

CereMark Pharma and Invicro to Collaborate on Development of F-18 Flornaptitrit

CereMark Prepares for Pivotal Phase 3 Clinical Trial for Prediction of Cognitive Decline in Alzheimer's Disease, CTE and Other Neurodegenerative Diseases

New York, New York – June 28, 2023: [CereMark Pharma LLC](#) (“CereMark”) today announced that it has entered into agreement with Invicro, LLC (“Invicro”), a leader in radiology and pathology services and a subsidiary of REALM IDx, for the continued development of [F-18]Flornaptitrit (formerly known as [F-18]FDDNP) in support of CereMark’s pivotal Phase 3 clinical trial protocol for [F-18]Flornaptitrit. [F-18]Flornaptitrit is an investigational 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. Earlier clinical trials of [F-18]Flornaptitrit demonstrated its unique imaging ability 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 today’s announcement, Invicro will collaborate with CereMark on the further development of [F-18]Flornaptitrit in this clinical trial and support CereMark with its manufacturing relationship with SpectronRx, the supply agreement for which was announced by CereMark and SpectronRx last month. CereMark anticipates its pivotal Phase 3 multi-site clinical investigational trial to start later this year.

Commenting on the announcement, CereMark’s Chief Executive Officer, Henry (“Hank”) Chilton, PharmD, said: “Invicro is an incredibly accomplished developmental partner whose expertise in the field of neuro imaging is universally respected and appreciated across the entire spectrum of the radiopharmaceutical industry. Our collaboration with Invicro will help us to accelerate our clinical investigation of [F-18]Flornaptitrit and fulfill another significant milestone towards the development and approval of this unique, dual-targeting, short-lived PET imaging biomarker.”

Invicro’s Chief Scientific Officer, Roger Gunn, Ph.D., joined Dr Chilton by saying: “Invicro is delighted to support CereMark in the development of [F-18]Flornaptitrit and to assist CereMark with its preparedness for its critical Phase 3 clinical investigational trial”. John Seibyl, MD, Distinguished Scientist at Invicro added, “The simultaneous interrogation of both amyloid and tau by [F-18]Flornaptitrit PET provides unique opportunities for earlier diagnosis and better clinical management of individuals suffering from these terrible proteinopathies. Invicro's mission is to enable precision in the quantification and qualification of biomarkers, such as [F-18] Flornaptitrit so that better tools may be put into the hands of clinicians for best care of those suffering from some of life’s most serious diseases. We are pleased to collaborate with CereMark in bridging our skills and services to their investigational new drug trial”.

Julian Bailes, MD, CereMark’s Chief Medical Officer, commented, “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.”

[About CereMark Pharma LLC](#)

CereMark is incorporated in Delaware and is focused upon creating better management of neurodegeneration, its diseases, and improved outcomes. 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 Invicro

Headquartered in Needham, MA, Invicro, a subsidiary of REALM IDx, Inc., was founded in 2008 with the mission of improving the role and function of imaging in translational drug discovery and development across all therapeutic areas. Today, Invicro’s multi-disciplinary team provides solutions to pharmaceutical and biotech companies across all stages of the drug development pipeline (Preclinical through Phase 0-IV), all imaging modalities and all therapeutic areas, including neurology, oncology, and systemic and rare diseases. Invicro’s quantitative biomarker services, advanced analytics and AI tools, and clinical operational services are backed by Invicro’s industry-leading software informatics platforms, VivoQuant® and iPACS®, as well as their pioneering IQ Analytics Platform, which includes Amyloid^{IQ}, Tau^{IQ} and DaT^{IQ}.

Invicro operates out of nine global laboratories, clinics and sites within the United States in Massachusetts, Michigan, California, Connecticut and globally in the United Kingdom, India, Japan and China.

Forward-Looking Statements: *This release contains forward-looking statements regarding CereMark’s business plans. The words “believe,” “look forward to,” “may,” “estimate,” “continue,” “anticipate,” “intend,” “should,” “plan,” “could,” “target,” “potential,” “is likely,” “will,” “expect” and similar expressions, as they relate to us, are intended to identify forward-looking statements. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy and financial needs. Actual results may differ materially from those included in these statements due to a variety of factors, including whether: CereMark is able to obtain acceptable results from on going or future clinical trials of its investigational products, CereMark’s products can produce desired responses, and those products can be used effectively, CereMark can develop and manufacture its products with the desired characteristics in a timely manner, CereMark’s products will be safe for human use, CereMark’s products will receive regulatory approvals necessary to be licensed and marketed, there is development of competitive products that may be more effective or easier to use than CereMark’s products, CereMark will be able to enter into favorable manufacturing and distribution agreements, and other factors, over which CereMark has no control. Factors or events that could cause our actual results to differ may emerge from time to time, and it is not possible for us to predict all of them. We undertake no obligation to publicly update any forward-looking statement, whether as a result of new information, future developments or otherwise, except as may be required by law.*

For More Information:

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