

## AC Immune's PI-2620 Tau-PET Diagnostic in Phase 3 Receives Fast Track Designation in Three Neurodegenerative Conditions

- PI-2620 is in Phase 3 development in Alzheimer's disease by AC Immune's partner, LMI
- This Fast Track designation applies across Alzheimer's disease, progressive supranuclear palsy, and corticobasal degeneration
- Follows two previous Fast Track designations for ACI-35.030 and ACI-24.060 active immunotherapies
- Affirms AC Immune's leadership and commitment to bringing precision medicine to the management of neurodegenerative diseases

**Lausanne, Switzerland, August 28, 2024** – AC Immune SA (NASDAQ: ACIU), a clinical-stage biopharmaceutical company pioneering precision therapeutics for neurodegenerative diseases, today announced that its partner Life Molecular Imaging (LMI) has received Fast Track Designation for the Tau positron emission tomography (PET) diagnostic, [18F]PI-2620, from the U.S. Food and Drug Administration (FDA) in three neurodegenerative conditions.

Fast Track designation for [18F]PI-2620 has been granted for clinical development in Alzheimer's disease (AD), progressive supranuclear palsy (PSP), and corticobasal degeneration (CBD).

The FDA's Fast Track program is designed to accelerate the development and review of drugs that address serious conditions and fulfill unmet medical needs. This designation underscores the broadening view in the medical community that early and accurate diagnoses of neurodegenerative disease may lead to improved outcomes, thanks to emerging treatments.

PI-2620 is a next-generation PET imaging agent currently in Phase 3 clinical development for detecting Tau pathology in Alzheimer's disease. The compound is also being investigated in other neurodegenerative diseases by many academic researchers and in drug development trials. Tau proteins are a hallmark of several neurodegenerative disorders including AD, PSP, CBD, and frontotemporal lobar dementia (FTLD), and accurately imaging the pathology could significantly enhance disease diagnosis and improve patient care.

**Dr. Andrea Pfeifer, CEO of AC Immune SA, commented:** "Fast Track designation for PI-2620 is an important reflection of its potential to accurately diagnose Alzheimer's and other neurodegenerative diseases. Early diagnosis of these conditions will be key for effective treatment before irreversible damage occurs, and is an essential element in our goal of achieving precision prevention. The FDA has previously granted Fast Track status to two of our active immunotherapies in Phase 2 development, ACI-35.030 and ACI-24.060, which target phospho-Tau and Abeta, respectively. The designation for PI-2620 is a further recognition of AC Immune's drug discovery and development platform and of how we, together with our partners, continue to drive innovation."

### About PI-2620

PI-2620 was discovered and developed as part of a research collaboration between AC Immune and LMI. LMI has the exclusive, worldwide license for research, development and commercialization of Tau-PET tracers generated within the discovery program. 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 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, a hallmark of neurodegenerative diseases. PI-2620 is currently under investigation in several clinical studies as a targeted radiopharmaceutical for the detection of Tau deposits in the human brain. PI-2620 also shows promise for non-AD tauopathies like progressive supranuclear palsy (PSP) and corticobasal syndrome (CBS).

### **About AC Immune SA**

AC Immune SA is a clinical-stage biopharmaceutical company and a global leader in precision prevention for neurodegenerative diseases, including Alzheimer's disease, Parkinson's disease, and NeuroOrphan indications driven by misfolded proteins. The Company's two clinically validated technology platforms, SupraAntigen® and Morphomer®, fuel its broad and diversified pipeline of first- and best-in-class assets, which currently features sixteen therapeutic and diagnostic programs, including five in Phase 2 development and one in Phase 3. AC Immune has a strong track record of securing strategic partnerships with leading global pharmaceutical companies, resulting in substantial non-dilutive funding to advance its proprietary programs and >\$4.5 billion in potential milestone payments plus royalties.

SupraAntigen® is a registered trademark of AC Immune SA in the following territories: AU, EU, CH, GB, JP, RU, SG and USA. Morphomer® is a registered trademark of AC Immune SA in CN, CH, GB, JP, KR, NO and RU.

The information on our website and any other websites referenced herein is expressly not incorporated by reference into, and does not constitute a part of, this press release.

### **For further information, please contact:**

#### **SVP, Investor Relations & Corporate Communications**

Gary Waanders, Ph.D., MBA  
AC Immune  
Phone: +41 21 345 91 91  
Email: [gary.waanders@acimmune.com](mailto:gary.waanders@acimmune.com)

#### **U.S. Investors**

Corey Davis, Ph.D.  
LifeSci Advisors  
Phone: +1 212 915 2577  
Email: [cdavis@lifesciadvisors.com](mailto:cdavis@lifesciadvisors.com)

#### **International Media**

Chris Maggos  
Cohesion Bureau  
Phone: +41 79 367 6254  
Email: [chris.maggos@cohesionbureau.com](mailto:chris.maggos@cohesionbureau.com)

### **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.