Lonza's Ibex Dedicate to Support the Commercial Manufacture of Kodiak’s KSI-301 - an Antibody Biopolymer Conjugate for Retinal Diseases

July 27, 2020

• Purpose-built bioconjugation facility in Lonza’s Ibex™ Dedicate Biopark to support the potential commercial launch of Kodiak's leading ophthalmic therapeutic candidate KSI-301 with a capacity to supply millions of doses per year

• Provides accelerated build-time and flex up and flex down capabilities with facility construction targeted for completion from end 2021

• The agreement also integrates Kodiak’s global pharmaceutical supply chain including antibody, small molecule, biopolymer and bioconjugate manufacturing

Quote from Jean Christophe Hyvert, Chief Commercial Officer, Lonza:

“We are committed to supporting Kodiak as they bring their highly innovative, sight-saving treatment option to patients with vision-threatening retinal diseases. Since 2014, we have been partnering with Kodiak to support the supply of KSI-301 drug substance for use in clinical trials. Together, we are now preparing for scale-up, BLA readiness and future commercial supply. These activities include the build of a new bioconjugation facility in an Ibex® Dedicate partnership with Kodiak with the capability to supply millions of doses of KSI-301 and to flex up / flex down capacities quickly in response to the market demand.”

Quote from Victor Perlroth, MD, Chairman and Chief Executive Officer, Kodiak Sciences:

“Manufacturing is a critical element of Kodiak’s 2022 Vision, as we scale our efforts and realize the potential of KSI-301 to be an extended durability medicine for treating retinal diseases. We are planning to file a Biologics Licensing Application (BLA) for KSI-301 in 2022, with the goal of commercial launch in wet age-related macular degeneration, diabetic macular edema and retinal vein occlusion in 2023. To meet our objectives for BLA readiness and large-scale commercial supply, we are thrilled to build on an already successful partnership with Lonza. The IBEX Dedicate allows us to build significant dedicated manufacturing capacity while also leveraging Lonza’s high-quality network and expertise that have enabled our manufacturing success thus far.”

Basel, Switzerland, and Palo Alto, US, 27 July 2020 – Kodiak Sciences, a clinical-stage biopharmaceutical company specializing in novel ophthalmic therapies, and Lonza announced today that the companies have signed a long-term contract for manufacturing KSI-301, an Antibody Biopolymer Conjugate (ABC) that is a potential first-line treatment for retinal vascular diseases.

Kodiak’s ABC PlatformTM is its core, proprietary technology for next-generation, long-durability ophthalmic therapies. KSI-301 is an antibody biopolymer conjugate comprising an antibody inhibiting Vascular Endothelial Growth Factor (VEGF), a potent cytokine known to contribute to the pathology of retinal vascular diseases, conjugated with a phosphorylcholine biopolymer. Emerging clinical data suggest the potential for extended dosing schedules of up to six months. With KSI-301 currently in a pivotal clinical trial for wet age-related macular degeneration and with additional pivotal clinical studies scheduled to begin this year in diabetic macular edema, retina vein occlusion and non-proliferative diabetic retinopathy, Lonza will support Kodiak in scaling up and securing their supply chain as the company moves through BLA readiness to commercial launch to meet growing market demands.

Building on a long-term partnership for the clinical supply of antibody and biopolymer, the new agreement will provide Kodiak with a custom-built bioconjugation facility as part of Lonza’s Ibex Dedicate business model. This agile, technology-agnostic biomanufacturing concept fits into prebuilt shells at Lonza’s new biopark in Visp (CH). In addition to reducing build-time, Ibex Dedicate taps into existing infrastructure and provides the flexibility needed for manufacturing a broad range of innovative medicines, from drug substance to drug product.

With construction targeted for completion in 2021, the Lonza-Kodiak Ibex facility is designed to provide Kodiak with the facility needed for commercial-scale manufacturing of KSI-301. Lonza will also utilize its global network of facilities, including Nansha (CN) and Visp (CH) to produce the biopolymer, and Portsmouth (US) to produce the antibody. The timing of this expanded partnership is designed to support Kodiak’s BLA submission timeline in 2022, and the scale is designed to support KSI-301’s potential to achieve significant market share as a new first-line agent designed to improve outcomes for patients with common and serious retinal vascular diseases.

Lonza’s leadership in bioconjugation, together with experience in managing the complex supply chains under one quality system, will help Kodiak meet the precision standards required for ophthalmic intravitreal injected therapies and retinal vascular diseases in particular. The new dedicated bioconjugation facility will allow for rapid product launch and provide flexible commercial manufacturing capacity that can scale to meet market needs.

About Lonza

At Lonza, we combine technological innovation with world class manufacturing and process excellence. Together, these enable our customers to deliver their discoveries in the healthcare, preservation, and protection sectors.

We are a preferred global partner to the pharmaceutical, biotech and specialty ingredients markets. We work to prevent illness and promote a healthier world by enabling our customers to deliver innovative medicines that help treat or even cure a wide range of diseases. We also offer a broad range of microbial control solutions, which help to create and maintain a healthy environment.

Founded in 1897 in the Swiss Alps, Lonza today operates in 120 sites and offices in more than 35 countries. With approximately 15,500 full-time employees, we are built from high-performing teams and of individual employees who make a meaningful difference to our own business, as well as the communities in which we operate. The company generated sales of CHF 5.9 billion in 2019 with a CORE EBITDA of CHF 1.6 billion. Find out more at www.lonza.comand follow us on Twitter @LonzaGroup or Facebook @LonzaGroupAG.

About Kodiak Sciences

Kodiak Sciences (Nasdaq: KOD) is a clinical stage biopharmaceutical company developing novel therapeutics to treat chronic, high-prevalence retinal diseases. Founded in 2009, we are focused on bringing new science to the design and manufacture of next generation retinal medicines to prevent and treat the leading causes of blindness globally.

Our ABC Platform™ uses molecular engineering to merge the fields of antibody-based and chemistry-based therapies and is at the core of Kodiak's discovery engine. Kodiak's lead product candidate, KSI-301, is a novel anti-VEGF antibody biopolymer conjugate being developed for the treatment of retinal vascular diseases, including age-related macular degeneration, a leading cause of blindness in elderly patients, and diabetic eye diseases, a leading cause of blindness in working-age patients.

Kodiak has leveraged its ABC Platform to build a pipeline of product candidates in various stages of development including KSI-501, our bispecific anti-IL-6/VEGF biopolymer conjugate for the treatment of neovascular retinal diseases with an inflammatory component, and we are expanding our early research pipeline to include ABC Platform based triplet inhibitors for multifactorial retinal diseases such as dry AMD and glaucoma. Kodiak is based in Palo Alto, CA. For more information, please visit www.kodiak.com.

Kodiak Sciences Inc. has its headquarters in Palo Alto, California, USA, and is listed on the NASDAQ Exchange. Kodiak has additional facilities in Zug, Switzerland and Valais, Switzerland.

About KSI-301

KSI-301 is an investigational therapy built on Kodiak's proprietary Antibody Biopolymer Conjugate (ABC) Platform and is designed to maintain potent and effective drug levels in ocular tissues for longer than existing agents. Kodiak's objective with KSI-301 is to develop a new first-line agent to improve outcomes for patients with retinal vascular diseases and to enable earlier treatment and prevention of vision loss for patients with diabetic eye disease.

Forward-Looking Statements for Kodiak Sciences

This release contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995. These forward-looking statements are not based on historical fact and include statements regarding the ability to commence operations at the Lonza-Kodiak Ibex facility in 2021; the ability of the Lonza-Kodiak Ibex facility to provide sufficient manufacturing capacity for the potential commercial launch of KSI-301; Kodiak’s potential BLA submission in wet AMD, DME, RVO and diabetic retinopathy in 2022; the potential licensure and commercial launch of KSI-301 in 2023; clinical and regulatory objectives and the timing thereof, expectations regarding the potential efficacy and commercial potential of Kodiak’s product candidates; and the results of our research and development efforts. Forward-looking statements generally include statements that are predictive in nature and depend upon or refer to future events or conditions, and include words such as "may," "will," "should," "would," "expect," "plan," "believe," "intend," "pursue," and other similar expressions among others. Any forward-looking statements are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. For a discussion of risks and uncertainties, and other important factors, any of which could cause our actual results to differ from those contained in the forward-looking statements, see the section entitled "Risk Factors" in our most recent Form 10-K, as well as discussions of potential risks, uncertainties, and other important factors in our subsequent filings with the Securities and Exchange Commission. These forward-looking statements speak only as of the date hereof and Kodiak undertakes no obligation to update forward-looking statements, and readers are cautioned not to place undue reliance on such forward-looking statements.

Additional Information and Disclaimer for Lonza

Lonza Group Ltd has its headquarters in Basel, Switzerland, and is listed on the SIX Swiss Exchange. It has a secondary listing on the Singapore Exchange Securities Trading Limited (“SGX-ST”). Lonza Group Ltd is not subject to the SGX-ST’s continuing listing requirements but remains subject to Rules 217 and 751 of the SGX-ST Listing Manual.

Certain matters discussed in this news release may constitute forward-looking statements. These statements are based on current expectations and estimates of Lonza Group Ltd, although Lonza Group Ltd can give no assurance that these expectations and estimates will be achieved. Investors are cautioned that all forward-looking statements involve risks and uncertainty and are qualified in their entirety. The actual results may differ materially in the future from the forward-looking statements included in this news release due to various factors. Furthermore, except as otherwise required by law, Lonza Group Ltd disclaims any intention or obligation to update the statements contained in this news release.

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