AC Immune and Takeda Sign Exclusive Option and License Agreement for Active Immunotherapy Targeting Amyloid Beta for Alzheimer's Disease

May 13, 2024

− Takeda to receive exclusive option to license global rights to ACI-24.060, a potential first-in-class active immunotherapy designed to delay or slow Alzheimer's disease progression

− AC Immune to receive upfront payment of $100 million upon closing and be eligible for an option exercise fee and additional potential milestones of up to approximately $2.1 billion

− AC Immune to host conference call and webcast today at 8:30 a.m. ET

OSAKA, Japan & CAMBRIDGE, Mass & LAUSANNE, Switzerland--(BUSINESS WIRE)--May 13, 2024-- Takeda **(TSE:4502/NYSE:TAK)** and AC Immune SA (NASDAQ: ACIU) today announced an exclusive, worldwide option and license agreement for AC Immune's active immunotherapies targeting toxic forms of amyloid beta (Abeta), including ACI-24.060 for the treatment of Alzheimer's disease.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20240510475155/en/

ACI-24.060 is an anti-Abeta active immunotherapy candidate designed to induce a robust antibody response against the toxic forms of Abeta believed to drive plaque formation and Alzheimer's disease progression. By inducing plaque clearance and efficiently inhibiting plaque formation in the brain, ACI-24.060 has the potential to delay or slow Alzheimer's disease progression. ACI-24.060 is being investigated in the ongoing ABATE randomized, double-blind, placebo-controlled Phase 1b/2 trial to assess the safety, tolerability, immunogenicity and pharmacodynamic effects of the investigational immunotherapy in subjects with prodromal Alzheimer's disease and in adults with Down syndrome.

"As pioneers in the field of active immunotherapy, we are developing an innovative approach that could change the treatment paradigm for Alzheimer's disease and address the multifaceted burden that patients and the broader community face. We believe the maximum impact of ACI-24.060 can best be realized by partnering with Takeda at this critical juncture in its development, which will help us move rapidly into Phase 3," said Dr. Andrea Pfeifer, CEO of AC Immune. "This agreement allows us to leverage the developmental expertise, strategic vision and financial capacity of an accomplished organization that has demonstrated its ability to execute the type of comprehensive global program required for Phase 3 trials in Alzheimer's disease while allowing us to focus on completing Phase 1b/2 development and accelerating our efforts to replicate this success with enhanced funding for our early-stage pipeline."

AC Immune will be responsible for completing the ABATE trial. Following option exercise, Takeda would conduct and fund all further clinical development and be responsible for all global regulatory activities as well as worldwide commercialization.

"At Takeda, we are committed to tackling some of society's most debilitating illnesses, including Alzheimer's disease. We are excited to partner with AC Immune on this ground-breaking treatment approach, which leverages novel technology with the potential to offer patients a treatment with differentiated efficacy, safety and ease of administration," said Sarah Sheikh, M.Sc., B.M., B.Ch, MRCP, Head, Neuroscience Therapeutic Area Unit and Head, Global Development at Takeda. "Combining AC Immune's deep experience with active immunotherapy approaches with Takeda's expertise in neuroscience drug development and commercialization, we have an incredible opportunity to deliver real impact to the Alzheimer's community."

Under the terms of the agreement, AC Immune will receive an upfront payment of $100 million and be eligible to receive an option exercise fee and additional potential development, commercial and sales-based milestones of up to approximately $2.1 billion if all related milestones are achieved over the course of the agreement. Upon commercialization, AC Immune will be entitled to receive tiered double-digit royalties on worldwide net sales.

Further details related to the agreement are available in the Form 6-K filed today by AC Immune with the U.S. Securities and Exchange Commission (SEC). The effectiveness of Takeda's license following option exercise is subject to the termination or expiration of any applicable waiting periods under the Hart-Scott-Rodino Act.

Conference Call and Webcast Information

AC Immune management will host a conference call and webcast today at 8:30 a.m. ET to provide a brief overview of the agreement.

Monday, May 13 at 8:30 a.m. ET
Participants wishing to ask questions or to join the event via phone may call the following numbers 10 – 15 minutes before conference start:

United States	+1 (1) 631 570 56 13
Switzerland / Europe	+41 (0) 58 310 50 00
United Kingdom	+44 (0) 207 107 06 13
Other international numbers available	HERE

Webcast:
https://event.choruscall.com/mediaframe/webcast.html?webcastid=YteAZhdg
Please note that there is a function to type in your questions via webcast.

A live and archived webcast will also be accessible in the Investors section of the Company's website at https://www.acimmune.com/.

About ACI-24.060

This product is AC Immune's anti-Abeta active immunotherapy candidate. The ABATE randomized, double-blind, placebo-controlled Phase 1b/2 trial of ACI-24.060 for treatment of Alzheimer's disease (AD) continues fully blinded (NCT05462106). Enrolled patients are required to have a diagnosis of prodromal AD: MCI due to AD according to the National Institute on Aging Alzheimer's Association (NIA-AA) criteria, and a PET scan at screening must be consistent with the presence of amyloid pathology. Patients will be randomized to one of several doses of ACI-24.060 or placebo. Following multiple data safety monitoring board (DSMB) reviews, no safety concerns have been raised to date, consistent with previous results. Immunogenicity of the immunotherapy is very encouraging with clear evidence of anti-Abeta antibody responses against toxic Abeta species observed in the blinded data. The six-month Abeta positron emission tomography (PET) imaging results are expected in Q2 2024, and the 12-month Abeta PET data are expected in Q4 2024.

About Takeda
Takeda is focused on creating better health for people and a brighter future for the world. We aim to discover and deliver life-transforming treatments in our core therapeutic and business areas, including gastrointestinal and inflammation, rare diseases, plasma-derived therapies, oncology, neuroscience and vaccines. Together with our partners, we aim to improve the patient experience and advance a new frontier of treatment options through our dynamic and diverse pipeline. As a leading values-based, R&D-driven biopharmaceutical company headquartered in Japan, we are guided by our commitment to patients, our people and the planet. Our employees in approximately 80 countries and regions are driven by our purpose and are grounded in the values that have defined us for more than two centuries. For more information, visit www.takeda.com.

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 sixteen therapeutic and diagnostic programs, five of which are currently in Phase 2 clinical trials and one of which is 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.

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.

Takeda Important Notice
For the purposes of this notice, "press release" means this document, any oral presentation, any question and answer session and any written or oral material discussed or distributed by Takeda Pharmaceutical Company Limited ("Takeda") regarding this release. This press release (including any oral briefing and any question-and-answer in connection with it) is not intended to, and does not constitute, represent or form part of any offer, invitation or solicitation of any offer to purchase, otherwise acquire, subscribe for, exchange, sell or otherwise dispose of, any securities or the solicitation of any vote or approval in any jurisdiction. No shares or other securities are being offered to the public by means of this press release. No offering of securities shall be made in the United States except pursuant to registration under the U.S. Securities Act of 1933, as amended, or an exemption therefrom. This press release is being given (together with any further information which may be provided to the recipient) on the condition that it is for use by the recipient for information purposes only (and not for the evaluation of any investment, acquisition, disposal or any other transaction). Any failure to comply with these restrictions may constitute a violation of applicable securities laws.

The companies in which Takeda directly and indirectly owns investments are separate entities. In this press release, "Takeda" is sometimes used for convenience where references are made to Takeda and its subsidiaries in general. Likewise, the words "we", "us" and "our" are also used to refer to subsidiaries in general or to those who work for them. These expressions are also used where no useful purpose is served by identifying the particular company or companies.

Takeda Forward-Looking Statements
This press release and any materials distributed in connection with this press release may contain forward-looking statements, beliefs or opinions regarding Takeda's future business, future position and results of operations, including estimates, forecasts, targets and plans for Takeda. Without limitation, forward-looking statements often include words such as "targets", "plans", "believes", "hopes", "continues", "expects", "aims", "intends", "ensures", "will", "may", "should", "would", "could", "anticipates", "estimates", "projects", "forecasts", "outlook" or similar expressions or the negative thereof. These forward-looking statements are based on assumptions about many important factors, including the following, which could cause actual results to differ materially from those expressed or implied by the forward-looking statements: the economic circumstances surrounding Takeda's global business, including general economic conditions in Japan and the United States; competitive pressures and developments; changes to applicable laws and regulations; challenges inherent in new product development, including uncertainty of clinical success and decisions of regulatory authorities and the timing thereof; uncertainty of commercial success for new and existing products; manufacturing difficulties or delays; fluctuations in interest and currency exchange rates; claims or concerns regarding the safety or efficacy of marketed products or product candidates; the impact of health crises, like the novel coronavirus pandemic; the success of our environmental sustainability efforts, in enabling us to reduce our greenhouse gas emissions or meet our other environmental goals; the extent to which our efforts to increase efficiency, productivity or cost-savings, such as the integration of digital technologies, including artificial intelligence, in our business or other initiatives to restructure our operations will lead to the expected benefits; and other factors identified in Takeda's most recent Annual Report on Form 20-F and Takeda's other reports filed with the U.S. Securities and Exchange Commission, available on Takeda's website at: https://www.takeda.com/investors/sec-filings-and-security-reports/ or at www.sec.gov. Takeda does not undertake to update any of the forward-looking statements contained in this press release or any other forward-looking statements it may make, except as required by law or stock exchange rule. Past performance is not an indicator of future results and the results or statements of Takeda in this press release may not be indicative of, and are not an estimate, forecast, guarantee or projection of Takeda's future results.

AC Immune 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.

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AC Immune Investor and Media Contacts:

SVP, Investor Relations & Corporate Communications
Gary Waanders, Ph.D., MBA
AC Immune
Phone: +41 21 345 91 91
gary.waanders@acimmune.com

U.S. Investors
Corey Davis, Ph.D.
LifeSci Advisors
Phone: +1 212 915 2577
cdavis@lifesciadvisors.com

U.S. and International Media
Chris Maggos Cohesion Bureau
Phone: +41 79 367 6254
chris.maggos@cohesionbureau.com

Takeda Media Contacts:

Japanese Media
Yuko Yoneyama
yuko.yoneyama@takeda.com
+81 70-2610-6609

U.S. and International Media
Chris Stamm
chris.stamm@takeda.com
+1 617-374-7726

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