



Exelixis and Iconic Therapeutics Announce Promising Preclinical Data That Support Best-in-Class Potential for ICON-2 in Treatment of Solid Tumors

September 15, 2020

- ICON-2 is pharmacologically more potent in vivo and in vitro, with better nonclinical tolerability, compared with a monomethyl auristatin E (MMAE) anti-TF antibody-drug conjugate (ADC) -

- Data presented this week at the World ADC Digital Conference -

ALAMEDA, Calif. & SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Sep. 15, 2020-- Exelixis, Inc. (Nasdaq: EXEL) and Iconic Therapeutics today announced new preclinical data that support the continued development of ICON-2, an ADC comprised of an anti-Tissue Factor (TF) antibody and Zymeworks' proprietary linker-payload, for the treatment of diverse solid tumors. Exelixis has an exclusive option and license agreement for ICON-2 in oncology indications under its [May 2019 agreement with Iconic Therapeutics](#), which discovered and is developing this novel ADC. The new data, which demonstrate the superior tolerability and exposure of ICON-2 compared with an MMAE anti-TF ADC, are being presented this week in a poster at the World ADC Digital Conference, which is being held online September 15-18.

This press release features multimedia. View the full release here: <https://www.businesswire.com/news/home/20200915005725/en/>

"These data provide additional preclinical validation both of our platform of proprietary anti-TF molecules designed to efficiently but safely bind TF, which is overexpressed in a variety of solid tumors, and specifically for Iconic Therapeutics' strategy to advance its next generation ADC targeting TF," said William L. Greene, M.D., Chief Executive Officer of Iconic Therapeutics. "Other anti-TF ADCs that use MMAE as a linker-payload have been associated with side effects that can reduce tolerability, including bleeding, neutropenia and skin toxicities. The data presented today demonstrate ICON-2 effectively kills solid tumor cells in a variety of preclinical studies with an improved tolerability profile, and support continued development of ICON-2 as a treatment for solid tumors. We are currently conducting additional preclinical and nonclinical studies in support of initiating human clinical trials of this potentially best-in-class anti-TF ADC."

TF plays a critical role in the coagulation cascade and its expression is generally restricted in normal tissue. However, solid tumors, including gastrointestinal, head and neck, cervical, ovarian and bladder tumors, frequently express TF at high levels, which is associated with poor prognosis. Although TF is an attractive target for ADC therapy, previous approaches have demonstrated the potential to interfere with the coagulation cascade and may have additional toxicities that could negatively impact their risk-benefit profile.

The data presented today include results from several preclinical studies of ICON-2. Key findings from these studies are:

- ICON-2 binds to TF on human and non-human primate (NHP) cells with high affinity but does not affect coagulation as measured by FXa conversion and thrombin generation assays.
- ICON-2 does not induce neutropenia in NHPs.
- ICON-2 is more potent than an ADC containing MMAE conjugated to the same anti-TF antibody in mouse xenograft model of human pancreatic tumor cells.
- ICON-2 is highly active in patient-derived xenograft models derived from multiple tumor types.
- ICON-2 exhibits superior tolerability and exposure when compared directly with an MMAE ADC using the same anti-TF antibody in a NHP study.

"We entered into our exclusive option and license agreement with Iconic Therapeutics because its expertise in TF biology and access to proprietary ADC technology provide a robust foundation for developing potentially best-in-class therapies for solid tumor indications with significant unmet clinical need," said Peter Lamb, Ph.D., Executive Vice President, Scientific Strategy and Chief Scientific Officer of Exelixis. "The data presented today continue to support that potential and differentiate ICON-2 from other anti-TF ADCs. These promising results also underscore Exelixis' ability to identify promising licensing opportunities as part of our ongoing pipeline expansion strategy, which includes both internally developed and in-licensed programs."

Under the terms of the May 2019 agreement, Exelixis has an exclusive option to license ICON-2 in exchange for an upfront option payment to Iconic of \$7.5 million and a commitment of preclinical development funding. Exelixis can exercise its option at any time up to a potential IND application, and upon doing so would make an option exercise payment to Iconic and assume responsibilities for all subsequent clinical development and commercialization activities. Should Exelixis elect to exercise its option, Iconic will become eligible for future development, regulatory and commercialization milestone payments, as well as royalties on potential sales.

About Iconic Therapeutics

Iconic Therapeutics, Inc. is a biopharmaceutical company dedicated to leveraging its deep insight into tissue factor biology and TF's role in inflammation, tumor growth, and angiogenesis to develop new therapeutics for serious diseases including retinal disease and cancer. The Company has developed a portfolio of proprietary molecules which bind to and antagonize TF expressed in several disease states. In May 2019, Iconic Therapeutics entered into a licensing agreement with Zymeworks that granted to Iconic non-exclusive rights to Zymeworks' proprietary ZymeLink™ antibody-drug conjugate (ADC) platform. Please visit www.iconictherapeutics.com for additional information.

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, CABOMETYX[®] (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 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](https://twitter.com/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: Exelixis' and Iconic Therapeutics' plans to present preclinical data in support of the continued development of ICON-2 at the World ADC Digital Conference; Exelixis' belief that Iconic Therapeutics' expertise in TF biology and access to proprietary ADC technology provide a robust foundation for developing potentially best-in-class therapies for solid tumor indications with significant unmet clinical need; Exelixis' potential future financial and other obligations under the exclusive option and license agreement with Iconic Therapeutics; 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 availability of data at the referenced times; 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 Iconic Therapeutics, including Iconic Therapeutics' adherence to its obligations under the collaboration and license option agreement and the level of Iconic Therapeutics' assistance to Exelixis in completing clinical trials, pursuing regulatory approvals or successfully commercializing partnered compounds in the territories where they may be approved; the continuing COVID-19 pandemic and its impact on Exelixis' research and development operations; complexities and the unpredictability of the regulatory review and approval processes in the U.S. and elsewhere; Exelixis' and Iconic Therapeutics' continuing compliance with applicable legal and regulatory requirements; Exelixis' and Iconic Therapeutics' ability to protect their respective intellectual property rights; market competition; changes in economic and business conditions; 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 August 6, 2020, 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.

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Exelixis Investors Contact:

Susan Hubbard
Executive Vice President,
Public Affairs & Investor Relations
(650) 837-8194
shubbard@exelixis.com

Exelixis Media Contact:

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

Iconic Therapeutics Media/Investors Contact:

Shari Annes
(650) 888-0902
sannes@annesassociates.com

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