



## PRESS RELEASE

# Tau-PET Tracer PI-2620 Could Set New Standards for an Improved Diagnosis of Progressive Supranuclear Palsy

Results published in JAMA Neurology demonstrate the potential for a best-in-class diagnostic tool

BERLIN, Germany and LAUSANNE, Switzerland, July 7, 2020 – Life Molecular Imaging and AC Immune SA (NASDAQ: ACIU) announce the publication of clinical data of the investigational Taupositron emission tomography (PET) tracer PI-2620 in patients with progressive supranuclear palsy (PSP). The tracer is shown to be a promising biomarker for the improved detection and characterization of this currently untreatable, fatal disease.

The observational study, which is published now in *JAMA Neurology*<sup>1</sup>, is a multi-center evaluation led by nuclear medicine physicians and neurologists from Munich and Leipzig, Germany, together with researchers at study sites in New Haven, Cologne and Melbourne. The results indicate that PI-2620 could facilitate an earlier and more reliable diagnosis of PSP, where previous Tau tracers and other biomarkers failed. The accumulation of 4R Tau protein deposits in specific brain regions is a pathological hallmark of PSP. PI-2620 shows signals in those regions of PSP patients and allows excellent discrimination from disease controls at the single-subject level by both visual inspection and quantitative analyses of brain scans.

These new results in PSP further demonstrate PI-2620's excellent characteristics as a strong diagnostic tool for studying Tau-related diseases following recent publications about its capabilities in early and more advanced Alzheimer's disease<sup>2-6</sup>.

PI-2620 was discovered in a research collaboration with Life Molecular Imaging and AC Immune, Life Molecular Imaging has the exclusive world-wide license for research, development and commercialization of Tau-PET tracers generated within the discovery program. PI-2620 is currently under investigation in several clinical studies as a targeted radiopharmaceutical for the detection of Tau deposits in the human brain.

**Dr. Andrew Stephens, Chief Medical Officer at Life Molecular Imaging, said:** "This large multicenter study demonstrates the power of PI-2620 as a biomarker to study 4R Tau-related diseases like PSP. The detection and monitoring of the underlying Tau pathology with PI-2620 for both 4R-Tauopathies like PSP and corticobasal degeneration (CBD), as well as 3R/4R Tauopathies like Alzheimer's disease will advance the field, leading to appropriate patient selection and monitoring target engagement in clinical trials of emerging therapeutic agents."

**Prof. Andrea Pfeifer, CEO of AC Immune SA, added:** "This real-world study provides first evidence that PI-2620 could provide an earlier and more accurate diagnosis of PSP. Highly specific PET tracers are a critical tool in the patient pathway to achieve an accurate diagnosis, a particular challenge in the complex spectrum of neurodegenerative disorders and often not achievable through clinical presentation alone. Such capabilities would enable early, targeted therapeutic

interventions for PSP patients and enhance the research community's ability to better advance more effective treatments and cures."

PSP is an orphan disease that affects up to 18 out of every 100,000 individuals worldwide. Patients can be challenging to diagnose because they show symptoms, such as movement difficulties, stiffness, clumsiness, cognitive impairment and frequent falls that are also present in many neurodegenerative diseases, like Parkinson's disease (PD). Misdiagnosis of PSP hampers drug development due to heterogeneous study populations, mixing patients with Tau-related pathologies and patients suffering from other proteinopathies.

#### References

- Brendel et al. "Assessment of <sup>18</sup>F-PI-2620 as a Biomarker in Progressive Supranuclear Palsy" JAMA Neurology online first: <a href="https://jamanetwork.com/journals/jamaneurology/fullarticle/2768084">https://jamanetwork.com/journals/jamaneurology/fullarticle/2768084</a>
- 2. Kroth *et al.* "Discovery and Preclinical Characterization of <sup>18</sup>F-PI-2620, a Next-Generation Tau PET Tracer for the Assessment of Tau Pathology in Alzheimer's Disease and Other Tauopathies" *Eur J Nucl Med Mol Imaging*. 2019 Sep;46(10):2178-2189
- 3. Mueller *et al.*, "Tau PET imaging with <sup>18</sup>F-PI-2620 in Patients with Alzheimer Disease and Healthy Controls: A First-in-Humans Study" *J Nucl Med.* 2020 Jun;61(6):911-919
- Bullich et al., "Evaluation of Dosimetry, Quantitative Methods, and Test-Retest Variability of <sup>18</sup>F-PI-2620 PET for the Assessment of Tau Deposits in the Human Brain" *J Nucl Med.* 2020 Jun;61(6):920-927
- 5. Beyer *et al.*, "Early-phase <sup>18</sup>F-PI-2620 tau-PET imaging as a surrogate marker of neuronal injury" *Eur J Nucl Med Mol Imaging*. 2020 Apr 21. <a href="https://doi.org/10.1007/s00259-020-04788-w">https://doi.org/10.1007/s00259-020-04788-w</a> Online ahead of print
- Mormino et al., "Tau PET imaging with <sup>18</sup>F-PI-2620 in aging and neurodegenerative diseases". Eur J Nucl Med Mol Imaging. 2020 Jun 23. <a href="https://doi.org/10.1007/s00259-020-04923-7">https://doi.org/10.1007/s00259-020-04923-7</a>
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## About Life Molecular Imaging (LMI)

LMI (formerly Piramal Imaging) was formed in 2012 with the acquisition of the molecular imaging research and development portfolio of Bayer Pharma AG, and is now part of the Alliance Medical Group, 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. LMI 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: <a href="https://life-mi.com">https://life-mi.com</a>

## **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<sup>TM</sup> and Morphomer<sup>TM</sup>, 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 Roche/Genentech, Eli Lilly and Company and Janssen Pharmaceuticals.

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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. Forwardlooking 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.