argenx announces orphan drug designation for ARGX-113 for the treatment of myasthenia gravis

Non-regulated information

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Breda, the Netherlands / Ghent, Belgium - argenx (Euronext & Nasdaq: ARGX), a clinical-stage biotechnology company developing a deep pipeline of differentiated antibody-based therapies for the treatment of severe autoimmune diseases and cancer, today announced that the Office of Orphan Products Development of the U.S. Food and Drug Administration (FDA) has granted orphan status for the use of ARGX-113 for the treatment of myasthenia gravis.

MG is an autoimmune disorder associated with muscle weakness that is triggered by IgG auto-antibodies. These antibodies attack critical signalling proteins at the junction between nerve and muscle cells, thereby impairing their communications signals. There are limited effective and sustainable treatments for MG. ARGX-113 has the potential to eliminate patient symptoms while minimizing common side effects seen with current treatments by reducing the pathogenic IgG levels.

About orphan drug designation
Orphan drug status is granted by FDA to a drug or biological product to treat a rare disease or condition upon request of a sponsor. Orphan drug designation qualifies for various development incentives, including tax credits for qualified clinical testing, a waiver from FDA's application User Free for marketing application, and a 7-year period of marketing exclusivity in the US.
The granting of an orphan designation request does not alter the standard regulatory requirements and process for obtaining marketing approval. Safety and effectiveness of a drug must be established through adequate and well-controlled studies.

About ARGX-113
ARGX-113 is an investigational therapy for treatment of IgG-mediated autoimmune diseases. ARGX-113 is the Fc-portion of an antibody that has been modified by the argenx proprietary ABDEG(TM) technology to increase its affinity for FcRn beyond that of normal IgG antibodies. As a result, ARGX-113 blocks antibody recycling and leads to fast depletion of the autoimmune disease-causing IgG autoantibodies. The development work on ARGX-113 is done in close collaboration with Prof. E. Sally Ward (University of Texas Southwestern Medical and Texas A&M University Health Science Center, a part of Texas A&M University (TAMHSC)).

About argenx
argenx is a clinical-stage biotechnology company developing a deep pipeline of differentiated antibody-based therapies for the treatment of severe autoimmune diseases and cancer. We are focused on developing product candidates with the potential to be either first-in-class against novel targets or best-in-class against known, but complex, targets in order to treat diseases with a significant unmet medical need. Our ability to execute on this focus is enabled by our suite of differentiated technologies. Our SIMPLE Antibody(TM) Platform, based on the powerful llama immune system, allows us to exploit novel and complex targets, and our three antibody engineering technologies are designed to enable us to expand the therapeutic index of our product candidates.
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Forward-looking Statements

The contents of this announcement include statements that are, or may be deemed to be, "forward-looking statements." These forward-looking statements can be identified by the use of forward-looking terminology, including the terms "believes," "estimates," "anticipates," "expects," "intends," "may," "will," or "should," and include statements argenx makes concerning the intended results of its strategy and argenx's advancement of, and anticipated clinical development and regulatory milestones and plans related to ARGX-113. By their nature, forward-looking statements involve risks and uncertainties and readers are cautioned that any such forward-looking statements are not guarantees of future performance. argenx's actual results may differ materially from those predicted by the forward-looking statements as a result of various important factors, including argenx's expectations regarding its the inherent uncertainties associated with competitive developments, preclinical and clinical trial and product development activities and regulatory approval requirements; argenx's reliance on collaborations with third parties; estimating the commercial potential of argenx's product candidates; argenx's ability to obtain and maintain protection of intellectual property for its technologies and drugs; argenx's limited operating history; and argenx's ability to obtain additional funding for operations and to complete the development and commercialization of its product candidates. A further list and description of these risks, uncertainties and other risks can be found in argenx's U.S. Securities and Exchange Commission (SEC) filings and reports, including in the final prospectus related to argenx's initial U.S. public offering filed with the SEC pursuant to Rule 424(b) of the Securities Act of 1933, as amended, as well as subsequent filings and reports filed by argenx with the SEC. Given these uncertainties, the reader is advised not to place any undue reliance on such forward-looking statements. These forward-looking statements speak only as of the date of publication of this document. argenx undertakes no obligation to publicly update or revise the information in this press release, including any forward-looking statements, except as may be required by law.