argenx reports first quarter 2019 financial results and provide business update

May 9, 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 financial results and provided a business update for the first quarter ended March 31, 2019.

“During the first quarter, we advanced our broad clinical development plan of efgartigimod across four autoimmune indications in both our IV and subcutaneous formulations. Enrollment of our Phase 3 ADAPT clinical trial in generalized myasthenia gravis is on track, and we intend to launch a second Phase 3 program in primary immune thrombocytopenia in the second half of 2019 that will encompass both formulations. There remains a gap in autoimmune disease innovation for therapies that are specific and well-tolerated, and it is this need that drives us in our goal to deliver our FcRn antagonist to patients quickly,” commented Tim Van Hauwermeiren, chief executive officer of argenx. “We also closed on our global collaboration with Janssen this quarter, receiving $500 million in upfront payments, to evaluate cusatuzumab for acute myeloid leukemia, myelodysplastic syndromes and other potential hematological indications.”

“We look forward to our upcoming R&D Day where we will showcase our formula for translating immunology breakthroughs into first-in-class medicines and unveil two new antibody assets in our wholly-owned pipeline.”

FIRST QUARTER 2019 AND RECENT HIGHLIGHTS

Pipeline Updates:

Efgartigimod (ARGX-113) Program

- Phase 3 ADAPT clinical trial, including one-year open-label extension study, is ongoing for treatment of generalized myasthenia gravis with topline data expected in 2020.
- argenx on track to launch global development program in primary immune thrombocytopenia (ITP) in second half 2019; update expected to be provided in third quarter 2019 on development strategy and regulatory feedback, including planned registration path and plan to bridge between intravenous (IV) and subcutaneous (SC) formulations.
  - Orphan drug designation granted in February 2019 by U.S. Food and Drug Administration (FDA) for treatment of primary ITP.
  - Ongoing open-label extension study from completed Phase 2 proof-of-concept clinical trial in ITP expected to close in mid-2019 in preparation for start of Phase 3 development program.
- Phase 2 proof-of-concept clinical trial ongoing for treatment of pemphigus vulgaris; data expected in 2020.
- Phase 2 clinical trial for treatment of chronic inflammatory demyelinating polyneuropathy expected to start in second half of 2019.
- Phase 1 clinical trial in healthy volunteers planned with ENHANZE® SC formulation of efgartigimod as part of collaboration with Halozyme announced in February 2019; data expected before end of 2019.
  - Collaboration provides argenx access to ENHANZE® subcutaneous delivery technology for up to three targets, including exclusive rights to develop therapeutic products targeting human neonatal Fc receptor FcRn.
  - Upfront payment of $30 million paid to Halozyme with potential future payments up to $160 million per selected target subject to achievement of specified development, regulatory and sales-based milestones.

Cusatuzumab (ARGX-110) Program

- Announced closing of exclusive global collaboration and license agreement with Janssen for cusatuzumab.
  - Received $300 million upfront cash payment, and Johnson & Johnson Innovation made equity investment of €176.7 million ($200.0 million based on exchange rate on date of signing) in argenx.
  - argenx retains right to co-promote cusatuzumab in United States and share such royalties with Janssen on 50-50 basis.
- Orphan drug designation granted by FDA in January 2019 for treatment of acute myeloid leukemia.

Additional Collaborations

- Received first clinical milestone payment of $30 million for initiation of first-in-human clinical trial with antibody product candidate ABBV-151 (ARGX-115) as part of option agreement with AbbVie.

Corporate Updates

- Torsten Dreier will resign from his function as chief development officer of argenx to focus on new role as chief development officer of AgomAb, a company founded through collaboration with argenx to advance ARGX-114, an HFG-mimetic SIMPLE Antibody® directed against the MET receptor. Mr. Dreier will continue to serve as a consultant to argenx.
- argenx Japan KK is being established as a wholly-owned subsidiary, and Hermann Strenger was appointed as General Manager of argenx Japan. In this role, Mr. Strenger will be responsible for all aspects of early commercial planning for efgartigimod in Japan. He has served in executive positions in the pharmaceutical industry in Japan for the last 23 years.

argenx R&D Day

- argenx to host its second R&D Day on Thursday, May 22, 2019, to present new pipeline programs

ARGX-117 and ARGX-118.

Q1 2019 FINANCIAL RESULTS

in thousands of €	Three months ended March 31, 2019	2018	Variance
Revenue	€ 36,453	€ 5,570	€ 30,883
Other operating income	3,564	1,324	2,240
Total operating income	**40,017**	**6,894**	**33,123**
Research and development expenses	(34,752)	(15,146)	(19,606)
Selling, general and administrative expenses	(11,306)	(5,894)	(5,412)
Operating loss	€ **(6,041)**	€ **(14,146)**	€ **8,105**
Financial income	3,458	481	2,977
Exchange gain/(losses)	9,512	(3,990)	13,502
Profit/(Loss) before taxes	€ **6,929**	€ **(17,656)**	€ **24,585**
Income tax expense	€ (180)	€ —	€ (180)
Profit/(Loss) for the period and total comprehensive loss	€ **6,749**	€ **(17,656)**	€ **24,405**
Weighted average number of shares outstanding	37,497,705	32,313,340	
Basic profit/(loss) per share (in €)	0.18	(0.55)	
Diluted profit/(loss) per share (in €)	0.17	(0.55)	
Net increase in cash, cash equivalents and current financial assets compared to year-end 2018 and 2017	397,052	(13,197)	
Cash, cash equivalents and current financial assets at the end of the period	961,621	346,577	

argenx adopted IFRS 16 on January 1, 2019, in accordance with the transitional provisions of IFRS 16, using the modified retrospective approach.

Details of Financial Results

Cash, cash equivalents and current financial assets totaled €961.6 million on March 31, 2019, compared to €564.6 million on December 31, 2018 and €346.6 million on March 31, 2018. The increase in the cash balance on March 31, 2019 resulted primarily from the closing of the exclusive global collaboration and license agreement for cusatuzumab with Janssen triggering a $300 million upfront payment and a $200 million equity investment in January 2019.

Operating income increased by €33.1 million for the three months ended March 31, 2019 to reach €40.0 million, compared to €6.9 million for the three months ended March 31, 2018. The increase of €30.9 million in revenue was primarily related to the recognition of a $30.0 million development milestone under the AbbVie collaboration agreement and the partial recognition of the upfront payment received under the Janssen collaboration agreement. Other operating income increased by €2.2 million, resulting mainly from an increase in payroll tax rebates for employing certain research and development personnel.

Research and development expenses increased by €19.6 million for the three months ended March 31, 2019 to €34.8 million, compared to €15.1 million for the three months ended March 31, 2018. The increase in 2019 resulted primarily from (i) an increase of €11.1 million in external research and development expenses, reflecting higher clinical trials costs and manufacturing expenses related to the development of the late-stage argenx product candidate portfolio, (ii) an increase of €4.3 million in license fee costs payable to one of argenx' licensors following the achievement of a development milestone under the AbbVie collaboration agreement and (iii) a €2.6 million increase in share-based compensation expenses linked to the grant of stock options to its research and development employees.

Selling, general and administrative expenses totaled €11.3 million and €5.9 million for the three months ended March 31, 2019 and 2018, respectively. The increase of €5.4 million in selling, general and administrative expenses for the three months ended March 31, 2019 primarily resulted from (i) an increase of €2.1 million in share-based compensation expenses linked to the grant of stock options to its selling, general and administrative employees and board members and (ii) higher personnel expenses and consulting fees related to the preparation of potential future commercialization of the lead product candidate efgartigimod.

For the three months ended March 31, 2019, financial income amounted to €3.5 million, compared to €0.5 million for the three months ended March 31, 2018. The increase of €3.0 million in 2019 related primarily to an increase in the interest received on cash, cash equivalents and current financial assets.

Exchange gains totaled €9.5 million for the three months ended March 31, 2019, compared to the €4.0 million exchange losses incurred for the three months ended March 31, 2018. The increase was mainly attributable to unrealized exchange rate gains on the cash, cash equivalents and current financial assets position in U.S. dollars due to the favorable fluctuation of the EUR/USD exchange rate in the first three months of 2019.

The company generated a total comprehensive profit of €6.7 million for the three months ended March 31, 2019, compared to a total comprehensive loss of €17.7 million for the three months ended March 31, 2018. The total comprehensive profit in the first quarter of 2019 mainly resulted from the recognition of a $30.0 million development milestone under the AbbVie collaboration agreement and the unrealized exchange rate gains accounted during the period.

EXPECTED 2019 FINANCIAL CALENDAR:

- August 1, 2019: HY 2019 business update and financial results
- October 24, 2019: Q3 2019 business update and financial results

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 argenx's, and its collaboration partners', advancement of, and anticipated clinical development, data readouts and regulatory milestones and plans related to argenx's product candidates and preclinical studies and clinical trials; the intended results of its strategy; its financial condition, results of operation and business outlook; the sufficiency and the intended uses of its cash, cash equivalents and current financial assets; the momentum of its product candidate pipeline; and interaction with regulators, including the potential approval of its current or future drug candidates. 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.