

Orphan Drug and Rare Pediatric Disease Designations for a Radiopharmaceutical to Treat Diffuse Intrinsic Pontine Glioma

Advanced Innovative Partners has been granted Designations by America's FDA in order to treat Diffuse Intrinsic Pontine Glioma

MIAMI, FLORIDA, UNITED STATES OF AMERICA, March 25, 2021 /EINPresswire.com/ -- AIP is pleased to announce that the U.S Food and Drug Administration (FDA) has granted Orphan Drug and Rare Pediatric Disease (RPD) Designations for a [radiopharmaceutical](#) for Positron Emission Tomography (PET) imaging, the clinical management of pediatric patients with Diffuse Intrinsic Pontine Glioma (DIPG).

The FDA defines a rare pediatric disease as a serious or life-threatening disease primarily affecting individuals aged 18 years or younger that impacts fewer than 200,000 people in the United States. The program is intended to facilitate development of new drugs and biologics for the prevention and treatment of RPDs. DIPG is recognized as a rare pediatric disease by the National Institute of Health's Office of Genetic and Rare Diseases (NIH)(GARD), the National Cancer Institute's (NCI) (SEER) and the European Community's Committee for Orphan Medicinal Products. The ailment can also be found in the Orphanet list of rare diseases.

Roseanne Satz, AIP's Chief Executive Officer commented "We are very pleased to be contributing to the development of advanced biomarkers for the management of pediatric rare diseases. A Pre-IND meeting was held with the FDA enabling completion of an IND, supported by a clinical protocol and a comprehensive Investigators Brochure."

The disorder has been observed throughout the world in individuals of many ethnic backgrounds, with increasing detection in American and European pediatric populations. A total of 987 children aged 0-19 years, or about 4.3 children out of every 1,000,000 were newly diagnosed with DIPG between 1975 and 2005 in the SEER 9 registries. DIPG affects 200-400 children in the United States each year who have a five-year survival rate less than 1 percent. The disease grows through the brain stem, where breathing and heartbeat are controlled, "with the healthy and diseased cells tangled like two colors of wool knitted together." The median overall survival of children diagnosed with DIPG is approximately 9 months. This statistic makes it one of the most devastating pediatric malignancies.

Upon FDA marketing approval of the molecule for DIPG with Orphan and 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). The voucher, if awarded, may be sold or transferred to another company to date, PRVs have been sold between \$68 and \$350 million.

ABOUT AIP

Advanced Innovative Partners is a clinical stage biotechnology company focused on development of companion diagnostics and 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 radiopharmaceutical portfolio includes specialty pharmaceuticals in nuclear medicine.

For additional information about AIP please visit www.advancedinnovativepartners.com

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. These forward-looking statements include terminology such as "believe," "will," "may," "estimate," "continue," "anticipate," "contemplate," "intend," "target," "project," "should," "plan," "expect," "predict," "could," "potentially" or the negative of these terms.

Forward-looking statements are our current statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, our anticipating significant milestones in 2020 and 2021, the timing of our ongoing and planned clinical development, including our ability to support the launch of a new product and ship to specialty pharmacies.

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