
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER
PURSUANT TO RULE 13a-16 OR 15d-16
UNDER THE SECURITIES EXCHANGE ACT OF 1934

For the Month of November 2018

Commission File Number: 001-38097

ARGENX SE

(Translation of registrant's name into English)

Willemstraat 5

4811 AH, Breda, the Netherlands

(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F ☒ Form 40-F ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): ☐

argenx SE

On November 1, 2018, argenx SE (the “Company”) issued a press release, a copy of which is attached hereto as Exhibit 99.1 and is incorporated by reference herein.

The information contained in this Current Report on Form 6-K, including Exhibit 99.1, is incorporated by reference into the Company’s Registration Statements on Forms F-3 (File No. 333-225370) and S-8 (File No. 333-225375).

EXHIBITS

Exhibit	Description
99.1	Press Release dated November 1, 2018
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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ARGENX SE

Date: November 1, 2018

By: /s/ Dirk Beeusaert
Dirk Beeusaert
General Counsel



Regulated information – Inside information

argenx announces new cusatuzumab (ARGX-110) AML data in abstracts published in connection with 60th American Society of Hematology Annual Meeting and Exposition

- 92% overall response rate with durability up to 14.4 months in ongoing analysis of Phase 1/2 trial
- Updated results from Phase 1/2 trial of cusatuzumab in CTCL also published

November 1, 2018

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 updated data from the ongoing Phase 1 dose-escalation part of its Phase 1/2 clinical trial of cusatuzumab (ARGX-110) in acute myeloid leukemia (AML) and high-risk myelodysplastic syndromes (MDS). As of the data cut-off on July 16, 2018, a 92% (11/12 patients) overall response rate (ORR) was observed, with 42% of patients achieving minimal residual disease (MRD) negativity. The median response duration was 6.9 months as of the data cut-off date.

Data from this ongoing AML trial are expected to be further updated, including ORR and duration of response, during a company workshop to be held around the American Society of Hematology (ASH) Annual Meeting.

“The clinical data published today are encouraging and underscore our decision to move forward into a Phase 2 clinical trial of cusatuzumab in AML, which we launched earlier this year. These data also support the deep understanding of the disease biology of CD70 as demonstrated by the preclinical work of our collaborators at the University of Bern, highlighting cusatuzumab’s potential to offer a novel mechanism of action in AML against leukemic blasts and leukemic stem cell compartments,” commented Nicolas Leupin, MD, Chief Medical Officer of argenx. “We look forward to providing an update on key metrics from the Phase 1 dose-escalation of the Phase 1/2 trial, including response rate and duration of response, at our annual workshop around ASH.”

Phase 1/2 Results for Cusatuzumab in AML

In this trial, argenx evaluated the safety, tolerability and efficacy of cusatuzumab in combination with azacytidine (AZA) in an open-label, Phase 1/2 clinical trial in 12 newly diagnosed AML patients unfit for intensive chemotherapy. The data published today are from all 12 patients across four dose cohorts (1 mg/kg, 3 mg/kg, 10 mg/kg and 20 mg/kg) from the Phase 1/2 dose-escalation trial.

As of the data cut-off on July 16, 2018, the ORR across the 12 patients was 92% (11/12 patients), including 9 patients (82%) with a complete response with or without hematologic recovery (CR/CRi), 1 patient (9%) who reached morphologic leukemia-free status, and 1 (9%) partial response (PR). The median duration on study as of data cut-off was 6.9 months, ranging from 2 to 14.4 months, with 7 patients still on study. Five patients (42%) achieved MRD negativity as measured by flow cytometry. Translational data demonstrated that cusatuzumab monotherapy and in combination with AZA

significantly reduced leukemic stem cells in the bone marrow of AML patients. Cusatuzumab continued to be well-tolerated in AML patients across the different doses. More details can be found [here](#).

Cusatuzumab in Cutaneous T-cell Lymphoma

argenx also announced today updated results from its non-randomized, open-label, multicenter Phase 1/2 trial of cusatuzumab in 27 patients with cutaneous T-cell lymphoma (CTCL). More details can be found [here](#).

argenx announced in May 2018 that it is no longer devoting resources to the development of cusatuzumab in CTCL in order to focus on the drug candidate's potential in AML.

About Cusatuzumab

Cusatuzumab (ARGX-110) is an investigational SIMPLE Antibody™ targeting CD70, an immune checkpoint target involved in hematological malignancies, several solid tumors and severe autoimmune diseases. Cusatuzumab is designed to: block CD70, kill cancer cells expressing CD70 through complement dependent cytotoxicity, enhanced antibody-dependent cell-mediated phagocytosis and enhanced antibody-dependent cell-mediated cytotoxicity, and restore immune surveillance against solid tumors (*Silence K. et al. mAbs 2014; 6 (2):523-532*). Cusatuzumab is currently being evaluated in patients with hematological malignancies, including a Phase 1/2 trial in combination with azacitidine in patients with newly diagnosed acute myeloid leukemia (AML) and high-risk myelodysplastic syndromes (MDS) and the Phase 2 part of a Phase 1/2 trial in patients with relapsed/refractory cutaneous T-cell lymphoma (CTCL). Preclinical work on cusatuzumab in AML was performed in collaboration with the Tumor Immunology Lab of Prof. A. F. Ochsenbein at the University of Bern, who won, together with Prof. Manz at the University Hospital of Zürich, the prestigious 2016 *Otto Naegeli Prize* for his breakthrough research on CD70/CD27 signaling with therapeutic potential for cancer patients.

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. 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 and argenx’s advancement of, and anticipated clinical development, data readouts and regulatory milestones and plans, including the timing of planned clinical trials and expected data readouts, related to cusatuzumab. 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.
