Dovitinib, a potential new treatment for osteosarcoma, receives Orphan Drug Designation from the U.S. FDA

BOSTON, MA, USA, October 13, 2023 /EINPresswire.com/ -- Oncoheroes Biosciences, a biotech focused on advancing new therapies for childhood cancer, today announced that the U.S. Food and Drug Administration has granted Orphan Drug Designation (ODD) to dovitinib for its use in treating osteosarcoma.

Key Points
- FDA awards Orphan Drug Designation to potential therapies addressing unmet needs of underserved patients with rare diseases.
- ODD may enable Oncoheroes to obtain partial tax credits for clinical trial expenditures.
- Dovitinib previously received Rare Pediatric Disease Designation by the FDA, which may also provide substantial financial incentives to Oncoheroes with the related Priority Review Voucher program.

The U.S. FDA has established initiatives aimed at incentivizing pharmaceutical companies to pursue drug development for rare diseases, which are characterized as conditions impacting fewer than 200,000 individuals in the U.S. at the time of designation. Following the enactment of the Orphan Drug Act in 1983, the FDA has granted Orphan Drug Designations (ODD) and subsequently approved the release of numerous drugs tailored to treat such rare diseases.

Under the Orphan Drug status, Oncoheroes will qualify for various development incentives, including a tax credit on expenditures incurred in clinical studies, exemption from filing fees such as the user fee, substantial cost savings, or eligibility for a research grant awarded by the FDA. Being granted orphan designation does not modify the standard regulatory requirements to obtain marketing approval.

“We are thrilled to have received another favorable notice from the FDA. This underscores the imperative demand for better treatments for children and adolescents with osteosarcomas,” stated Cesare Spadoni, Oncoheroes’ Founder and COO. “We anticipate that this excellent news

will expedite the drug's clinical development, benefiting not just osteosarcoma patients but also other pediatric solid tumors given the design of dovitinib's Phase 1/2a clinical trial, which has been recently allowed to proceed by the FDA".

In September 2022, dovitinib was also granted the Rare Pediatric Disease Designation (RPDD), making Oncoheroes eligible for a fast-track review and for a Priority Review Voucher (PRV) that is fully transferable to other sponsor companies and has a current average market value of $100 million.

Bone tumors are a group of histologically diverse diseases. Osteosarcoma is the most common cause of bone cancer in children and adolescents, associated with high treatment failure rates and morbidity. Annually, the United States sees 800-900 new osteosarcoma cases, and those that experience disease progression or recurrence have a low prognosis. The 5-year overall survival rates remain at approximately 20% for patients who develop metastatic disease.

About dovitinib:
Dovitinib is a pan-tyrosine kinase inhibitor (TKI) of multiple proteins known to be overexpressed in osteosarcomas and other bone sarcomas, including fibroblast growth factor receptor (FGFR), vascular endothelial growth factor receptor (VEGFR), and other receptor tyrosine kinases (RTKs). Oncoheroes acquired the pediatric exclusive license of dovitinib from Allarity Therapeutics in 2022. This drug class is considered interesting for the treatment of pediatric bone sarcomas, and the clinical development of dovitinib is supported by an exploratory biomarker that would allow the identification of potential responders to the drug. In September 2023, Oncoheroes received the green light from the FDA to move forward an Investigational New Drug (IND) application for dovitinib for the treatment of advanced or relapsed pediatric solid tumors, including osteosarcoma.

About Oncoheroes Biosciences:
Oncoheroes Biosciences is a Boston-based biotech company exclusively focused on the discovery and development of better drugs for children and adolescents with cancer. Our vision is to deliver benefits to young cancer patients and create value in the process. Oncoheroes is actively looking for in-licensing opportunities in the pediatric oncology space while working to generate new proprietary assets for a number of pediatric cancer indications with high unmet medical needs.

For more information, please visit: oncoheroes.com

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