

AC Immune Receives Milestone Payment in Connection with Initiation of a Phase 2 Trial of Tau PET Tracer PI-2620

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Next generation Tau tracer offers potential for earlier and more accurate diagnosis in Alzheimer's and neurodegenerative diseases

The clinical milestone highlights the strength of AC Immune's Tau pipeline, one of the broadest in the field

Reflects the compelling trend for positive data across the field on pathological Tau and its pivotal role in neurodegenerative diseases

LAUSANNE, Switzerland, Sept. 17, 2019 (GLOBE NEWSWIRE) -- AC Immune SA (NASDAQ: ACIU), a Swiss-based, clinical-stage biopharmaceutical company with a broad pipeline focused on neurodegenerative diseases, today announced it has received a milestone payment from its partner Life Molecular Imaging in connection with the initiation of a Phase 2 study of the Tau positron-emission tomography (PET) tracer PI-2620.

PI-2620 is a next generation Tau PET tracer developed using AC Immune's proprietary Morphomer™ discovery platform in a research collaboration with Life Molecular Imaging. It binds to Tau deposits which, along with beta-amyloid plaques, represent a critical pathological hallmark of Alzheimer's disease (AD). Tau deposits also play an important role in other neurodegenerative diseases.

The Phase 2 longitudinal study is being conducted in the UK and is expected to last approximately three years, with the overall goal being to evaluate PI-2620 as a targeted radiopharmaceutical for the detection of Tau deposits in the human brain. The data generated are intended to be used for obtaining regulatory approval in the U.S. and Europe.

Prof. Andrea Pfeifer, CEO of AC Immune SA, commented: "The clinical advancement of PI-2620 is based on its excellent properties and imaging characteristics, and it further reinforces the proficiency of AC Immune's Morphomer™ technology and our ability to establish highly productive partnerships with well-respected companies such as Life Molecular Imaging. Treating earlier and targeting Tau are both key elements of our <u>Roadmap</u> to <u>Successful Therapies for Neurodegenerative Diseases</u>.

"There is a growing body of clinical evidence that Tau pathology drives disease progression, and this new Phase 2 trial further broadens AC Immune's world leading anti-Tau clinical pipeline, which also includes therapeutic antibodies (partnered with Roche/Genentech), small molecule inhibitors (partnered with Eli Lilly), and vaccines (partnered with Janssen). We are advancing these programs in parallel to generate robust clinical data, having most recently vaccinated the first patient in a Phase 1b/2a study of our clinically advanced anti-phospho-Tau vaccine candidate ACI-35.030."

The open label Phase 2 study will evaluate the safety and imaging characteristics of PI-2620 as a PET radioligand for imaging Tau deposition in the brains of patients with mild cognitive impairment (MCI) and mild to moderate AD in comparison with non-demented control (NDC) participants.

PI-2620 was discovered and developed in a research collaboration between AC Immune and Life Molecular Imaging. It has demonstrated robust brain uptake and fast wash-out in non-target regions, a broad imaging window between 30 and 90 minutes post-injection (p.i.) for AD, and excellent reproducibility between test and retest scans. The absence of significant off-target binding enables PI-2620 to detect and quantify early Tau deposition in the brain. PI-2620 also shows promise for non-AD Tauopathies like progressive supranuclear palsy (PSP). Life Molecular Imaging has the exclusive, worldwide license for research, development and commercialization of Tau PET tracers generated within the discovery program.

About AC Immune SA

AC Immune SA is a Nasdaq-listed clinical-stage biopharmaceutical company, which aims to become a global leader in precision medicine for neurodegenerative diseases. The Company is utilizing two proprietary discovery platforms, SupraAntigen™ and Morphomer™, to design, discovery and develop small molecule and biological therapeutics as well as diagnostic products intended to diagnose, prevent and modify neurodegenerative diseases caused by misfolding proteins. The Company's pipeline features nine therapeutic and three diagnostic product candidates, with five currently in clinical trials. It has collaborations with major pharmaceutical companies including Roche/Genentech, Eli Lilly and Janssen Pharmaceuticals Inc.

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Forward-looking statements

This press release contains statements that constitute "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Forward-looking statements are statements other than historical fact and may include statements that address future operating, financial or business performance or AC Immune's strategies or expectations. In some cases, you can identify these statements by forward-looking words such as "may," "might," "will," "should," "expects," "plans," "anticipates," "believes," "estimates," "predicts," "projects," "potential," "outlook" or "continue," and other comparable terminology. Forward-looking statements are based on management's current expectations and beliefs and involve significant risks and uncertainties that could cause actual results, developments and business decisions to differ materially from those contemplated by these statements. These risks and uncertainties include those described under the captions "Item 3. Key Information – Risk Factors" and "Item 5. Operating and Financial Review and Prospects" in AC Immune's Annual Report on Form 20-F and other filings with the Securities and Exchange Commission. Forward-looking statements speak only as of the date they are made, and AC Immune does not undertake any obligation to update them in light of new information, future developments or otherwise, except as may be required under applicable law. All forward-looking statements are qualified in their entirety by this cautionary statement.



Source: AC Immune SA