Regeneron and SillaJen Announce Immuno-Oncology Clinical Study Agreement for Combination Treatment in Kidney Cancer

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TARRYTOWN, N.Y. and SAN FRANCISCO and SEOUL, South Korea, May 8, 2017 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) and SillaJen, Inc. (KOSDAQ: 215600) today announced a new clinical and supply agreement for a Phase 1b dose-escalation study in renal cell carcinoma (RCC), or kidney cancer. The study will evaluate Regeneron's PD-1 inhibitor, REGN2810, in combination with SillaJen's oncolytic vaccinia virus, Pexa-Vec, in patients with previously treated metastatic or unresectable renal cell carcinoma.

The open-label trial is expected to begin later this year, and is designed to evaulate the safety and efficacy of REGN2810 in combination with Pexa-Vec compared to treatment with REGN2810 as monotherapy. The study will initially open in Korea, with expansion to sites in the U.S.

Renal cell carcinoma is the most common type of kidney cancer in adults, and accounts for approximately three percent of adult malignancies and 90-95 percent of neoplasms arising from the kidney.

"We are pleased to announce this immuno-oncology agreement with Regeneron—another company doing groundbreaking work in oncology," said Eun Sang Moon, MD, DDS, Chief Executive Officer of SillaJen. "We believe that there may be synergies between our compounds and look forward to investigating this in our upcoming clinical trial in renal cell carcinoma."

Pexa-Vec has been shown to increase inflammation in the tumor micro-environment and potentially reverse the immunosuppressive microenvironment by activating T-cell mediated anti-tumor immune response. This may help "prime" the tumor by increasing sensitivity to anti-PD-1 treatment, such as REGN2810.

"Pairing our PD-1 inhibitor with other innovative approaches like Pexa-Vec allows us to evaluate multiple routes in the quest to provide important new treatments to people in need," Israel Lowy, MD, PhD, Vice President of Translation Sciences and Oncology, Regeneron. "Renal cell carcinoma is a devastating and currently under-treated disease, and combination therapies that enable the body's immune response in novel ways may help improve these patients' lives."

Under the terms of the agreement, the trial will be solely conducted and funded by SillaJen based upon a mutually developed study design," and Regeneron will provide REGN2810. Regeneron, in collaboration with Sanofi, is developing REGN2810 both alone and in combination with other therapies for the treatment of various cancers.

"Given the results reported thus far for monotherapy anti-PD1 immunotherapy and initial studies of Pexa-Vec for the treatment of advanced kidney cancer, we believe the combination of Pexa-Vec and REGN-2810 holds great promise," stated James Burke, MD, Chief Medical Officer of SillaJen. "This combination immunotherapy approach in RCC joins the oncolytic immunotherapy expertise of SillaJen with the well-known leadership of Regeneron in antibody targeted therapies."

About Pexa-Vec and the SOLVE Platform
Pexa-Vec is the most advanced product candidate from SillaJen's proprietary SOLVE™ (Selective Oncolytic Vaccinia Engineering) platform. The vaccinia strain backbone of Pexa-Vec has been used safely in millions of people as part of a worldwide vaccination program, and over 300 cancer patients have been treated with Pexa-Vec to date. Pexa-Vec was engineered to target common genetic defects in cancer cells by deleting its thymidine kinase (TK) gene, thus making Pexa-Vec dependent on the cellular TK expressed at persistently high levels in cancer cells. Pexa-Vec is also engineered to express GM-CSF protein. GM-CSF complements the cancer cell lysis of the product candidate, leading to a cascade of events resulting in tumor necrosis, tumor vasculature shutdown and sustained anti-tumoral immune attack. Pexa-Vec has been shown to be effective when delivered both intratumorally and systemically by intravenous administration. Pexa-Vec is currently being evaluated in a worldwide Phase 3 clinical trial for advanced primary liver cancer, and more information can be found at http://www.pexavectrials.com.

About Regeneron Pharmaceuticals, Inc.
Regeneron (NASDAQ: REGN) is a leading science-based biopharmaceutical company that discovers, invents, develops, manufactures and commercializes medicines for the treatment of serious medical conditions. Regeneron commercializes medicines for eye diseases, high LDL-cholesterol, atopic dermatitis and a rare inflammatory condition and has product candidates in development in other areas of high unmet medical need, including rheumatoid arthritis, asthma, pain, cancer and infectious diseases. For additional information about the company, please visit www.regeneron.com or follow @Regeneron on Twitter.

About SillaJen
SillaJen, Inc. (KOSDAQ: 215600) is a South Korean-based biotechnology company headquartered in Busan, South Korea, with satellite offices in Seoul, South Korea and San Francisco, CA. The company is focused on the development and commercialization of oncolytic immunotherapy products using the SOLVE ™platform, including its lead product Pexa-Vec, which is currently in Phase 3 trials for the treatment of advanced primary liver cancer. Additional information about SillaJen is available at **www.sillajen.com**.

Regeneron Forward-Looking Statements and Use of Digital Media
This news 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 nature, timing, and possible success and therapeutic applications of

Regeneron's products, product candidates, and research and clinical programs now underway or planned, including without limitation Regeneron's immuno-oncology program, REGN2810 (Regeneron's PD-1 inhibitor), and the Phase 1b dose-escalation study evaluating the combination therapy consisting of REGN2810 and SillaJen, Inc.'s oncolytic vaccinia virus, Pexa-Vec, in patients with previously treated metastatic or unresectable renal cell carcinoma (the "RCC Combination Therapy"); unforeseen safety issues resulting from the administration of products and product candidates in patients, including serious complications or side effects in connection with the use of Regeneron's and its collaborators' product candidates in clinical trials, such as the RCC Combination Therapy; 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; the likelihood, timing, and scope of possible regulatory approval and commercial launch of Regeneron's late-stage product candidates and new indications for marketed products; ongoing regulatory obligations and oversight impacting Regeneron's marketed products, research and clinical programs (such as the trial evaluating the RCC Combination Therapy), and business, including those relating to patient privacy; competing drugs and product candidates that may be superior to Regeneron's products and product candidates; 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 ability of Regeneron's collaborators, suppliers, or other third parties to perform filling, finishing, packaging, labelling, distribution, and other steps related to Regeneron's products and product candidates; coverage and reimbursement determinations by third-party payers, including Medicare and Medicaid; the ability of Regeneron to manufacture and manage supply chains for multiple products and product candidates; unanticipated expenses; the costs of developing, producing, and selling products; the ability of Regeneron to meet any of its sales or other financial projections or guidance and changes to the assumptions underlying those projections or guidance; the potential for any license or collaboration agreement, including Regeneron's agreements with Sanofi, Bayer HealthCare LLC, and Teva Pharmaceutical Industries Ltd. (or their respective affiliated companies, as applicable), as well as Regeneron's clinical study agreement with SillaJen, Inc. discussed in this news release, to be cancelled or terminated without any further product success; and risks associated with intellectual property of other parties and pending or future litigation relating thereto, including without limitation the patent litigation relating to Praluent® (alirocumab) Injection, the permanent injunction granted by the United States District Court for the District of Delaware that, if upheld on appeal, would prohibit Regeneron and Sanofi from marketing, selling, or commercially manufacturing Praluent in the United States, the outcome of any appeals regarding such injunction, the ultimate outcome of such litigation, 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 United States Securities and Exchange Commission, including its Form 10-K for the year ended December 31, 2016 and its Form 10-Q for the quarterly period ended March 31, 2017. 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).

SillaJen Forward-Looking Statement:
This press release contains certain forward-looking statements regarding, among other things, statements relating to goals, plans and projections regarding the Company's financial position, results of operations, market position, product development and business strategy. Such forward-looking statements are based on current expectations and involve inherent risks and uncertainties, including factors that could delay, divert or change any of them, and could cause actual outcomes and results to differ materially from current expectations. No forward-looking statements can be guaranteed and actual results may differ materially from such statements. The information in this release is provided only as of the date of this release, and SillaJen undertakes no obligation to update any forward-looking statements contained in this release on account of new information, future events, or otherwise, except as required by law.

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