

---

---

**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 August 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 August 29, 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).*

2

---

**EXHIBITS**

<u>Exhibit</u>	<u>Description</u>
99.1	Press Release dated August 29, 2018

3

---

**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: August 29, 2018

By: /s/ Dirk Beeusaert  
Dirk Beeusaert  
General Counsel

4

---



## argenx receives feedback from Japan's PMDA on Phase 3 clinical trial and regulatory pathway for efgartigimod in generalized myasthenia gravis

August 29, 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 it has received feedback from the Pharmaceuticals and Medical Devices Agency (PMDA) in Japan on the design of a Phase 3 trial and regulatory pathway towards potential marketing authorization of efgartigimod (ARGX-113) in patients with generalized myasthenia gravis (gMG).

Based on feedback from the PMDA, argenx expects the data from the planned global Phase 3 registration trial, if positive, will serve as the basis to submit for marketing authorization in Japan.

"Japan represents a very important potential market for us and one we see as a top priority as we advance the development of efgartigimod in gMG patients globally. There remains a significant unmet need in Japan for new treatment options for MG, and we are grateful for the feedback from the PMDA in facilitating a regulatory path towards achieving this goal," commented Keith Woods, Chief Operating Officer of argenx. "We look forward to launching the global Phase 3 trial of efgartigimod in gMG before the end of the year, including in sites across Japan, and continuing the ongoing discussions with the PMDA as we map out a potential path to market for our drug candidate, if approved."

The global Phase 3 trial expects to enroll approximately 150 patients with gMG, including patients from Japan as well as North America and Europe. The trial will be placebo-controlled and will evaluate the efficacy over 26 weeks of a 10 mg/kg dose of efgartigimod in approximately 150 gMG patients, including both acetylcholine receptor (AChR) autoantibody positive and AChR autoantibody negative patients whose disease is driven primarily by MuSK and LRP4 autoantibodies. In addition, patients can roll over into an open-label extension study for a period of one year.

argenx plans to initiate the global Phase 3 registration trial of efgartigimod in gMG before the end of 2018. Data from the trial, if positive, may also serve as the basis for a Biologics License Application (BLA) in the U.S. based on feedback from the U.S. Food and Drug Administration (FDA).

### About efgartigimod

Efgartigimod (ARGX-113) is an investigational therapy for IgG-mediated autoimmune diseases and was designed to exploit the natural interaction between IgG antibodies and the recycling receptor FcRn. Efgartigimod is the Fc-portion of an antibody that has been modified by the argenx proprietary ABDEG™ technology to increase its affinity for FcRn beyond that of normal IgG antibodies. As a result, efgartigimod blocks antibody recycling through FcRn binding and leads to fast depletion of the autoimmune disease-causing IgG autoantibodies. The development work on efgartigimod is conducted 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. 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. [www.argenx.com](http://www.argenx.com)

### For further information, please contact:

Joke Comijn, Director Corporate Communications & Investor Relations (EU)  
+32 (0)477 77 29 44  
+32 (0)9 310 34 19  
[info@argenx.com](mailto:info@argenx.com)

Beth DelGiacco, VP Investor Relations (US)  
+1 518 424 4980  
[bdelgiacco@argenx.com](mailto:bdelgiacco@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," "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, including the timing of planned clinical trials and expected data readouts, related to efgartigimod; and the commercial potential of efgartigimod. 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.

---