



AC Immune Partner Life Molecular Imaging Initiates Phase 3 Study of Tau PET Diagnostic PI-2620 for Alzheimer's Disease

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- First Alzheimer's patient imaged with PI-2620 in **ADvance**, the pivotal Phase 3 trial
- PI-2620 potentially best-in-class Tau PET tracer with high binding affinity and selectivity for aggregated Tau
- Tau accumulation, a key Alzheimer's disease pathology, correlates with cognitive impairment

Lausanne, Switzerland, January 18, 2023 – AC Immune SA (NASDAQ: ACIU), a clinical-stage biopharmaceutical company pioneering precision medicine for neurodegenerative diseases, today announced that its collaboration partner, Life Molecular Imaging (LMI), has imaged the first patient in **ADvance**, the pivotal Phase 3 trial of PI-2620, a Tau PET (positron emission tomography) imaging agent for AD (Alzheimer's disease). PI-2620 was discovered in collaboration between AC Immune and LMI and is developed under a strategic collaboration and exclusive licensing agreement with LMI.

Dr. Andrea Pfeifer, Chief Executive Officer of AC Immune SA, commented: "We are delighted to see LMI launching this pivotal Phase 3 trial of PI-2620, our next generation, potentially best-in-class Tau PET tracer. The ability to detect and quantify aggregated Tau with enhanced sensitivity and specificity, will improve our diagnostic confidence and accelerate clinical development of therapeutic interventions. This development underscores the strength of our Morphomer® platform which continues to generate excellent candidates against multiple pathological proteins involved in neurodegenerative diseases."

This histopathology study's objective is to confirm the tracer's safety, diagnostic efficacy and accuracy in detecting and staging Tau pathology of PI-2620 before seeking market approval. The decision to [advance PI-2620 into Phase 3 development in AD](#) was supported by Phase 2 results presented at this year's Alzheimer's Association International Conference (AAIC)¹.

Reference

¹Minyoung Oh et al.; One year longitudinal change of Tau accumulation on [¹⁸F]PI-2620 PET in Alzheimer spectrum; Virtual poster presentation; AAIC 2022

About the [¹⁸F]PI-2620 ADvance Phase 3 Histopathological Study

The **ADvance** Phase 3 trial ([ClinicalTrials.gov: NCT05641688](https://clinicaltrials.gov/ct2/show/study/NCT05641688)) is an open-label, multi-center, non-randomized pivotal study to assess the efficacy and safety of PET imaging with [¹⁸F]PI-2620 for detection of Tau deposition in subjects with Alzheimer's disease (AD) during lifetime when compared to histopathology obtained after death and completion of brain autopsy. It will enroll approximately 200 end-of-life. The primary study objective is to determine the sensitivity and specificity of the visual assessment of PI-2620 images compared to post-mortem histopathological verification of Tau neurofibrillary pathology associated with AD as the standard of truth. Subjects included in the study will include people who have been clinically diagnosed as having AD as well as people without cognitive impairment. All subjects included will undergo ante-mortem PI-2620 PET scan and agree to autopsy and brain donation post-mortem. Abeta PET and MRI scans may also be performed. LMI is currently targeting study completion in 2026.

About PI-2620

PI-2620 was discovered and developed using the Morphomer® platform 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 (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 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 that aims to become a global leader in precision medicine 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 ten therapeutic and three diagnostic candidates, six of which are currently in phase 2 clinical trials. AC Immune has a strong track record of securing strategic partnerships with leading global pharmaceutical companies including Genentech, a member of the Roche Group, Eli Lilly and Company, and others, resulting in substantial non-dilutive funding to advance its proprietary programs and >\$3 billion in potential milestone payments.

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.

About Life Molecular Imaging (LMI)

Life Molecular Imaging (LMI, formerly Piramal Imaging) was formed in 2012 with the acquisition of the molecular imaging research and development portfolio of Bayer Pharma AG. It is now part of the Alliance Medical Group (a member of the Life Healthcare Group) offering an integrated business including research and development laboratories, a network of cyclotrons, radiopharmacies and imaging facilities. By developing novel PET tracers for molecular imaging, LMI is focusing on a key field of modern medicine. The organization strives to be a leader in the Molecular Imaging field by developing innovative products that improve early detection and characterization of chronic and life-threatening diseases, leading to better therapeutic outcomes and improved quality of life. Please visit <https://life-mi.com>.

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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. 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.

Attachment

- [20230118_LMI_PI-2620_P3_Initiation_FINAL](#)



Source: AC Immune SA