Alexion and Halozyme Enter License Agreement for ENHANZE Technology

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--Halozyme to Receive $40 Million Upfront Payment, Future Milestones and Royalties--

--Provides Alexion Access to ENHANZE Technology for up to Four Targets--

NEW HAVEN, Conn. & SAN DIEGO--(BUSINESS WIRE)--Alexion Pharmaceuticals, Inc. (NASDAQ:ALXN) and Halozyme Therapeutics, Inc. (NASDAQ:HALO) announced today a collaboration and license agreement that enables Alexion to use Halozyme’s ENHANZE® drug-delivery technology in the development of subcutaneous formulations for their portfolio of products. The agreement provides Alexion with the opportunity for exclusive development of up to four targets, including a next generation subcutaneous formulation of ALXN1210 (ALXN1210 SC), the company’s investigational long-acting C5 complement inhibitor, to potentially further extend the dosing interval of ALXN1210 SC to once every two weeks or once per month.

“Alexion’s goal is to provide continued innovation and more treatment options that can significantly improve the lives of patients with rare diseases,” said John Orloff, M.D., Executive Vice President and Head of Research & Development at Alexion. “We are excited to partner with Halozyme and look forward to utilizing its ENHANZE technology, which enables rapid injection of subcutaneous treatments and potentially increases bioavailability, in our development programs.”

“We are delighted to support Alexion’s innovative development initiatives focused on improving the lives of patients with rare diseases,” said Dr. Helen Torley, president and CEO of Halozyme. “ENHANZE has become the industry standard for converting intravenous therapies to a subcutaneous delivery, helping partners and health care providers reduce the treatment burden and administration time for patients.”

Under the terms of the agreement, Halozyme will receive an initial $40 million with the potential to earn additional payments of up to $160 million for each target developed, subject to achievement of specified development, regulatory and sales-based milestones. Halozyme will also receive mid-single digit royalties on sales of commercialized products.

The Halozyme ENHANZE technology is based on a proprietary recombinant human hyaluronidase enzyme (rHuPH20) that temporarily degrades hyaluronan -- a glycosaminoglycan or chain of natural sugars in the body -- to aid in the dispersion and absorption of other injected therapeutic drugs. For Halozyme partners, this technology may allow for more rapid delivery of injectable medications through subcutaneous injection (just under the skin). This delivery has been shown in studies to reduce health care practitioner time required for administration and shorten time for drug administration.

Alexion is Halozyme’s eighth global collaboration and license partner for the ENHANZE technology, and the third partnership formed in 2017. These partnerships cover nearly 50 therapeutic targets and include three commercialized products.

About Alexion

Alexion is a global biopharmaceutical company focused on developing and delivering life-transforming therapies for patients with devastating and rare disorders. Alexion is the global leader in complement inhibition and has developed and commercializes the first and only approved complement inhibitor to treat patients with paroxysmal nocturnal hemoglobinuria (PNH), atypical hemolytic uremic syndrome (aHUS), and anti-acetylcholine receptor (AchR) antibody-positive generalized myasthenia gravis (gMG). In addition, Alexion has two highly innovative enzyme replacement therapies for patients with life-threatening and ultra-rare metabolic disorders, hypophosphatasia (HPP) and lysosomal acid lipase deficiency (LAL-D).
As the leader in complement biology for over 20 years, Alexion focuses its research efforts on novel molecules and targets in the complement cascade, and its development efforts on the core therapeutic areas of hematology, nephrology, neurology, and metabolic disorders. Alexion’s lead development program is ALXN1210, an innovative, long-acting C5 inhibitor that is currently being evaluated in Phase 3 clinical studies as a potential treatment for patients with paroxysmal nocturnal hemoglobinuria (PNH) and atypical hemolytic uremic syndrome (aHUS) administered intravenously every eight weeks. Alexion also plans to initiate a single, PK-based Phase 3 clinical study of ALXN1210 delivered subcutaneously once per week as a potential treatment for patients with PNH or aHUS. In addition, Alexion plans to explore studying longer dosing intervals of subcutaneous administration of ALXN1210, including every other week and once per month, using the ENHANZE technology. This press release and further information about Alexion can be found at: www.alexion.com.

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About Halozyme

Halozyme Therapeutics is a biotechnology company focused on developing and commercializing novel oncology therapies that target the tumor microenvironment. Halozyme's lead proprietary program, investigational drug PEGPH20, applies a unique approach to targeting solid tumors, allowing increased access of co-administered cancer drug therapies to the tumor in animal models. PEGPH20 is currently in development for metastatic pancreatic cancer, non-small cell lung cancer, gastric cancer, metastatic breast cancer and has potential across additional cancers in combination with different types of cancer therapies. In addition to its proprietary product portfolio, Halozyme has established value-driving partnerships with leading pharmaceutical companies including Roche, Baxalta, Pfizer, Janssen, AbbVie, Lilly and Bristol-Myers Squibb for its ENHANZE® drug delivery technology. Halozyme is headquartered in San Diego. For more information visit www.halozyme.com.

Alexion Safe Harbor Statement

This news release contains forward-looking statements, including statements related to the potential benefits that may be achieved through the license agreement with Halozyme, the potential benefits, safety, efficacy and clinical effects of ALXN1210, the timing and status of regulatory filings, and the potential of Alexion's development programs. Forward-looking statements are subject to factors that may cause Alexion's results and plans to differ from those expected, including for example, decisions of regulatory authorities regarding the adequacy of our research, marketing approval or material limitations on the marketing of our products, delays, interruptions or failures in the manufacture and supply of our products and our product candidates, failure to satisfactorily address matters raised by the FDA and other regulatory agencies, the possibility that results of clinical trials are not predictive of safety and efficacy results of our products in broader patient populations, the possibility that current rates of adoption of Soliris in PNH, aHUS or other diseases are not sustained, the possibility that clinical trials of our product candidates could be delayed, the adequacy of our pharmacovigilance and drug safety reporting processes, the risk that third party payors (including governmental agencies) will not reimburse or continue to reimburse for the use of our products at acceptable rates or at all, uncertainties surrounding legal proceedings, company investigations and government investigations, including investigations of Alexion by the U.S. Securities and Exchange Commission (SEC) and U.S. Department of Justice, the risk that anticipated regulatory filings are delayed, the risk that estimates regarding the number of patients with PNH, aHUS, gMG, HPP and LAL-D are inaccurate, the risks of changing foreign exchange rates, risks relating to the potential effects of the Company's restructuring and relocation of its corporate headquarters, and a variety of other risks set forth from time to time in Alexion's filings with the SEC, including but not limited to the risks discussed in Alexion's Quarterly Report on Form 10-Q for the period ended September 30, 2017 and in Alexion's other filings with the SEC. Alexion does not intend to update any of these forward-looking statements to reflect events or circumstances after the date hereof, except when a duty arises under law.

Halozyme Safe Harbor Statement

In addition to historical information, the statements set forth above include forward-looking statements including, without limitation, statements concerning the possible activity, benefits and attributes of ENHANZE, the possible method of action of ENHANZE, its potential application to aid in the dispersion and absorption of other injected therapeutic drugs, the number of collaborative targets actually chosen, whether such products are ultimately developed or commercialized, whether milestones triggering milestone payments will be achieved, and statements concerning facilitating more rapid delivery of injectable medications through subcutaneous delivery that involve risk and uncertainties that could cause actual results to differ materially from those in the forward-looking statements. The forward-looking statements are typically, but not always, identified through use of the words "believe," "enable," "may," "will," "could," "intends," "estimate," "anticipate," "plan," "predict," "probable," "potential," "possible," "should," "continue," and other words of similar meaning. Actual results could differ materially from the expectations contained in forward-looking statements as a result of several factors, including unexpected expenditures and costs, unexpected results or delays in development and
regulatory review, regulatory approval requirements, unexpected adverse events and competitive conditions. These and other factors that may result in differences are discussed in greater detail in Halozyme’s Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission. Except as required by law, Halozyme undertakes no duty to update forward-looking statements to reflect events after the date of this release.

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English
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