AC Immune Initiates IND-Enabling Studies for First-in-Class Antibody Targeting TDP-43 to Treat Neurodegeneration

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First-in-class TDP-43 antibody developed using SurpraAntigen™ platform

The only TDP-43 antibody with reported in vivo activity

LAUSANNE, Switzerland, Aug. 03, 2020 (GLOBE NEWSWIRE) -- AC Immune SA (NASDAQ: ACIU), a Swiss-based, clinical-stage biopharmaceutical company, with a broad pipeline focused on neurodegenerative diseases, today announced the initiation of investigational new drug (IND)-enabling studies for the Company's first-in-class therapeutic antibody targeting TDP-43 (TAR DNA-binding protein 43). The anti-TDP-43 antibody is the first therapeutic candidate shown to mitigate TDP-43 neuropathology *in vivo* and the Company plans to develop the antibody for the treatment of NeuroOrphan indications.

Advancing the anti-TDP-43 antibody towards clinical development is the latest in a series of important milestones already achieved this year in the Company's cutting-edge therapeutic and diagnostic programs targeting TDP-43 – which are amongst the most comprehensive in the field. TDP-43 pathology is strongly associated with cognitive decline and episodic memory loss in neurodegenerative diseases. Effectively slowing or stopping the spread of TDP-43 pathology throughout the brain could provide the first TDP-43 targeted therapeutic approach for treating conditions such as amyotrophic lateral sclerosis (ALS) and frontotemporal lobar degeneration with TDP-43 pathology (FTLD-TDP), where almost half of all FTLD cases exhibit TDP-43 pathology with significant market potential for AC Immune's TDP-43 antibody. Other indications include limbic-predominant age-related TDP-43 encephalopathy (LATE), and sub-populations of argyrophilic grain disease and Lewy Body Dementia.

Additionally, pathological aggregation of TDP-43 has emerged as an important co-pathology in Alzheimer's disease linked to disease severity and occurring in ~50% of patients. Recognition that neurodegenerative diseases are driven by a complex interplay of pathologies highlights that successful treatments and cures will likely require combination therapy powered by precision medicine. This diversified approach is pioneered by AC Immune through parallel development of highly selective therapeutics and diagnostics for established targets like Tau and Abeta alongside newer targets such as TDP-43.

Prof. Andrea Pfeifer, CEO of AC Immune SA, commented: "This milestone reinforces AC Immune's position as a leader in developing novel therapies against neurodegenerative diseases, with our anti-TDP-43 antibody on track to become the first in the world to reach clinical development. Aggregation of pathological forms of TDP-43 is an increasingly validated therapeutic target and a well-established hallmark of neurodegeneration. Initiation of IND-enabling studies for our first-in-class lead anti-TDP-43 antibody is a major step toward addressing pressing unmet need in NeuroOrphan indications.

"The Company's success is driven in part by our proprietary SupraAntigen™ platform, which has already produced therapeutic monoclonal antibody candidates targeting Abeta and Tau that were successfully out-licensed to leading pharmaceutical companies and are currently advancing in multiple Phase 2 clinical studies. Advancement of the anti-TDP-43 antibody further validates the continuing productivity of this platform, which, together with our Morphomer™ platform for small molecule development, are responsible for discovery and development of our maturing pipeline of first-in-class or best-in-class therapeutic and diagnostic candidates."

TDP-43 is an RNA/DNA-binding protein that functions primarily in the nucleus as a regulator of gene transcription and RNA metabolism. TDP-43 pathology has been shown to start from a focal point in the brain and spread to other brain regions with disease progression. Antibody-mediated clearance of pathological TDP-43 therefore represents an attractive strategy for therapeutic intervention – potentially slowing the spread by blocking the ability of pathological TDP-43 to seed aggregation in neighboring healthy cells. The anti-TDP-43 antibody binds all forms of TDP-43 with high affinity and is the only antibody with reported *in vivo* activity. Proof-of-concept data presented at the 2020 AAT-AD/PD™ Conference demonstrated anti-TDP-43 antibody's ability to mitigate TDP-43 neuropathology in a mouse model of TDP-43 proteinopathies.

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 utilizes two proprietary 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 six currently in clinical trials. It has collaborations with major pharmaceutical companies including Genentech, a member of the Roche group, Eli Lilly and Company, and Janssen Pharmaceuticals.

For further information, please contact:

Head of Investor Relations
Joshua Drumm, Ph.D.
AC Immune
Phone: +1 917 809 0814
Email: joshua.drumm@acimmune.com

US Media
Katie Gallagher
LaVoieHealthScience
Phone: +1 617 792 3937
Email: kgallagher@lavoiehealthscience.com

Global Head of Communications
Judith Moore
AC Immune
Phone: +41 79 826 63 82
Email: judith.moore@acimmune.com

European Investors & Media
Chris Maggos
LifeSci Advisors
Phone: +41 79 367 6254
Email: chris@lifesciadvisors.com

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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. These include: the impact of Covid-19 on our business, suppliers, patients and employees and any other impact of Covid-19. 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