Alexion and Affibody Announce Partnership to Co-Develop Anti-FcRn Affibody® Molecule

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- Agreement provides opportunity to expand Alexion's clinical-stage anti-FcRn portfolio with ABY-039 -

- Affibody to receive $25 million upfront payment with potential for additional milestone-dependent and royalty payments, and option for U.S. co-promote -

- Affibody's technology offers potential for extended half-life compared to other anti-FcRn therapies and low volume subcutaneous administration -

BOSTON & SOLNA, Sweden--(BUSINESS WIRE)--Mar. 20, 2019-- Alexion Pharmaceuticals, Inc. (NASDAQ:ALXN) and Affibody AB today announced a partnership to co-develop ABY-039 for rare Immunoglobulin G (IgG)-mediated autoimmune diseases. Currently in Phase 1 development, ABY-039 is a bivalent antibody-mimetic that targets the neonatal Fc receptor (FcRn). ABY-039 has been specifically designed to combine Affibody's protein therapeutics platform (Affibody® molecules) and Albumod™ technology to achieve a long half-life, which, along with its small size provides the potential for less frequent, convenient, at-home subcutaneous administration.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20190320005268/en/

"We believe there is significant opportunity to transform patient care with FcRn-targeted therapies and are thrilled to add a second clinical-stage anti-FcRn medicine to our pipeline with this collaboration," said John Orloff, M.D., Executive Vice President and Head of Research & Development at Alexion. "While clinical development is still early, we are excited by ABY-039's potential to be an optimal subcutaneous therapy across a number of IgG-mediated diseases, providing patients with the possibility of a convenient self-administered treatment option."

"ABY-039 offers an innovative and novel approach to treating IgG-mediated diseases. Its rapid onset, sustained response, long half-life and potential for low volume administration hold great promise as a self-administered subcutaneous anti-FcRn therapy of choice," said David Bejker, Chief Executive Officer of Affibody. "We look forward to building our partnership with Alexion and leveraging their significant development and commercial experience to accelerate the development of ABY-039. This collaboration is another key step in the evolution of our company that is aligned with our key strategic objectives."

ABY-039 is being evaluated in a Phase 1 study in healthy volunteers. This adaptive, double-blind, placebo-controlled study is evaluating the safety, tolerability, pharmacokinetics and pharmacodynamics of ABY-039 and will aid in dose selection for future studies. The companies are assessing potential indications for future development.

Under the terms of the agreement, Alexion will provide Affibody with an upfront payment of $25 million, with the potential for additional development- and sales-based milestones of up to $625 million and tiered low double-digit royalty payments. Alexion will lead joint clinical development of ABY-039 and commercialization activities. Affibody has the option to co-promote ABY-039 in the U.S. and will lead clinical development for an undisclosed indication.

The companies expect to close the transaction in the second quarter of 2019, subject to clearance under the Hart-Scott Rodino Antitrust Improvements Act.

Alexion will discuss the partnership further during today's Investor Day event and webcast.

About FcRn
Antibodies play an important role in a healthy body's defense by fighting infections from bacteria and other invaders. In autoimmune diseases, however, the body mistakenly attacks itself through the production of pathogenic (disease-causing) antibodies of the Immunoglobulin G (IgG) subtype. Neonatal Fc receptor (FcRn) rescues IgGs from lysosomal degradation by binding them to endosomes and returning them to the bloodstream. This helps prolong the half-life of IgG. In healthy individuals, this function contributes to a normal immune response. In many autoimmune conditions, however, FcRn prevents lysosomal degradation of pathogenic IgGs associated with driving the disease. Therefore, blocking the FcRn-IgG interaction has the potential to drive degradation of IgG within cells and rapidly reduce circulating pathogenic IgG.

About ABY-039
ABY-039 is a novel anti-FcRn antibody-mimetic, which has been specifically designed to utilize the advantages of Affibody's technology platform to differentiate from competing antibody and Fc-based approaches. ABY-039 is a small protein ligand (~19 kDa, approximately an eighth of the size of an antibody) and has an in vivo half-life exceeding that of antibody-based approaches.

About Affibody's Technology Platform
Affibody® molecules are a class of small optimized proteins with high affinity based on a non-immunoglobulin three-helix bundle domain scaffold. Affibody® molecules have certain potentially advantageous features for therapeutic applications including (i) small size resulting in rapid tissue penetration and efficient delivery of higher molar doses for the same mass vs. larger proteins, and (ii) robustness resulting in potential for alternative administration routes. The Albumod™ Platform uses a small optimized protein with an albumin binding domain (5 kDa) with high affinity to albumin (sub pM) to provide half-life extension and a wider distribution profile than antibodies to Affibody® molecules and other therapeutic proteins. The Affibody® technology, which includes the Affibody® molecules (6 kDa size, no Fc function) and Albumod™ platform, enables modified and enhanced pharmacokinetics through the albumin binding domain, offering the same distribution profile as albumin.

About Alexion

Alexion is a global biopharmaceutical company focused on serving patients and families affected by rare diseases through the discovery, development and commercialization of life-changing therapies. As the global leader in complement biology and inhibition for more than 20 years, Alexion has developed and commercializes two approved complement inhibitors to treat patients with paroxysmal nocturnal hemoglobinuria (PNH) as well as the first and only approved complement inhibitor to treat atypical hemolytic uremic syndrome (aHUS) and anti-acetylcholine receptor (AchR) antibody-positive generalized myasthenia gravis (gMG), and is also developing it for patients with neuromyelitis optica spectrum disorder (NMOSD). Alexion also 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). In addition, the company is developing several mid-to-late-stage therapies, including a second complement inhibitor, a copper-binding agent for Wilson disease and an anti-neonatal Fc receptor (FcRn) antibody for rare Immunoglobulin G (IgG)-mediated diseases as well as several early-stage therapies, including one for light chain (AL) amyloidosis and a second anti-FcRn therapy. 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 has been named to the *Forbes* list of the World's Most Innovative Companies seven years in a row and is headquartered in Boston, Massachusetts' Innovation District. The company also has offices around the globe and serves patients in more than 50 countries. This press release and further information about Alexion can be found at: www.alexion.com.

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About Affibody
Affibody is a private clinical-stage Swedish biotech company focused on developing into an integrated biopharma company utilizing next generation biotherapeutics based on its unique proprietary technology platforms: Affibody® molecules and Albumod™. The company operates a focused experimental medicine model and currently has three clinical-stage programs. The first two are therapeutic programs that target psoriasis and rare Immunoglobulin G (IgG)-mediated autoimmune diseases. The third program is a diagnostic imaging program that is directed primarily towards metastatic breast cancer. In addition to its portfolio of innovative drug projects, the company offers the half-life extension technology, Albumod™, for outlicensing. For more information on Affibody, please visit the company's website at www.affibody.com.

Affibody AB is a holding of Patricia Industries, a subsidiary of investment holding company Investor AB. Investor AB, a Swedish investment company founded in 1916 by the Wallenberg family, is the leading owner of high quality Nordic-based international companies. The company makes controlled investments in leading companies with strong market positions, brands and corporate cultures within industries positioned for secular growth with the ambition to be the sole owner of their companies, together with strong management teams and boards.

Forward-Looking Statement
This press release includes forward-looking statements, including statements related to the therapeutic and commercial potential of ABY-039, the research and development plans for ABY-039, the potential of ABY-039 and other anti-FcRn-targeted therapies and the potential benefits of the collaboration. Such forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied in such statements. The process by which an early stage product such as ABY-039 could potentially lead to an approved product is long and subject to highly significant risks, 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 manufacture and supply, failure to satisfactorily address matters raised by the U.S. Food and Drug Administration and other regulatory agencies, the possibility that results of clinical trials are not predictive of safety and efficacy results in broader patient populations, the possibility that clinical trials could be delayed, the risk that anticipated regulatory filings are delayed, 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 Annual Report on Form 10-K for the fiscal year ended December 31, 2018 and in Alexion's other filings with the SEC. Alexion and Affibody AB disclaim any obligation to update any of these forward-looking statements to reflect events or circumstances after the date hereof, except when a duty arises under law.

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