AC Immune Hosts Key Opinion Leader Event: 'Untangling' Tau Pathology to Treat Alzheimer's and Neurodegenerative Diseases

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Company Provides Key Updates on Tau Pipeline Candidates

LAUSANNE, Switzerland, Nov. 06, 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 highlights from its Key Opinion Leader (KOL) meeting focused on "untangling" Tau pathology as an important therapeutic and diagnostic target for Alzheimer's disease (AD) and other neurodegenerative diseases, held in New York City today at 12pm ET. The archived webcast of the event can be viewed here.

The event included presentations and a roundtable discussion featuring Prof. Keith Johnson, Professor of Radiology and Neurology at Harvard Medical School and Director of Molecular Neuroimaging at Massachusetts General Hospital; Dr. Andrew Stephens, Founder, Chief Medical Officer, and Head of R&D, Life Molecular Imaging; Prof. Andrea Pfeifer, Chief Executive Officer, AC Immune SA; and Dr. Marie Kosco-Vilbois, Chief Scientific Officer, AC Immune SA.

Key highlights include:

- AC Immune continues to demonstrate strong progress across the Tau pipeline of potentially best-in-class small molecule, antibody, and vaccine therapeutics, as well as cutting-edge diagnostic agents
- AC Immune received milestone payments of CHF 30 million from Eli Lilly and Company and EUR 2 million (CHF 2.2 million) from Life Molecular Imaging in 2019
- ACI-3024 is a first-in-class, Tau-specific disease-modifying small molecule that has an excellent preclinical safety and tolerability profile, and has entered Phase 1 clinical development in collaboration with Eli Lilly and Company
- AC Immune is advancing ACI-35.030, its optimized, 2nd generation liposomal vaccine targeting Tau, in a Phase 1b/2a clinical study in collaboration with Janssen Pharmaceuticals
- PI-2620 is a best-in-class Tau imaging agent with excellent properties including high binding affinities to different forms of Tau, high selectivity, high brain penetration and fast washout; currently in Phase 2 clinical development in collaboration with Life Molecular Imaging

Prof. Andrea Pfeifer, Ph.D., CEO of AC Immune, commented: "Developing therapeutics that target Tau and using Tau PET tracers to diagnose and select patients is one of the most promising areas in our search for effective treatments for neurodegenerative diseases. As such, it is one of five elements in AC Immune's Roadmap to Successful Therapies for Neurodegenerative Diseases."

"Our unique approach targets the full spectrum of Tau pathology by inhibiting both early seeding and extracellular spreading of Tau, leveraging the Company's proprietary technology platforms, including a differentiated small molecule Tau inhibitor that acts intracellularly through a novel mechanism to address Tau pathology at the earliest stage. We are pleased to provide an overview and update on some of our key clinical programs."

Highlights from Prof. Pfeifer's presentation include:

- AC Immune has a strong track record of successful execution and anticipates key clinical news flow across its Tau-focused programs:
  - Semorinemab (anti-Tau antibody partnered with Roche/Genentech): Anticipate primary completion of two ongoing Phase 2 studies in prodromal/mild AD and moderate AD is estimated for Q2 2020 and Q3 2021, respectively
  - 2nd generation anti-phospho-Tau (pTau) vaccine (ACI.35.030, partnered with Janssen): Expect interim analysis of safety and immunogenicity anticipated in Q2 2020
  - Small molecule Tau Morphomer™ (ACI-3024, partnered with Eli Lilly): Phase 1 interim data in Q4 2019 followed by readout of multiple ascending dose part in Q1 2020
  - Diagnostic Tau PET tracer (PI-2620, partnered with Life Molecular Imaging): Clinical results in progressive supranuclear palsy (PSP) expected in Q4 2020
- Achieved key preclinical milestones for anti-alpha synuclein (a-syn) antibody and anti-TAR DNA-binding protein 43 (TDP-43) antibody
  - Both programs demonstrate high target affinity and *in vivo* activity
  - Investigational new drug (IND)-enabling studies expected to begin in Q1 2020 and Q2 2020 for anti-a-syn and anti-TDP-43, respectively

Highlights of Prof. Johnson's presentation include:

- Non-invasive positron emission tomography (PET) imaging of pathological species of amyloid beta (Abeta) and Tau proteins in the brain can help answer important questions about the progression of AD, with potential uses in clinical drug

development and medical practice
- Key findings from longitudinal clinical studies in at-risk patients include:
    - Abeta increase is observable prior to cognitive decline
    - Abeta increase is greater with higher Abeta at baseline
    - Abeta increase predicts subsequent Tau increase
    - There is a catastrophic rise in Tau once Abeta reaches a critical threshold
    - Tau changes are more closely associated with the rate of cognitive decline
    - Tau begins in more ancient parts of the brain and spreads under the influence of amyloidosis to more recently evolved regions
- Repeated Tau PET may permit more rapid assessment of pharmacodynamic effects, which may facilitate early phase proof-of-concept trials
- CSF fluid studies are generally consistent, rapidly improving, but with dynamic properties that are still being evaluated; plasma measures are also being developed

Highlights from Dr. Stephens's presentation include:

- Life Molecular Imaging and AC Immune have collaborated successfully to generate a best-in-class Tau PET tracer PI-2620
- PI-2620 shows excellent properties with high binding affinities to different forms of Tau, high selectivity, high brain penetration and fast washout
- PI-2620 uptake in brains of subjects with both 3R/4R and 4R Tau found in regions consistent with pathological findings
- PI-2620 used in pharma AD drug trials to characterize subjects and assess the role of therapeutic intervention on Tau accumulation
- Results in PSP indicate potential of PI-2620:
    - To detect and assess PSP pathology *in vivo*
    - To establish earlier and more reliable diagnosis of PSP

Highlights from Dr. Kosco-Vilbois's presentation include:

- AC Immune's selective small molecule Tau aggregation inhibitor (Tau Morphomer™), ACI-3024, specifically targets misfolded and aggregated Tau and has shown effects on Tau pathology and neuroinflammation in an aggressive animal model of Tau pathology
- ACI-3024 has shown an excellent nonclinical safety profile and has entered clinical a Phase 1 clinical trial as a first-in-class, Tau-specific disease-modifying small molecule for the treatment of neurodegenerative diseases characterized by misfolded Tau in collaboration with Lilly
- AC Immune's 1 st generation anti-phospho-Tau (anti-pTau) liposomal vaccine candidate, ACI-35, induced an early target-specific antibody response against pTau in the vast majority of patients and was safe at all doses tested in a Phase 1b study
- ACI-35.030, a 2nd generation optimized liposomal vaccine, has shown an excellent safety profile and an enhanced antibody response in rodent and non-human primate studies, and is currently in a Phase 1b/2a clinical study in collaboration with Janssen

Key Opinion Leader Biographies

Keith Johnson, M.D.
Prof. Keith Johnson is a Professor of Radiology and Neurology at the Harvard Medical School. He is also Associate Radiologist and Director of Molecular Neuroimaging in the Division of Nuclear Medicine and Molecular Imaging (Department of Radiology) at the Massachusetts General Hospital (MGH). Prof. Johnson serves as an associate physician and staff neurologist in the Memory Disorders Unit at the Brigham and Women's Hospital as well as a Clinical Associate in Neurology at the MGH.

Prof. Johnson has extensive experience in imaging research in neurodegenerative diseases, is a Principal Investigator of the Harvard Aging Brain Study, and oversees the brain PET imaging program at MGH, which includes active research programs in imaging of amyloid-beta and PHF Tau, as well as Lewy body diseases and 4R Tauopathies. Prof. Johnson leads the PET component of the A4 Study, as well as several other AD clinical trials. He leads the PET Unit of the Alzheimer Clinical Trials Consortium (ACTC).

Prof. Johnson is a practicing Neurologist in Behavioral Neurology, Associate Physician in Neurology at Massachusetts General Hospital, and Associate Neurologist in the Division of Cognitive and Behavioral Neurology at Brigham and Women's Hospital.

Andrew Stephens, M.D., Ph.D.
Dr. Stephens is a founder and the Chief Medical Officer and Head of Research and Development for Life Molecular Imaging, GmbH. He has more than 25 years of experience in the pharmaceutical industry, primarily in the areas of translational medicine, and diagnostic imaging of neurodegenerative, oncological and cardiovascular diseases. Dr. Stephens was responsible for regulatory approval and market authorization of Neuraceq (18F-florbetaben) in US, EU, South Korea, and Japan.

Before joining the current company, he was VP, Head Experimental Medicine Oncology/Diagnostic Imaging for Bayer Pharma. Dr. Stephens received an M.D. and a Ph.D. in biochemistry, biophysics and genetics from the University of Colorado. He was Board certified in Internal Medicine and had a clinical practice before entering pharmaceutical development. He began his pharmaceutical industry career investigating RNA aptamers at

NeXagen/NeXstar, and Gilead Sciences. As Senior Director of Translational Medicine at OSI Pharmaceuticals he was responsible for early clinical studies of several anti-cancer oral signal transduction inhibitors. He is an author of more than 150 original articles, abstracts and patents.

About AC Immune

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, discover 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, Lilly and Janssen.

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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