

Advanced Innovative Partners Announces Designation for Rare Pediatric Disease Drug

MIAMI, FLORIDA, UNITED STATES, March 1, 2022 /EINPresswire.com/ -- AIP is pleased to announce that the U.S Food and Drug Administration (FDA) has granted Orphan Drug and Rare Pediatric Disease Designation to a radiopharmaceutical for Positron Emission Tomography (PET) diagnosis and clinical management of pediatric patients with Atypical Teratoid Rhabdoid Tumors (AT/RT).

Rare Disease Day is the globally coordinated movement on rare diseases, working towards equity in social opportunity, healthcare, and access to diagnosis and therapies for people living with a rare disease. Since its creation in 2008, Rare Disease Day has played a critical part in building an international rare disease community that is multi-disease, global, and diverse– but united in purpose.

AT/RT is recognized as a rare pediatric disease by the National Institute of Health's Office of Genetic and Rare Diseases (GARD), the National Cancer Institute's Surveillance, Epidemiology and End Results Program (SEER) and the European Community's Committee for Orphan Medicinal Products.

Atypical teratoid/rhabdoid tumor (AT/RT) is a very rare, clinically aggressive fast-growing tumor of the brain and spinal cord that most often affects children aged 3 years and younger but can occur in older children. AT/RT is a rare disease in which malignant cells form in the tissues of the brain with very short median survival at diagnosis. About half of these tumors form in the cerebellum or brain stem. The cerebellum is the part of the brain that controls movement, balance, and posture. The brain stem controls breathing, heart rate, and the nerves and muscles used in seeing, hearing, walking, talking, and eating.

"We are very pleased to be contributing to monitoring the effectiveness of treatment and assist prognosis for AT/RT pediatric patients", Chief Executive Officer Roseanne Satz commented. AIP is embarking in a clinical trial with a prestigious institution in South Africa to support the study for pediatric patients. Upon FDA marketing approval of the molecule for AT/RT with RPD designation, AIP would be eligible to receive a Priority Review Voucher (PRV). A PRV allows any company to use the voucher to accelerate FDA review period of a New Drug Application (NDA).

About AIP

Advanced Innovative Partners is a late-stage clinical biotechnology company focused on

development diagnostics and companion therapeutics in oncology, neurology, rare pediatric diseases, and medical countermeasures. True to our name, our mission is to deliver transformative science to people with underserved medical needs, making a difference in their lives. The company's robust nuclear medicine product portfolio includes specialty pharmaceuticals enabling personalized medicine.

Note Regarding Forward-Looking Statements

This press release contains "forward-looking" statements that involve substantial risks and uncertainties. All statements other than statements of historical facts, including statements regarding our future financial condition, timing for and outcomes of clinical results, business strategy and plans and objectives for future operations, are forward-looking statements.

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