

Advanced Innovative Partners Receives Multiple Rare Pediatric Disease and Orphan Designations from the FDA

SURFSIDE, FLORIDA, UNITED STATES, February 26, 2021 /EINPresswire.com/ -- Advanced Innovative Partners (AIP), a privately held life sciences company developing [rare disease](#) drugs for cancer, today announced that the U.S. Food and Drug Administration (FDA) granted two rare pediatric disease designations (RPDDs) for programs in its development pipeline, Osteosarcoma and Ewing's Sarcoma, potentially devastating bone ailments in children. The company has also received orphan drug designations (ODDs), for its Diffuse Intrinsic Pontine Glioma (DIPG) and Acute Lymphoblastic Leukemia (ALL) cancer programs.

AIP is developing innovative technologies enabling the management or treatment of these diseases more effectively. Though rare, Osteosarcoma is the most common type of bone cancer. Ewing sarcoma is another rare oncological disease that presents with lesions in and around bone. Advancements in the treatment of Ewing's sarcoma is significantly improving outcomes and AIP's novel technology has the promise of further advancement of diagnosis and treatment.

"Cancers that affects the bones represent significant burdens for patients, their families, and the healthcare systems," said Roseanne Satz, AIP Chief Executive Officer. "Our innovative platform promises to enable more efficient clinical management of these pediatric diseases, helping physicians to implement the best treatment for children suffering from these cancers. We are proud to have developed these new agents that have potential to enable best-in-class treatments for bone cancer. We greatly appreciate the FDA granting these multiple orphan and rare pediatric disease designations."

Designation as an orphan drug serves to advance drug development for rare diseases. The FDA grants the designation to drugs or biologics that demonstrate promise for the diagnosis and/or treatment of rare diseases or conditions. Under the RPDD program, the FDA grants a Priority Review Voucher (PRV) to the sponsor who receives a product approval for a "rare pediatric disease," defined as a serious or life-threatening condition of fewer than 200,000 Americans that primarily affects individuals from birth to 18 years. AIP may be eligible to receive a PRV for each RPDD that gains marketing approval.

Orphan designation provides development and commercial incentives including exemption from FDA user fees and eligibility for a seven-year period of market exclusivity upon approval in the

U.S. The vouchers may be sold or transferred or redeemed for a subsequent marketing application for a different drug enabling accelerated review of a drug application.

About Advanced Innovative Partners

AIP is a clinical stage biotechnology company focused on the development of novel therapeutics and diagnostics in oncology, neurology, rare pediatric and infectious diseases, as well as medical countermeasures. Our vision is to deliver transformative science to underserved patients. Our name symbolizes a mission to partner with clinicians and scientists to help people who are in urgent need.

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