Advanced Innovative Partners Receives FDA'S Orphan Drug and RPD Designations for Hepatoblastoma Imaging Biomarker

MIAMI, FLORIDA, UNITED STATES OF AMERICA, May 6, 2021 /EINPresswire.com/ -- Advanced Innovative Partners (AIP) is pleased to announce that the U.S Food and Drug Administration (FDA) has granted Orphan Drug and Rare Pediatric Disease (RPD) Designation for a radiopharmaceutical for Positron Emission Tomography (PET) imaging, diagnosis and clinical management of pediatric patients with Hepatoblastoma (HB).

Roseanne Satz, AIP's Chief Executive Officer commented "We are very excited to be contributing to advancing management for children suffering from rare diseases. In addition to the award of these designations, we are now completing our IND application enabled by a successful meeting with FDA."

HB is a malignant hepatic tumor and is the most common pediatric liver cancer. It is more common in patients with familial adenomatous polyposis and can occur in patients with other pre-existing liver conditions. About 5% of HB cases are associated with genetic factors, especially overgrowth syndromes. HB is the most common pediatric liver tumor in children under 5 years old and accounts for approximately 1-4% of all malignant tumors in children. 0.5-1.5 children per million are diagnosed with HB each year in the US, with incidence increasing in recent years.

The FDA defines an RPD as a serious or life-threatening disease primarily affecting individuals aged 18 years or younger that impacts fewer than 200,000 children in the United States. The program is intended to facilitate development of new drugs and biologics for the prevention and treatment of RPDs. Hepatoblastoma 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.

Upon FDA marketing approval of the Hepatoblastoma imaging biomarker with RPD designation, AIP would be eligible to receive a tradable Priority Review Voucher (PRV). A PRV allows a company to use the voucher to accelerate the FDA review period of a New Drug Application (NDA). The voucher, if awarded, may be sold or transferred; PRVs have been sold for between US$ 68 million and $ 350 million.

About AIP

Advanced Innovative Partners is a late-stage clinical biotechnology company focused on development diagnostics and companion therapeutics in oncology, are pediatric diseases, and neurology. True to our name, our mission is to deliver transformative science to people with underserved medical needs, is focused on 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. 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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