Advanced Innovative Partners Receives Orphan Drug and Rare Pediatric Disease Designation from the FDA for Acute Radiation Syndrome

MIAMI, November 23, 2020 – 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 material threat medical countermeasures for treatment of Acute Radiation Syndrome.

Roseanne Satz, AIP's Chief Executive Officer commented "We are very pleased to be contributing to the developed of molecules for pediatric rare diseases. A Pre-IND meeting was held with the FDA enabling completion of an IND, Protocol and Investigators Brochure."

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. Acute Radiation Syndrome 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. The ailment can also be found in the Orphanet list of rare diseases.

According to the Centers for Disease Control, Acute Radiation Syndrome (ARS) (sometimes known as radiation toxicity or radiation sickness) is an acute illness caused by irradiation of the entire body (or most of the body) by a high dose of penetrating radiation in a short period of time. The major cause of this syndrome is depletion of immature parenchymal stem cells in specific tissues. Clinical manifestations are skin burns, nausea, vomiting, confusion, fever and chills. ARS can result in pneumonia, and give rise to cancer.

Upon FDA marketing approval of the molecule for Acute Radiation Syndrome with RPD designation, AIP would be eligible to receive a tradable 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 for between US$67.5 million and US$350 million.

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.

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.