argenx Announces Receipt of First Milestone Payment under Janssen Collaboration and Provides Data Update from Phase 1 Dose Escalation Trial of Cusatuzumab in Acute Myeloid Leukemia at ASH Annual Meeting

-argenx to receive $25 million from Janssen for achievement of enrollment milestone in first Phase 2 trial under collaboration

December 7, 2019

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 the receipt of a development milestone payment from Janssen and the presentation of updated data from the Phase 1 dose escalation trial of cusatuzumab in combination with azacytidine for the treatment of newly diagnosed acute myeloid leukemia (AML) at the 61st American Society of Hematology (ASH) Annual Meeting.

argenx will receive the first development milestone payment of $25 million from its global collaboration and license agreement with Cilag GmbH International, an affiliate of the Janssen Pharmaceutical Companies of Johnson & Johnson. The milestone payment was triggered by the achievement of a prespecified enrollment threshold in the first trial to start under the collaboration. This dose-confirming Phase 2 pivotal CULMINATE trial of cusatuzumab is being conducted in combination with azacytidine for the treatment of newly diagnosed elderly patients with AML who are unfit for intensive chemotherapy.

“This milestone payment marks the progress made across our global collaboration with Janssen. Two trials are now underway in newly diagnosed populations with more trials expected to intiate next year in different AML settings and subpopulations. We continue to believe in the potential of the CD70/CD27 axis as a novel approach within the AML treatment landscape. The data update today further support the use of cusatuzumab in combination to treat this vulnerable patient population,” commented Tim Van Hauwermeiren, Chief Executive Officer of argenx.

Key Highlights from ASH

Adrian Ochsenbein, M.D. from the University of Bern presented translational data in support of the dual modes of action of cusatuzumab, including the blocking of CD70/CD27 signaling to stop proliferation of leukemic stem cells and cell killing via Fc-dependent, complement-dependent cytotoxicity and enhanced antibody-dependent cellular cytotoxicity (ADCC) via POTELLIGENT® technology. Dr. Ochsenbein also showed updated data as of the new cut-off date of February 2019 from the Phase 1 dose escalation trial of cusatuzumab in combination with azacytidine in 12 newly diagnosed elderly patients with AML who are unfit for intensive chemotherapy.

- 100% of patients achieved a response including eight with a complete response (CR), two with a complete response with incomplete hematologic recovery (CRi), and two with a partial response (PR); 83% of patients achieved either a CR or CRi
- Of the nine CR/CRi patients evaluable for minimal residual disease (MRD) negativity, four achieved MRD negativity using a threshold of 10^{-3} which is consistent with the previous data cut-off in October 2018
- Four patients have remained in the study for at least 12 months
- Three patients from the study have been re-classified with risk category based on new mutation information or a reassessment of existing mutation information
- Cusatuzumab continued to be well-tolerated in patients with AML across the different doses

In addition to the CULMINATE trial in the newly diagnosed unfit AML population, cusatuzumab is also being evaluated in a Phase 1b platform study to explore combinations with standard AML therapies with the first trial exploring combinations of venetoclax, cusatuzumab and azacytidine.

About argenx
argenx is a clinical-stage biotechnology company developing a deep pipeline of differentiated antibody-based therapies for the treatment of severe auto-immune diseases and cancer. The company is 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. argenx’s ability to execute on this focus is enabled by its suite of differentiated technologies. The SIMPLE Antibody™ Platform, based on the powerful llama immune system, allows argenx to exploit novel and complex targets, and its three complementary Fc engineering technologies are designed to expand the therapeutic index of its 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. 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 argenx's most recent annual report on Form 20-F filed with the SEC 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.