arGEN-X Reports First Quarter 2015 Financial Results and Provides Business Update

15 May 2015

Breda, the Netherlands / Ghent, Belgium – arGEN-X N.V. (Euronext Brussels: ARGX), a clinical-stage biopharmaceutical company focused on creating and developing differentiated therapeutic antibodies for the treatment of cancer and severe autoimmune diseases, today provided development program updates and announced financial results for the first quarter ended 31 March 2015.

FIRST QUARTER AND RECENT OPERATIONAL HIGHLIGHTS

- Launched Innovative Access Program (IAP), providing the SIMPLE Antibody™ platform to academic centers of excellence and emerging biotech companies.
- In-licensed first program under IAP: ARGX-115, a first-in-class SIMPLE Antibody™ targeting GARP, a novel immune checkpoint. Published preclinical proof of mechanism of ARGX-115 in *Science Translational Medicine* suggesting potential for the antibody candidate in cancer immunotherapy.
- Advanced ARGX-111, a best-in-class SIMPLE Antibody™ targeting c-MET-driven malignancies, into the safety and efficacy expansion part of its Phase 1b study.
- Entered into a multi-product commercial license agreement with Lonza for the production of arGEN-X' therapeutic antibodies.
- Announced the resignation of Non-executive Directors Dr. Bruno Montanari and Dr. Harrold van Barlingen from the Board of Directors, effective 13 May 2015. Dr. J. Donald deBethizy was appointed as Non-executive Director by the General Meeting of Shareholders on 13 May 2015. Furthermore, Dr. Pam Klein has agreed to serve as an advisor to the Board of Directors, effective 13 May 2015. As per 1 June 2015, Christina Takke will leave her employment at Forbion Capital Partners and will therefore qualify as an independent Non-executive board member within the meaning of the Dutch Corporate Governance Code (provision III.2.2).

FIRST QUARTER FINANCIAL HIGHLIGHTS

- Operating income of EUR 1.8 million (2014: EUR 0.8 million).
- Net loss for the quarter of EUR 3 million (2014: EUR 1.9 million).
- Net cash burn of EUR 3.8 million, resulting in EUR 52.2 million in cash, cash-equivalents and financial assets.

DETAILS OF OPERATIONAL RESULTS

Products in clinical development

- **ARGX-110**
    - Waldenström's macroglobulinemia (WM)
        - Investigational New Drug Application (IND) approved by the FDA.

- Promising preclinical data in several leukemias expands the opportunity in hematological malignancies.
- Recent increase in competitive activity in WM necessitates strategic re-assessment of clinical development options.

- T-Cell Lymphoma (TCL)
  - Current Phase 1 study results demonstrate drug safety and biological activity for doses ranging between 0.1mg/kg and 10mg/kg across CD70 positive tumor types, including TCL.
  - Based on dose-escalation results, TCL was selected for safety expansion cohort.
  - Novel biomarkers identified to determine most meaningful dosing regimen in this indication. Inclusion of a real time biomarker read out will enrich data but will delay recruitment.
  - Data will be presented at the 13th International Conference on Malignant Lymphoma (17 – 20 June 2015, Lugano).

- Nasopharyngeal Carcinoma (NPC)
  - First 3 patients enrolled in Phase 1b safety expansion cohort.

- **ARGX-111**
  - Phase 1 dose escalation study testing biological activity in c-MET positive cancer indications has been successfully concluded. Results will be presented at ASCO (29 May – 2 June 2015, Chicago).
  - Safety expansion part of Phase 1b study initiated and on track with four clinical sites open to enroll patients.

Preclinical development programs

- **ARGX-113**
  - GLP toxicology studies completed.
  - Program on track for Clinical Trial Authorisation (CTA) filing by end of 2015.

- **ARGX-115**
  - First-in-class antibody targeting novel immune checkpoint GARP with potential for cancer immunotherapy application.
  - First program to originate from IAP.
  - Data published in Science Translational Medicine.

Collaborations & strategic alliances

- arGEN-X has an ongoing strategic alliance with Shire and a collaboration with Bayer for the discovery of SIMPLE Antibodies™ for rare disease and complex targets.

KEY FIGURES (CONSOLIDATED)

Financial overview

in thousands of euros	Three months period ended March 31, 2015	Three months period ended March 31, 2014	Variance
Revenue	1,210	341	869
Other operating income	614	496	118
Total operating income	**1,825**	**837**	**988**
Research and development expenses	(3,950)	(2,132)	(1,818)
General and administrative expenses	(1,105)	(601)	(503)
Operating profit/(loss)	**(3,230)**	**(1,897)**	**(1,334)**
Financial income	91	35	56
Exchange gains/(losses)	160	0	160
Profit/loss for the period	**(2,979)**	**(1,862)**	**(1,117)**
Net increase (decrease) in cash, cash-equivalents and financial assets	(3,809)	(2,305)	(1,504)
Cash, cash-equivalents and financial assets at the end of the period	52,164	20,915	31,250

Operating income was EUR 1.8 million for the three-month period ended 31 March 2015 compared to EUR 0.8 million for the same period in 2014. The higher operating income in 2015 is mainly explained by the increased revenue from collaborations following the signature of a new collaboration agreement with Bayer in May 2014, a new Strategic Alliance with Shire and a research, development and commercialization agreement with the Leukemia and Lymphoma Society (LLS) in the U.S in June 2014.

For the first three months of 2015, research and development expenses amounted to EUR 3.9 million, compared to EUR 2.1 million during the same period in 2014. The EUR 1.8 million increase in 2015 reflects (i) increased clinical trial and product manufacturing activities, and (ii) the recruitment of additional R&D personnel following the signature of the collaboration agreement with Bayer and the new Strategic Alliance with Shire in 2014.

General and administrative expenses were EUR 1.1 million and EUR 0.6 million for the three-month period ended 31 March 2015 and 2014, respectively. The EUR 0.5 million increase in 2015 is principally explained by additional expenses incurred for supporting activities as a public company such as investor relations, legal and audit fees.

In the three-month period ended 31 March 2015, the Company generated a net loss of EUR 3 million compared to a net loss of EUR 1.9 million in the same period of 2014.

On 31 March 2015 the Company's cash, cash equivalents and financial assets amounted to EUR 52.2 million compared to EUR 56 million on 31 December 2014 and EUR 21 million on 31 March 2014.

FINANCIAL CALENDAR

26 August 2015: Half year 2015 Business Update and financial results
17 November 2015: Q3 2015 Business Update and financial results

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About arGEN-X

arGEN-X combines the diversity of the llama immune system with antibody engineering to advance a clinical pipeline to treat patients with cancer and autoimmune diseases. Our platforms allow us to unlock novel and complex targets and develop antibody-based drugs designed for longer duration of effect and greater efficacy. The strength of our team, our deep understanding of the biology, and our committed collaborations with industry leaders contribute to the success of our journey.

arGEN-X is listed on the Euronext Brussels exchange under the symbol ARGX.

www.arGEN-X.com

For further information, please contact:

Joke Comijn, Corporate Communications Manager
+32 (0)477 77 29 44
+32 (0)9 243 40 70
info@arGEN-X.com

Mark Swallow/David Dible
Citigate Dewe Rogerson
+44 207 282 2948
arGEN-X@citigatedr.co.uk

Beth DelGiacco (US IR)
Stern Investor Relations
+1 212 362 1200
beth@sternir.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 arGEN-X 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. arGEN-X' actual results may differ materially from those predicted by the forward-looking statements. arGEN-X undertakes no obligation to publicly update or revise forward-looking statements, except as may be required by law.