Regeneron and Zai Lab Announce Regional Strategic Collaboration for REGN1979 (CD20xCD3 Bispecific Antibody)

April 8, 2020

Zai Lab obtains rights to develop and exclusively commercialize REGN1979 in oncology in mainland China, Hong Kong, Taiwan and Macau

Collaboration will also support enrollment of regional patients into Regeneron's global trials evaluating REGN1979 in B-cell non-Hodgkin lymphoma (B-NHL)

Zai Lab to host conference call and webcast today at 8:00 a.m. EST

TARRYTOWN, N.Y. and SHANGHAI, China, April 08, 2020 (GLOBE NEWSWIRE) -- Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) and Zai Lab Limited (NASDAQ: ZLAB) today announced a strategic collaboration for the development and commercialization of REGN1979 (CD20xCD3 bispecific antibody) in mainland China, Hong Kong, Taiwan and Macau. The collaboration will support global clinical development for REGN1979, starting with the ongoing potentially registrational Phase 2 program in B-cell non-Hodgkin lymphoma (B-NHL). Additionally, if REGN1979 is approved, Zai Lab will leverage its capabilities to commercialize REGN1979 in this region. REGN1979 is the most advanced investigational bispecific monoclonal antibody from Regeneron's bispecific platform and is designed to trigger tumor killing by linking and activating a cytotoxic T-cell (binding to CD3) to a lymphoma cell (binding to CD20).

Under the terms of the agreement, Regeneron will receive a $30 million upfront payment and is eligible to receive up to $160 million in additional regulatory and sales milestones. Zai Lab will contribute to the global development costs for REGN1979 for certain trials and will receive the rights to develop and exclusively commercialize REGN1979 in oncology in mainland China, Hong Kong, Taiwan and Macau. Additionally, Zai Lab will make payments to Regeneron based on net sales, such that Regeneron shares in a significant portion of any potential profits. Regeneron will be responsible for the manufacture and supply of REGN1979 for development and commercialization in the region.

"Zai Lab is an ideal collaborator for us, with an established and respected track record that aligns with our mission to use the power of science to repeatedly bring new medicines to patients with serious diseases," said Israel Lowy, M.D., Ph.D., Senior Vice President and Head of Clinical and Translational Sciences for Oncology at Regeneron. "Zai's support will not only help bolster enrollment into global REGN1979 trials, but will also enable this promising investigational medicine to reach patients faster in this key region, if approved."

"Regeneron is a global leader in the research and development of innovative medicines, and we are delighted to collaborate on the investigational bispecific antibody REGN1979 as we expand our oncology franchise into hematologic cancers," said Samantha Du, Ph.D., Founder, Chairperson and Chief Executive Officer at Zai Lab. "Zai looks forward to contributing significantly to the success of REGN1979 with our regulatory and clinical expertise, and commercial footprint in mainland China, Hong Kong, Taiwan and Macau. We are committed to collaborating with Regeneron to expand its global effort and bring innovative medicines to patients with unmet medical needs."

REGN1979 was granted orphan drug designation by the U.S. Food and Drug Administration (FDA) for the treatment of follicular lymphoma (FL) and diffuse large B-cell lymphoma (DLBCL). REGN1979 is currently being investigated as a treatment for late stages of FL, DLBCL and other lymphomas in a Phase 1 trial as well as a potentially registrational Phase 2 trial. Positive data for REGN1979 from the Phase 1 trial were last shared at the 2019 American Society of Hematology (ASH) Annual Meeting.

Conference Call and Webcast Information

Zai Lab will host a live conference call and webcast today, April 8, 2020 at 8:00 a.m. EST to discuss the strategic collaboration. Listeners may access the live webcast by visiting the Company's website at http://ir.zailaboratory.com. Participants must register in advance of the conference call. Details are as follows:

Registration Link: http://apac.directeventreg.com/registration/event/4299594

Conference ID: 4299594

All participants must use the link provided above to complete the online registration process in advance of the conference call. Upon registering, each participant will receive a dial-in number, Direct Event passcode, and a unique access PIN, which can be used to join the conference call.

A replay will be available shortly after the call and can be accessed by visiting the Company's website at http://ir.zailaboratory.com.

About the Regeneron Bispecific Antibody Platform
All of Regeneron's bispecifics are designed to closely resemble natural human antibodies and bind to two different targets. They are derived from a next-generation version of Regeneron's proprietary *VelocImmune*® technology that utilizes a proprietary genetically-engineered mouse platform endowed with a genetically-humanized immune system to produce optimized fully-human antibodies and further created using the company's *Veloci-Bi*® platform. These allow for the creation of bispecifics with no linkers or artificial sequences. Additionally, Regeneron bispecifics are manufactured using similar approaches used for human antibody medicines, with similar pharmacokinetics.

VelocImmune has been used to create multiple antibodies including Dupixent® (dupilumab), Praluent® (alirocumab), Libtayo® (cemiplimab-rwlc) and Kevzara® (sarilumab), which are approved in multiple countries around the world. Regeneron previously used these technologies to rapidly develop a treatment for Ebola virus infection, which is currently under review by the FDA, and is now being used in efforts to create prophylactic and treatment medicines for COVID-19.

There are six Regeneron investigational bispecific antibodies currently in ongoing clinical trials for multiple blood cancers and solid tumors. These bispecifics fall into three categories:

- **CD3 bispecifics** are designed to bridge T-cells and tumor cells. At the tumor site, they activate T-cells via their CD3 receptors and promote T-cell killing of the cancer cells. Investigational candidates include:
  - CD20xCD3 (REGN1979) for non-Hodgkin B-cell lymphomas;
  - Two distinct BCMAxCD3s (REGN5458 and REGN5459) for multiple myeloma;
  - MUC16xCD3 (REGN4018) for ovarian cancer.
- **CD28 costimulatory bispecifics** are also designed to bridge T-cells and tumor cells. At the tumor site, they costimulate T-cells via their CD28 receptors and may synergize with PD-1 inhibitors and/or CD3 bispecifics. Investigational candidates include:
  - PSMAxCD28 (REGN5678) in combination with Libtayo for prostate cancer.
- **Tumor-targeted bispecifics** are designed to target proteins only on the cancer cell. In this way, they may affect various signaling pathways to hamper the cancer cell's ability to survive and proliferate. Investigational candidates include:
  - METxMET (REGN5093) for non-small cell lung cancer that is driven by MET mutations and/or amplifications. REGN5093 targets two different parts of the MET receptor on cancer cells to degrade the receptor and block its ability to trigger cell proliferation.

Regulatory Status of Regeneron Oncology Programs
The bispecifics mentioned in this press release are currently under clinical development, and their safety and efficacy have not been fully evaluated by any regulatory authority.

Libtayo in combination with REGN5678 is currently under clinical development for prostate cancer, and its safety and efficacy have not been evaluated by any regulatory authority for this use. Libtayo is currently approved in the U.S. for the treatment of patients with metastatic cutaneous squamous cell carcinoma (CSCC) or locally advanced CSCC who are not candidates for curative surgery or curative radiation, and in other countries for similar indications. In the U.S., the generic name for Libtayo is cemiplimab-rwlc, with rwlc as the suffix designated in accordance with Nonproprietary Naming of Biological Products Guidance for Industry issued by the U.S. Food and Drug Administration.

As part of a global collaboration agreement, Regeneron and Sanofi are jointly developing Libtayo, as well as Regeneron's BCMAxCD3 and MUC16xCD3 bispecific programs.

About B-cell non-Hodgkin lymphoma (B-NHL) in China
Non-Hodgkin lymphomas (NHL) represent a diverse group of cancers that originate from B-, T- or natural killer-cells, with annual incidence and death rates in China of more than 88,000 and 48,000, respectively, as of 2018. NHL originating in B-cells (B-NHL) make up 85% of all NHL cases, with the two most common subtypes being DLBCL and FL.

DLBCL is an aggressive form of B-NHL with up to 50% of patients with advanced stage disease progressing after first-line treatment (e.g., relapsing or becoming refractory to treatment). For patients with R/R DLBCL, treatment options are limited and the prognosis is poor.

FL is a slow-growing (indolent) form of B-NHL with most cases diagnosed in advanced stages. Although median survival ranges from 8 to 15 years in advanced FL, current therapeutic options are not curative, and most patients relapse within 5 years regardless of the regimen. In some cases, FL can transform into DLBCL, at which point it is often treated in the same way as DLBCL.

About Regeneron Pharmaceuticals
Regeneron (NASDAQ: REGN) is a leading biotechnology company that invents life-transforming medicines for people with serious diseases. Founded and led for over 30 years by physician-scientists, our unique ability to repeatedly and consistently translate science into medicine has led to seven FDA-approved treatments and numerous product candidates in development, all of which were homegrown in our laboratories. Our medicines and pipeline are designed to help patients with eye diseases, allergic and inflammatory diseases, cancer, cardiovascular and metabolic diseases, pain, infectious diseases and rare diseases.

Regeneron is accelerating and improving the traditional drug development process through our proprietary *VelociSuite*® technologies, such as *VelocImmune* which uses unique genetically-humanized mice to produce optimized fully-human antibodies and bispecific antibodies, and through ambitious research initiatives such as the Regeneron Genetics Center, which is conducting one of the largest genetics sequencing efforts in the world.

For additional information about the company, please visit www.regeneron.com or follow @Regeneron on Twitter.

About Zai Lab
Zai Lab (NASDAQ:ZLAB) is a China and U.S.-based innovative commercial stage biopharmaceutical company focused on bringing transformative medicines for cancer, infectious and autoimmune diseases to patients in China and around the world. To quickly target the large, fast-growing segments of China's pharmaceutical market and address unmet medical needs, Zai Lab's experienced team has secured partnerships with leading global biopharma companies, generating a broad pipeline of innovative drug candidates. Zai Lab has also built an in-house team with strong drug discovery and translational research capabilities, aiming to establish a global pipeline of proprietary drug candidates against targets in our focus areas. Zai Lab's vision is to become a fully integrated biopharmaceutical company, discovering, developing, manufacturing and commercializing its portfolio in order to impact human health worldwide.

For additional information about the company, please visit www.zailaboratory.com.

Regeneron Forward-Looking Statements

This press release includes forward-looking statements that involve risks and uncertainties relating to future events and the future performance of Regeneron Pharmaceuticals, Inc. ("Regeneron" or the "Company"), and actual events or results may differ materially from these forward-looking statements. Words such as "anticipate," "expect," "intend," "plan," "believe," "seek," "estimate," variations of such words, and similar expressions are intended to identify such forward-looking statements, although not all forward-looking statements contain these identifying words. These statements concern, and these risks and uncertainties include, among others, the impact of SARS-CoV-2 (the virus that has caused the COVID-19 pandemic) on Regeneron's business and its employees, collaborators, suppliers, and other third parties on which Regeneron relies, Regeneron's and its collaborators' ability to continue to conduct research and clinical programs, Regeneron's ability to manage its supply chain, net product sales of products marketed by Regeneron and/or its collaborators (collectively, "Regeneron's Products"), and the global economy; the nature, timing, and possible success and therapeutic applications of Regeneron's Products and Regeneron's product candidates and research and clinical programs now underway or planned, such as the programs discussed in this press release evaluating REGN1979 in collaboration with Zai Lab Limited (including the program evaluating REGN1979 for the treatment of B-cell non-Hodgkin lymphoma) and Regeneron's other investigational bispecific antibodies; the extent to which the results from the research and development programs conducted by Regeneron and/or its collaborators (including based on the collaboration discussed in this press release) may be replicated in other studies and lead to therapeutic applications; the potential for any license or collaboration agreement, including Regeneron's agreements with Sanofi, Bayer, and Teva Pharmaceutical Industries Ltd. (or their respective affiliated companies, as applicable), as well as Regeneron's collaboration with Zai Lab Limited discussed in this press release, to be cancelled or terminated without any further product success; the likelihood, timing, and scope of possible regulatory approval and commercial launch of Regeneron's product candidates and new indications for Regeneron's Products, such as REGN1979 for the treatment of follicular lymphoma, diffuse large B-cell lymphoma, and other lymphomas; unforeseen safety issues resulting from the administration of Regeneron's Products and product candidates (such as REGN1979) in patients, including serious complications or side effects in connection with the use of Regeneron's Products and product candidates in clinical trials; determinations by regulatory and administrative governmental authorities which may delay or restrict Regeneron's ability to continue to develop or commercialize Regeneron's Products and product candidates, including without limitation REGN1979; ongoing regulatory obligations and oversight impacting Regeneron's Products, research and clinical programs, and business, including those relating to patient privacy; uncertainty of market acceptance and commercial success of Regeneron's Products and product candidates and the impact of studies (whether conducted by Regeneron or others and whether mandated or voluntary) on the commercial success of Regeneron's Products and product candidates; the availability and extent of reimbursement of Regeneron's Products from third-party payers, including private payer healthcare and insurance programs, health maintenance organizations, pharmacy benefit management companies, and government programs such as Medicare and Medicaid; coverage and reimbursement determinations by such payers and new policies and procedures adopted by such payers; competing drugs and product candidates that may be superior to Regeneron's Products and product candidates; the ability of Regeneron to manufacture and manage supply chains for multiple products and product candidates; the ability of Regeneron's collaborators, suppliers, or other third parties (as applicable) to perform manufacturing, filling, finishing, packaging, labeling, distribution, and other steps related to Regeneron's Products and product candidates; unanticipated expenses; the costs of developing, producing, and selling products; the ability of Regeneron to meet any of its financial projections or guidance and changes to the assumptions underlying those projections or guidance; and risks associated with intellectual property of other parties and pending or future litigation relating thereto (including without limitation the patent litigation and other related proceedings relating to Dupixent® (dupilumab) and Praluent® (alirocumab)), other litigation and other proceedings and government investigations relating to the Company and/or its operations, the ultimate outcome of any such proceedings and investigations, and the impact any of the foregoing may have on Regeneron's business, prospects, operating results, and financial condition. A more complete description of these and other material risks can be found in Regeneron's filings with the U.S. Securities and Exchange Commission, including its Form 10-K for the year ended December 31, 2019. Any forward-looking statements are made based on management's current beliefs and judgment, and the reader is cautioned not to rely on any forward-looking statements made by Regeneron. Regeneron does not undertake any obligation to update publicly any forward-looking statement, including without limitation any financial projection or guidance, whether as a result of new information, future events, or otherwise.

Regeneron uses its media and investor relations website and social media outlets to publish important information about the Company, including information that may be deemed material to investors. Financial and other information about Regeneron is routinely posted and is accessible on Regeneron's media and investor relations website (http://newsroom.regeneron.com) and its Twitter feed (http://twitter.com/regeneron).

Zai Lab Forward-Looking Statements

This press release contains statements about future expectations, plans and prospects for Zai Lab, including, without limitation, statements regarding business strategy, plans and objectives for future operations of REGN1979 within mainland China, Hong Kong, Taiwan and Macau. Such statements constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are not statements of historical fact nor are they guarantees or assurances of future performance. Forward-looking statements are based on Zai Lab's expectations and assumptions as of the date of this press release and are subject to inherent uncertainties, risks and changes in circumstances that may differ materially from those contemplated by the forward-looking statements. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including but not limited to (1) Zai Lab's ability to obtain additional future funding, (2) Zai Lab's results of clinical and pre-clinical development of its drug candidates, (3) the content and timing of decisions made by the relevant regulatory authorities regarding regulatory approvals of Zai Lab's drug candidates, (4) Zai Lab's ability to generate revenue from its drug candidates, and (5) other factors discussed in Zai Lab's Annual Report on Form 20-F for the fiscal year ended December 31, 2018 and its other filings with the Securities and Exchange Commission. Zai Lab anticipates that subsequent events and developments will cause Zai Lab's expectations and assumptions to change and undertakes no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required by law. These forward-looking statements should not be relied upon as representing Zai Lab's views as of any date subsequent to the date of this press release.

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