

News Release

Media Contacts:

Brian Kenney
Phone: 215-620-0111
Email: bkenney1@its.jnj.com

Satu Glawe
Phone: +49 172 294 6264
Email: sschmid2@its.jnj.com

Investor Contacts:

Christopher DelOrefice
Phone: 732-524-2955

Lesley Fishman
Phone: 732-524-3922

Janssen Affiliate Cilag GmbH International Enters Worldwide Collaboration and License Agreement with argenx for Cancer Immunotherapy Cusatuzumab

Addition of investigational antibody cusatuzumab to robust oncology pipeline reflects Janssen's commitment to advance innovative therapies for blood cancers where unmet medical needs remain

Zug, Switzerland (December 3, 2018) – Cilag GmbH International, an affiliate of the Janssen Pharmaceutical Companies of Johnson & Johnson, announced today it has entered into a worldwide collaboration and license agreement with argenx BVBA and argenx SE, to develop and commercialize cusatuzumab (ARGX-110). Cusatuzumab is an investigational therapeutic antibody that targets CD70, an immune checkpoint implicated in numerous cancers, including hematological malignancies. This first-in-class SIMPLE Antibody™ is currently in Phase 1/2 clinical trials to evaluate its safety, tolerability and efficacy in the treatment of acute myeloid leukemia (AML) and high-risk myelodysplastic syndromes (MDS). Separately, an equity investment by Johnson & Johnson Innovation – JJDC, Inc. (JJDC) will be made in argenx SE.

Updated data from the ongoing Phase 1/2 clinical study evaluating cusatuzumab in combination with azacytidine in newly diagnosed patients with AML unfit for intensive chemotherapy are being presented during an argenx workshop held in conjunction with the 60th Annual Meeting of the American Society of Hematology (ASH). The data showed promising anti-leukemia activity in these patients.¹

“We believe CD70 is an important target in the biology of select cancers, and we are eager to accelerate the development of this innovative antibody together with argenx,” said Yusri Elsayed, M.D., MHSc., Ph.D., Vice President, Hematologic Malignancies Disease Area Leader, Janssen Research & Development, LLC. “Phase 1/2 data in acute myeloid leukemia showed the activity of cusatuzumab, and we hope to translate these findings to improve outcomes for patients with myeloid malignancies.”

Under the terms of the agreement, Janssen will jointly develop and globally commercialize cusatuzumab in AML, MDS, and potential future indications, as well as next generation CD70 antibodies. Janssen will make an upfront payment of \$300 million USD and additional payments based upon the achievement of certain development, regulatory and sales milestones. Janssen is responsible for commercialization worldwide. In the U.S., argenx has the option to participate in commercialization efforts. Janssen will record worldwide net trade sales. In the U.S., the companies have agreed to share the economics 50/50, and outside the U.S., Janssen will pay double-digit sales royalties to argenx.

“We are pleased to enter into this strategic partnership with argenx and advance a promising antibody for the treatment of AML and other blood cancers where current treatment is limited and effective new interventions are needed for patients,” said Mathai Mammen, M.D., Ph.D., Global Head, Janssen Research & Development, LLC. “The addition of cusatuzumab deepens our portfolio and adds to our expertise in oncology, and more importantly, it reflects our commitment to combine Janssen’s strengths with those of other outstanding teams to advance science that we believe can transform the treatment of diseases and the lives of patients worldwide.”

The transactions are subject to customary closing conditions, including clearance under the Hart-Scott-Rodino Antitrust Improvements Act, and expected to close in the first quarter of 2019.

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.ⁱⁱ

About AML

Acute myeloid leukemia (AML) starts in the bone marrow (the soft inner part of certain bones, where new blood cells are made), but most often it quickly moves into the blood, as well. It can sometimes spread to other parts of the body including the lymph nodes, liver, spleen, central nervous system (brain and spinal cord), and testicles.ⁱⁱⁱ

About MDS

Myelodysplastic Syndromes (MDS) are a group of diverse bone marrow disorders in which the bone marrow does not produce enough healthy blood cells. MDS is often referred to as a “bone marrow failure disorder.” MDS is primarily a disease of the elderly (most patients are older than age 65), but MDS can affect younger patients as well.^{iv}

About Cilag GmbH International

Cilag GmbH International was founded in 1984 as the supply chain coordination center for the pharmaceuticals sector in Zug. Today, it offers a wide range of support activities for numerous Swiss companies in the pharmaceutical, consumer and medical device and diagnostics segments of the Johnson & Johnson Family of Companies.

About the Janssen Pharmaceutical Companies of Johnson & Johnson

At the Janssen Pharmaceutical Companies of Johnson & Johnson, we are working to create a world without disease. Transforming lives by finding new and better ways to prevent, intercept, treat and cure disease inspires us. We bring together the best minds and pursue the most promising science. We are Janssen. We collaborate with the world for the health of everyone in it. Learn more at www.janssen.com. Follow us at [@JanssenGlobal](https://twitter.com/JanssenGlobal). Cilag GmbH International and Janssen Research & Development, LLC are part of the Janssen Pharmaceutical Companies of Johnson & Johnson.

About Johnson & Johnson Innovation - JJDC, Inc.

Johnson & Johnson Innovation - JJDC, Inc. (JJDC) is the strategic venture capital arm of Johnson & Johnson and a long-term investment partner to global healthcare entrepreneurs. Founded in 1973, JJDC continues a legacy of customizing deals for data-driven companies across the continuum of healthcare, with the goal of turning great ideas into transformative new pharmaceutical, medical device and consumer healthcare products. Visit our website at www.jjdc.com.

About Johnson & Johnson

At Johnson & Johnson, we believe good health is the foundation of vibrant lives, thriving communities and forward progress. That's why for more than 130 years, we have aimed to keep people well at every age and every stage of life. Today, as the world's largest and most broadly-based health care company, we are committed to using our reach and size for good. We strive to improve access and affordability, create healthier communities, and put a healthy mind, body and environment within reach of everyone, everywhere. We are blending our heart, science and ingenuity to profoundly change the trajectory of health for humanity.

###

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding product development and the potential benefits and treatment impact of the collaboration and license agreement with argenx to develop and commercialize cusatuzumab (ARGX-110). The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and

projections of Cilag GmbH International, Janssen Research & Development, LLC, Johnson & Johnson Innovation - JJDC, Inc. any of the other Janssen Pharmaceutical Companies of Johnson & Johnson and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: the satisfaction of closing conditions for the transactions, including clearance under the Hart-Scott-Rodino Antitrust Improvements Act; the potential that the expected benefits and opportunities related to the collaboration may not be realized or may take longer to realize than expected; challenges inherent in new product development, including the uncertainty of clinical success and obtaining regulatory approvals; competition, including technological advances, new products and patents attained by competitors; uncertainty of commercial success for new products; the ability of the company to successfully execute strategic plans; impact of business combinations and divestitures; challenges to patents; changes in behavior and spending patterns or financial distress of purchasers of health care products and services; and global health care reforms and trends toward health care cost containment. A further list and descriptions of these risks, uncertainties and other factors can be found in Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended December 31, 2017, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," in the company's most recently filed Quarterly Report on Form 10-Q, and the company's subsequent filings with the Securities and Exchange Commission. Copies of these filings are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. Neither the Janssen Pharmaceutical Companies nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

ⁱ Ochsenbein, Adrian (2018, December). 2680 Argx-110 Targeting CD70, in Combination with Azacitidine, Shows Favorable Safety Profile and Promising Anti-Leukemia Activity in Newly Diagnosed AML Patients in an Ongoing Phase 1/2 Clinical Trial. American Society of Hematology Annual Meeting, San Diego, CA, U.S.

ⁱⁱ Silence K. et al. *mAbs* 2014; 6 (2):523-532

ⁱⁱⁱ "What Is Acute Myeloid Leukemia (AML)?" American Cancer Society. Retrieved from <https://www.cancer.org/cancer/acute-myeloid-leukemia/about/what-is-aml.html>

^{iv} "What is MDS?" MDS Foundation. Retrieved from <https://www.mds-foundation.org/what-is-mds/>