or arthritis
- Subcutaneous nodules
- Weak or hoarse voice

Patients may also present with systemic inflammation (including fever), severe pain, peripheral osteolysis, failure to thrive, and developmental delay. Like other lysosomal storage diseases, Farber disease has a broad phenotypic spectrum and is likely underdiagnosed.

About RVT-801
RVT-801 is a recombinant form of human acid ceramidase (rhAC) that Enzyvant is developing for potential use as an enzyme replacement therapy in acid ceramidase deficiency, manifesting as Farber disease. Enzyvant is currently conducting preclinical studies to enable a clinical trial of rhAC in patients with Farber disease. Orphan drug designation for RVT-801 has been granted by regulatory agencies in the United States and the European Union.

About Enzyvant
Enzyvant is a biopharmaceutical company focused on developing innovative treatments for patients with rare diseases. Enzyvant is conducting a natural history study of patients with Farber disease to better define the natural course of disease and the relationship between specific symptoms, biomarkers, and prognosis. Enzyvant is simultaneously preparing a clinical trial of RVT-801, an investigational enzyme replacement therapy for the treatment of Farber disease.

Enzyvant is also advancing the development of RVT-802, an investigational tissue-based biologic therapy for the potential treatment of primary immune deficiency associated with complete DiGeorge Syndrome. RVT-802 has been granted orphan drug designation, Breakthrough Therapy designation, Regenerative Medicine Advanced Therapy designation, and pediatric rare disease designation by the U.S. Food and Drug Administration. Enzyvant anticipates a potential BLA filing for RVT-802 later this year. Enzyvant plans to develop treatments for additional rare diseases with high unmet need. For more information, please visit www.enzyvant.com.

About Avid Bioservices, Inc.
Avid Bioservices is a dedicated contract development and manufacturing organization (CDMO) focused on development and cGMP manufacturing of biopharmaceutical products derived from mammalian cell culture. The company provides a comprehensive range of process development, high quality cGMP clinical and commercial manufacturing services for the biotechnology and biopharmaceutical industries. With nearly 25 years of experience producing monoclonal antibodies and recombinant proteins in batch, fed-batch and perfusion modes, Avid's services include cGMP clinical and commercial product manufacturing, purification, bulk packaging, stability testing and regulatory strategy, submission and support. The company also provides a variety of process development activities, including cell line development and optimization, cell culture and feed optimization, analytical methods development and product characterization. www.avidbio.com

Forward-Looking Statements
Statements in this press release which are not purely historical, including statements regarding Avid Bioservices' intentions, hopes, beliefs, expectations, representations, projections, plans or predictions of the future, are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements include statements regarding the expected closing of the offering and the intended use of the net proceeds from the offering, and involve risks and uncertainties. Our business could be affected by a number of other factors, including the risk factors listed from time to time in our reports filed with the Securities and Exchange Commission including, but not limited to, our annual report on Form 10-K for the fiscal year ended April 30, 2017 and subsequent quarterly reports on Form 10-Q, as well as any updates to these risk factors filed from time to time in our other filings with the Securities and Exchange Commission. We caution investors not to place undue reliance on the forward-looking statements contained in this press release, and we disclaim any obligation, and do not undertake, to update or revise any forward-looking statements in this press release except as may be required by law.

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