CereMark Announces Supply Agreement with SpectronRx for Production of F-18 Flornaptitril For Phase 3 Clinical Trials

Phase 3 Clinicals To Evaluate Prediction of Cognitive Decline in Alzheimer's Disease, Chronic Traumatic Encephalopathy and Other Neurodegenerative Diseases

NEW YORK , NEW YORK , USA, May 3, 2023 /EINPresswire.com/ -- CereMark Pharma LLC ("CereMark") today announced that it has entered into a supply agreement with SpectronRx for the production of [F-18]Flornaptitril (formerly known as [F-18]FDDNP), an investigational new Positron Emission Tomography (PET) imaging radiopharmaceutical that is being studied for usefulness in the management of neurodegenerative diseases including the development and progression of Alzheimer's Disease (AD), Chronic Traumatic Encephalopathy (CTE), and other diseases associated with cognitive impairment. Previous clinical studies with [F-18]Flornaptitril have demonstrated unique imaging abilities - as seen on PET scans - to simultaneously detect both beta-amyloid plaques and tau macroaggregates. The presence and distribution of these proteins in the brain have been linked to the development and progression of life-threatening neurodegenerative diseases such as AD and CTE. Under the new agreement, SpectronRx will manufacture [F-18]Flornaptitril for CereMark using the patented radiochemical synthetic technique (#10,626,083B2 in the United States and #. 3538161 in the European Union) held exclusively by CereMark under license from UCLA. CereMark plans to use [F-18]Flornaptitril manufactured by SpectronRx in its pivotal Phase 3 multi-site clinical investigational study that is planned to start later this year.

Commenting on the announcement, CereMark's Chief Executive Officer, Henry ("Hank") Chilton, PharmD, said, "We are pleased to be working with SpectronRx for the manufacture, supply and distribution of [F-18]Flornaptitril. SpectronRx is a leader in the cyclotron-assisted production and clinical trial support of investigational new radiopharmaceuticals and is globally respected for its clinical development capabilities and manufacturing services. Our engagement of SpectronRx is another significant milestone towards fulfilling the regulatory requirements for the development and approval of this unique, dual-targeting, short-lived PET imaging biomarker."

Anwer Rizvi, President of SpectronRx commented, "SpectronRx is delighted to offer its services to support the manufacturing and distribution of [F-18]Flornaptitril for CereMark's clinical trials and to create the necessary radiochemistry synthesis platform that could be used in commercializing Flornaptitril when approved by FDA."

Julian Bailes, MD, CereMark's Chief Medical Officer, joined Dr. Chilton by commenting, "Major medical and research publications increasingly report that the presence of both beta-amyloid plaque and tau aggregates are associated with progression to mild cognitive impairment (MCI) and risk of further serious cognitive decline, even in individuals without current cognitive impairment. This finding is the premise upon which CereMark is working to demonstrate the role a single PET imaging agent can play in defining the presence of both neuroproteins in the predictive likelihood of the clinical development of neurodegenerative diseases. That is our goal," he said.

About CereMark Pharma LLC
CereMark is incorporated in Delaware. Its management team includes Dr. Henry ("Hank') Chilton (formerly Vice President, Business Development, Cardinal Health (NYSE: CAH), and PETNet Solutions); Dr. Julian Bailes (Chair, Department Neurosurgery, Co-Director NorthShore Neurological Institute; Clinical Professor of Neurosurgery, University of Chicago Pritzker School of Medicine).

About SpectronRx
SpectronRx is a Radiopharmaceutical Contract Manufacturing/Contract Development and Manufacturing Organization (RCMO/RCDMO) with 140,000 sq. ft. of manufacturing space in Indiana, with an additional facility in Danbury, Connecticut. SpectronRx supplies therapeutic and diagnostic radiopharmaceuticals to six Continents, has been EMA and FDA inspected, can both produce and procure any currently used radioisotopes. The company performs all scales of development, from initial conjugations through scale-up and commercial distribution, as well as the capability of running clinical trials. With a large staff of radiochemists, radio pharmacists, scientists, engineers, and dozens of qualified clean rooms, SpectronRx has a broad capability to develop and distribute diagnostic and therapeutic radiopharmaceuticals. More information can be found at SpectronRx.com or on LinkedIn.

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