



argenx to regain global rights to cusatuzumab

Regulated Information/Inside Information

June 7, 2021

Breda, the Netherlands – argenx SE (Euronext & Nasdaq: ARGX), a global immunology company committed to improving the lives of people suffering from severe autoimmune diseases and cancer, today announced it will regain worldwide rights to its anti-CD70 antibody cusatuzumab from Cilag GmbH International, one of the Janssen Pharmaceutical Companies of Johnson & Johnson. Interim data from the Phase 1b ELEVATE trial support continued development in acute myeloid leukemia (AML) and argenx plans to evaluate options to enable a path forward.

"We have valued the productive collaboration with Janssen that has advanced our understanding of cusatuzumab and its role in AML biology. Together we have generated clinical and translational data that have optimized the dose of cusatuzumab and further characterized its effect on cells in the bone marrow," said Tim Van Hauwermeiren, Chief Executive Officer of argenx. "We set our target high with the ELEVATE trial, recognizing that cusatuzumab would have to add benefit to an already-established combination regimen. We believe these interim data show that cusatuzumab could be meaningful to AML patients. We plan to evaluate all alternatives to advance cusatuzumab on behalf of the AML community, while maintaining our focus on our priorities - the launch of efgartigimod and the development of our autoimmune pipeline."

The ongoing Phase 1b ELEVATE trial is evaluating cusatuzumab in combination with venetoclax and azacitidine in newly-diagnosed, elderly patients with AML. The intent-to-treat (ITT) population included 44 patients. Early efficacy analyses conducted in all evaluable patients (N=42) after ongoing patients had completed at least two disease evaluations showed:

- Complete remission (CR) was observed in 48% (20/42), composite complete remission (CRc) including CRs with incomplete hematologic recovery was observed in 81% (34/42), and overall response rate (ORR) in 93% (39/42) of the evaluable population.
- Cusatuzumab was observed to be well-tolerated and the safety profile was consistent with prior studies.
- ELEVATE is ongoing; complete results will be presented in an upcoming peer-reviewed forum.

Additionally, ongoing translational research on AML patient bone marrow samples from the Phase 2 CULMINATE trial show a decrease in primitive, monocytic-like blasts and leukemic stem cells, and an increase in normal myeloid cells, following treatment with cusatuzumab and azacitidine.

The collaboration and licensing agreement between argenx and Janssen was initiated in 2018 to develop cusatuzumab to treat AML and myelodysplastic syndromes (MDS). Under the terms of the agreement, argenx received \$300 million in an upfront payment, approximately \$200 million in an equity investment from Johnson & Johnson Innovation – JJDC, Inc. (JJDC), and \$25 million in milestone payments to date. argenx was notified of Janssen's decision to discontinue the collaboration agreement during a regularly scheduled steering committee meeting on June 4, 2021. Following termination of the collaboration, argenx can elect that Janssen operationally support the treatment and follow-up of patients enrolled in ongoing cusatuzumab clinical trials.

About argenx

argenx is a global immunology company committed to improving the lives of people suffering from severe autoimmune diseases and cancer. Partnering with leading academic researchers through its Immunology Innovation Program (IIP), argenx aims to translate immunology breakthroughs into a world-class portfolio of novel antibody-based medicines. argenx is evaluating efgartigimod in multiple serious autoimmune diseases. argenx is also advancing several earlier stage experimental medicines within its therapeutic franchises. argenx has offices in Belgium, the United States, Japan, and Switzerland. For more information, visit www.argenx.com and follow us on [LinkedIn](#).

For further information, please contact:

Media:

Kelsey Kirk
kkirk@argenx.com

Joke Comijn
jcomijn@argenx.com

Investors:

Beth DelGiacco
bdelgiacco@argenx.com

Michelle Greenblatt
mgreenblatt@argenx.com

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," "could," "estimates," "anticipates," "expects," "intends," "plan," "may," "will," or "should" and include statements argenx makes concerning the clinical and commercial potential of cusatuzumab and future clinical studies of cusatuzumab and statements concerning continued operational support to be provided by Janssen following termination of the collaboration agreement. 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 the effects of the COVID-19 pandemic, 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.