Armistice Capital And Other Institutional Investors Show Support For Rare Disease Research

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PATIENT CARE

While the number of biotech funding deals has declined the past few years — reaching the lowest level since 2018 earlier this year, according to Chemical & Engineering News — the interest in research that involves treatments for rare diseases appears to be rising.

The Orphan Drug Act defines rare diseases as conditions that affect no more than 200,000 individuals in the U.S. More than 7,000 exist, according to the U.S. Food and Drug Administration; many are life-threatening, and the agency says treatments aren't available for most of the conditions.

That may soon change, however. The number of rare disease-related drugs in existence now is more than four times the amount that were available 40 years ago, according to FDA research — and analysts have suggested the industry could be poised for further growth.

Consulting company Grand View Research predicts the value of rare disease clinical trials, on a global scale, will rise at a compound annual growth rate of 9.7% through 2030 — due in part to personalized medicine improvements, enhanced cell and gene therapies and greater financial support from pharmaceutical and biotech companies and non-profit organizations.

Funding Solutions For Infrequent, Yet Devastating Diseases

Research organizations working on medications that could address rare conditions —

such as clinical-stage biotechnology company Cyclo Therapeutics, Inc. — have received funds from institutional investors in recent years.

In February 2023, Nasdaq reported that global value-oriented and event-driven hedge fund Armistice Capital had filed a 13G form with the SEC that disclosed ownership of 1.03 million shares, approximately 11% of the company — which marked a roughly 378% increase in Armistice's shares since 2020.

Other significant Cyclo Therapeutics shareholders at that time included VTSMX – Vanguard Total Stock Market Index Fund Investors Shares, Renaissance Technologies and Geode Capital Management.

Cyclo Therapeutics' work includes the development of Trappsol Cyclo, a proprietary formulation of hydroxypropyl beta cyclodextrin that is currently being evaluated in clinical trials for potential use in the treatment of Niemann-Pick Disease Type C1, a rare, fatal and progressive genetic disorder, and Alzheimer's disease — which is also a progressive and irreversible neurological disorder.

In April 2024, Protara, a clinical-stage company that creates transformative therapies for the treatment of cancer and rare diseases, closed a $45.0 million private placement, led by RA Capital Management and Acorn Bioventures. New and existing investors such as Boxer Capital, Woodline Partners LP and Armistice Capital also participated in the private placement.

In an update on its overall business and first quarter financial results, the company said it was continuing to enroll pediatric patients — a demographic CEO Jesse Shefferman referred to as “an underserved population with no FDA-approved therapies” — in the phase 2 trial of TARA-002, an investigational cell therapy being developed to treat non-muscle invasive bladder cancer and lymphatic malformations.

Rare, congenital malformations can cause the lymphatic vessel structures to fail to connect or drain into the venous system. Most are found in the head and neck region and are often diagnosed in early childhood.

Some of the most common issues that can arise due to the condition include compression of the upper aerodigestive tract, including airway obstruction that can require intubation and possibly tracheostomy dependence; intralesional bleeding; impingement on nerves and other critical structures; recurrent infection; and other functional disabilities.

The U.S. Food and Drug Administration has given TARA-002 a rare pediatric disease designation. In the FDA’s rare pediatric disease PRV program, designed to incentivize rare pediatric disease drug development, a sponsor who receives approval for a rare pediatric disease-related drug or biological product may qualify for a voucher — which can be redeemed to receive priority review for a different product.

Other Afflictions Are Also Getting Support

Institutional investors have also invested in recent years in a number of biopharmaceutical companies that are conducting research on serious, yet often more commonly found conditions — such as CervoMed Inc., a clinical-stage company that develops treatments for age-related neurologic disorders.

In March, CervoMed said in a press release that it had entered into a definitive securities purchase agreement for a private placement to sell an aggregate of 2,532,285 common stock shares — and warrants to purchase shares of its common stock — to a group of institutional and accredited healthcare specialist investors, including Armistice Capital, RA Capital Management, Special Situations Funds and Soleus Capital.

CervoMed said, in addition to operational expenses, it planned put the net proceeds from the potential $50 million in upfront financing toward research that relates to its clinical-stage medication neflamapimod[EB1], which is being developed to treat central nervous system disorders, including dementia with Lewy bodies, Alzheimer’s disease and strokes.

In mid-June, Assembly Biosciences, Inc. — which currently has in-development drugs that may be able to treat chronic hepatitis B virus infection, and research and preclinical programs that focus on discovering novel antivirals to treat viral diseases, including HBV, hepatitis delta virus and herpesviruse — also announced that it had closed the issuance of shares of its common stock and warrants to investors. Armistice Capital and research-based biopharmaceutical company Gilead Sciences were involved in the sale.

Armistice Capital obtained 634,500 shares; and Gilead purchased 179,500. The two equity financings, according to Assembly Biosciences, collectively totaled approximately $12.6 million.

[EB1] https://www.cervomed.com/clinical-results/

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