



Exelixis and Catalent Enter into New License Agreement for Three Antibody-Drug Conjugate Programs with the Potential to Accelerate Exelixis' Biologics Pipeline

November 3, 2022

—New priority discovery programs focused on three oncology targets with potential to develop antibody-drug conjugates (ADCs) for a variety of solid tumor indications —

ALAMEDA, Calif. & SOMERSET, N.J.--(BUSINESS WIRE)--Nov. 3, 2022-- [Exelixis, Inc.](#) (Nasdaq: EXEL) and Catalent, Inc. (NYSE: CTLT) today announced a new license agreement under which Catalent's Redwood Bioscience subsidiary will grant Exelixis an exclusive license to three target programs with lead antibody and/or ADC candidates. The ADC candidates have been developed using Catalent's proprietary SMARTag[®] technology, and each of the licensed antibodies has potential for development as an ADC or other biologic therapy using a variety of technologies to which Exelixis has access through its partner network. In September 2020, Exelixis and Catalent entered into a separate agreement under which Catalent is applying its SMARTag bioconjugation platform to build ADCs using monoclonal antibodies from Exelixis' growing preclinical pipeline.

This press release features multimedia. View the full release here: <https://www.businesswire.com/news/home/20221103005547/en/>

Under the terms of the new agreement, Exelixis will make an upfront payment to Catalent of \$30 million in exchange for rights to the three biologics programs. Exelixis will fund the development work conducted by Catalent until development candidate selection is complete, after which Exelixis will assume responsibility for conducting preclinical, clinical, and commercial activities. Catalent will be eligible for development and sales milestone payments, as well as sales-based royalties.

"Exelixis is committed to building a robust biologics pipeline, and this agreement expands our portfolio to include three highly promising targets with broad potential in multiple solid tumor indications, including bladder, breast, lung, ovarian, pancreatic, and other cancers," said Peter Lamb, Ph.D., Executive Vice President, Scientific Strategy and Chief Scientific Officer, Exelixis. "We believe that the antibodies, ADCs and data Catalent has generated to date will enable rapid advancement of these programs, enabling an acceleration of our in-house biotherapeutics pipeline. We are excited for this new opportunity to continue our work together to advance additional programs that have the potential to provide patients with new therapeutic options."

"Catalent Biologics is a leader in applying precision protein engineering and novel chemistries to develop optimized therapeutics," said Mike Riley, President, Division Head for BioProduct Delivery, Catalent Biologics. "Our versatile SMARTag platform and growing portfolio of preclinical ADCs against promising targets create multiple opportunities for Catalent to partner with leading biopharmaceutical companies, such as Exelixis. We expect the new license agreement with Exelixis will yield innovative and differentiated therapies with the potential to improve care and outcomes for cancer patients."

The SMARTag technology platform was developed by Redwood Bioscience based on discoveries in the lab of Carolyn Bertozzi, recent winner of the Nobel Prize in Chemistry and Chair of Redwood's scientific advisory board. The platform provides optimized site-specific protein-modification, as well as linker and payload technologies for ADCs and other bioconjugates. The SMARTag platform overcomes the limitations associated with traditional protein chemistries that produce heterogeneous products with variable conjugate potency, toxicity, and stability, and enables the development of ADCs with a wider therapeutic window and improved manufacturability.

About Catalent Biologics

For nearly three decades, Catalent Biologics has built capabilities and expertise in development, manufacturing, and analytical services, now spanning new biological entities, biosimilars, plasmid DNA, cell and gene therapies, vaccines, sterile injectables, mRNA, and antibody-drug conjugates. It has developed 600+ antibodies and 80+ recombinant proteins, with 120+ active clinical trials and 16 marketed biotherapeutics use GPEX[®] cell line engineering technology. An additional 45+ commercially approved products have employed Catalent Biologics' manufacturing and packaging capabilities.

Catalent Cell & Gene Therapy is an industry-leading technology, development, and manufacturing partner for advanced therapeutics. With a comprehensive cell therapy portfolio and deep expertise in viral vector development, scale-up and manufacturing, Catalent is a full-service partner for plasmid DNA, adeno-associated viral (AAV) and other viral vectors, viral vaccines, iPSCs and autologous and allogeneic cell therapies.

Using advanced technologies and tailored solutions from clinical to commercial supply, Catalent brings better biologic and advanced treatments to patients, faster.

About Catalent

Catalent is the global leader in enabling pharma, biotech, and consumer health partners to optimize product development, launch, and full life-cycle supply for patients around the world. With broad and deep scale and expertise in development sciences, delivery technologies, and multi-modality manufacturing, Catalent is a preferred industry partner for personalized medicines, consumer health brand extensions, and blockbuster drugs.

Catalent helps accelerate over 1,000 partner programs and launch over 150 new products every year. Its flexible manufacturing platforms at over 50 global sites supply around 80 billion doses of nearly 8,000 products annually. Catalent's expert workforce of over 18,000 includes more than 3,000 scientists and technicians.

More products. Better treatments. Reliably supplied.™

About Exelixis

Founded in 1994, Exelixis, Inc. (Nasdaq: EXEL) is a commercially successful, oncology-focused biotechnology company that strives to accelerate the discovery, development and commercialization of new medicines for difficult-to-treat cancers. Following early work in model system genetics, we established a broad drug discovery and development platform that has served as the foundation for our continued efforts to bring new cancer therapies to patients in need. Our discovery efforts have resulted in four commercially available products, CABOMETRYX[®] (cabozantinib), COMETRIQ[®] (cabozantinib), COTELLIC[®] (cobimetinib) and MINNEBRO[®] (esaxerenone), and we have entered into partnerships with leading pharmaceutical companies to bring these important medicines to patients worldwide. Supported by revenues from our marketed products and collaborations, we are committed to prudently reinvesting in our business to maximize the potential of our pipeline. We are supplementing our existing therapeutic assets with targeted business development activities and internal drug discovery — all to deliver the next generation of Exelixis medicines and help patients recover stronger and live longer. Exelixis is a member of the Standard & Poor's (S&P) MidCap 400 index, which measures the performance of profitable mid-sized companies. For more information about Exelixis, please visit www.exelixis.com, follow @ExelixisInc on Twitter or like [Exelixis, Inc.](https://www.facebook.com/ExelixisInc) on Facebook.

Exelixis Forward-Looking Statements

This press release contains forward-looking statements, including, without limitation, statements related to: the potential for the licensed target programs to lead to the development of ADCs or other biologic therapy for multiple solid tumor indications; Exelixis' immediate and future financial and other obligations under the license agreement with Catalent; Exelixis' belief that the antibodies, ADCs and data Catalent has generated to date will enable an acceleration of Exelixis' in-house biotherapeutics pipeline, and that the two companies' continued work together can advance additional programs that have the potential to provide patients with new therapeutic options; the potential for Catalent's SMARTag platform and growing portfolio of preclinical ADCs against promising targets to create multiple opportunities for partnerships with leading biopharmaceutical companies; and Exelixis' plans to reinvest in its business to maximize the potential of the company's pipeline, including through targeted business development activities and internal drug discovery. Any statements that refer to expectations, projections or other characterizations of future events or circumstances are forward-looking statements and are based upon Exelixis' current plans, assumptions, beliefs, expectations, estimates and projections. Forward-looking statements involve risks and uncertainties. Actual results and the timing of events could differ materially from those anticipated in the forward-looking statements as a result of these risks and uncertainties, which include, without limitation: the level of costs associated with Exelixis' commercialization, research and development, in-licensing or acquisition of product candidates, and other activities; uncertainties inherent in the drug discovery and product development process; Exelixis' dependence on its relationship with Catalent, including Catalent's adherence to its obligations under the license agreement; complexities and the unpredictability of the regulatory review and approval processes in the U.S. and elsewhere; Exelixis' and Catalent's continuing compliance with applicable legal and regulatory requirements; Exelixis' and Catalent's ability to protect their respective intellectual property rights; market competition; changes in economic and business conditions, including as a result of the COVID-19 pandemic and other global events; and other factors affecting Exelixis and its product pipeline discussed under the caption "Risk Factors" in Exelixis' Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on November 1, 2022, and in Exelixis' future filings with the SEC. All forward-looking statements in this press release are based on information available to Exelixis as of the date of this press release, and Exelixis undertakes no obligation to update or revise any forward-looking statements contained herein, except as required by law.

Exelixis, the Exelixis logo, CABOMETRYX and COMETRIQ are registered U.S. trademarks of Exelixis.

COTELLIC is a registered trademark of Genentech, Inc.

MINNEBRO is a registered trademark of Daiichi Sankyo Company, Limited.

Catalent and SMARTag are registered trademarks of Catalent Pharma Solutions, Inc., or its subsidiaries in the U.S. or other countries.

View source version on [businesswire.com](https://www.businesswire.com/news/home/20221103005547/en/): <https://www.businesswire.com/news/home/20221103005547/en/>

Exelixis Investors Contact:

Varant Shirvanian
Associate Director, Investor Relations
Exelixis, Inc.
650-837-7917
vshirvanian@exelixis.com

Exelixis Media Contact:

Hal Mackins
For Exelixis, Inc.
415-994-0040
hal@torchcommunications.com

Catalent Media Contact:

Chris Halling
+44 (0)7580 041073
chris.halling@catalent.com

Catalent Investors Contact:

Paul Surdez
(732) 537-6325
investors@catalent.com

Source: Exelixis, Inc.