



Exelixis In-Licenses Iconic Therapeutics' Tissue Factor-Targeting Antibody-Drug Conjugate Ahead of Planned Investigational New Drug Application

December 2, 2020

– Phase 1 clinical trial planned for early 2021, pending the FDA's acceptance of Exelixis' planned IND filing –

– Under the terms of the companies' agreement, Exelixis has made an option exercise payment of \$20 million to Iconic Therapeutics –

– Preclinical data underscore best-in-class potential for XB002 (formerly ICON-2) in treatment of solid tumors –

ALAMEDA, Calif., SOUTH SAN FRANCISCO, Calif. & VANCOUVER, British Columbia--(BUSINESS WIRE)--Dec. 2, 2020-- Exelixis, Inc. (Nasdaq: EXEL), Iconic Therapeutics, Inc. (Iconic) and Zymeworks Inc. (NYSE:ZYME) today announced that Exelixis has exercised its exclusive option for Iconic's lead oncology antibody-drug conjugate (ADC) program under the companies' [May 2019 agreement](#). As a result, Exelixis now has responsibility for the future clinical development, commercialization, and manufacturing of the Tissue Factor (TF)-targeting ADC now known as XB002 (formerly ICON-2). A rationally designed next-generation ADC, XB002 comprises a Tissue Factor-targeting antibody with Zymeworks' proprietary ZymeLink™ linker-payload, creating the potential for an improved therapeutic index and favorable safety profile as compared to earlier-generation, TF-targeting ADCs. Exelixis plans to file an Investigational New Drug application (IND) with the U.S. Food and Drug Administration (FDA) for XB002 in the near-term and, pending the FDA's acceptance of the IND, initiate a phase 1 clinical trial of XB002 in early 2021.

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"XB002 is an important addition to the Exelixis pipeline given its potential differentiation from other Tissue Factor-targeting antibody-drug conjugates and its status as the first program in our growing biologics portfolio to reach IND filing stage," said Peter Lamb, Ph.D., Executive Vice President and Chief Scientific Officer of Exelixis. "Iconic designed a highly promising molecule and advanced it through a rigorous preclinical evaluation, setting the stage for Exelixis to complete our planned IND filing in the coming weeks. We are grateful for Iconic's partnership over the past 18 months and look forward to fully evaluating the potential of XB002 to help patients with cancer."

Under the terms of the May 2019 agreement between Exelixis and Iconic, Exelixis gained an exclusive option to license XB002 (then ICON-2) in exchange for an upfront payment to Iconic of \$7.5 million and a commitment of preclinical development funding. In exercising its exclusive option, Exelixis has made an additional option exercise payment of \$20 million to Iconic. Iconic is now also eligible for future development, regulatory and commercialization milestone payments, as well as royalties on potential sales. The ZymeLink ADC technology in XB002 was originally licensed to Iconic from Zymeworks. Under the terms of their 2019 agreement, Zymeworks will receive a share of the \$20 million option fee and is eligible to receive a share of all future revenue received by Iconic, as well as tiered royalties on worldwide sales.

"Exelixis' decision to in-license our lead oncology program provides important validation of Iconic's discovery and development capabilities, our platform of proprietary anti-Tissue Factor molecules designed to efficiently but safely bind Tissue Factor, and the potential of Tissue Factor as an oncology antibody-drug conjugate target," said William L. Greene, M.D., Chief Executive Officer of Iconic Therapeutics. "Preclinical data [presented earlier this year](#) demonstrate that XB002 binds Tissue Factor without affecting the coagulation cascade, which has hindered prior development of Tissue Factor-targeting molecules, has activity in multiple solid tumor cancer models and has improved tolerability compared to other Tissue Factor-targeting ADCs. We are excited to see XB002 make further progress as part of Exelixis' highly-regarded clinical development organization."

"We are excited to see this promising molecule take an important step towards clinical trials backed by the experienced clinical team at Exelixis," said Tony Polverino, Ph.D., Executive Vice President, Early Development and Chief Scientific Officer of Zymeworks. "This would mark the second ZymeLink-based therapeutic to enter the clinic in addition to our bispecific HER2 antibody-drug conjugate, ZW49, further highlighting the differentiative potential of our novel antibody-drug conjugate platform."

Pending the completion of Exelixis' planned IND and the FDA's acceptance of the filing, Exelixis intends to initiate a phase 1 dose escalation and expansion study of XB002 in subjects with inoperable locally advanced or metastatic solid tumors early in 2021.

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. In November 2020, the company was named to *Fortune's* 100 Fastest-Growing Companies list for the first time, ranking 17th overall and the third-highest biopharmaceutical company. For more information about Exelixis, please visit www.exelixis.com, follow [@ExelixisInc](#) on Twitter or like [Exelixis, Inc.](#) on Facebook.

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 Zymeworks

Zymeworks is a clinical-stage biopharmaceutical company dedicated to the development of next-generation multifunctional biotherapeutics. Zymeworks' suite of therapeutic platforms and its fully integrated drug development engine enable precise engineering of highly differentiated product candidates. Zymeworks' lead clinical candidate, zanidatamab (ZW25), is a novel Azymetric™ bispecific antibody which has been granted Breakthrough Therapy designation by the FDA and is currently enrolling in a registration-enabling clinical trial for refractory HER2+ biliary tract cancer as well as several Phase 2 clinical trials for HER2+ gastroesophageal and breast cancers. Zymeworks' second clinical candidate, ZW49, is a bispecific antibody-drug conjugate currently in Phase 1 clinical development and combines the unique design and antibody framework of zanidatamab with Zymeworks' proprietary ZymeLink™ linker-cytotoxin. Zymeworks is also advancing a deep preclinical pipeline in oncology (including immuno-oncology agents) and other therapeutic areas. In addition, its therapeutic platforms are being leveraged through strategic partnerships with nine biopharmaceutical companies. For additional information about Zymeworks, visit www.zymeworks.com and follow [@ZymeworksInc](https://twitter.com/ZymeworksInc) on Twitter.

Exelixis Forward-Looking Statements

This press release contains forward-looking statements, including, without limitation, statements related to: Exelixis' plans to file an IND with the FDA for XB002 in the near-term and, pending the FDA's acceptance of the IND, initiate a phase 1 clinical trial of XB002 in early 2021; the therapeutic potential of XB002 for cancer patients and favorable safety profile of the molecule as compared to earlier-generation, TF-targeting ADCs; Exelixis' potential future financial and other obligations under the exclusive option and license agreement with Iconic; 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 Iconic, including Iconic's adherence to its obligations under the exclusive option and license agreement and the level of Iconic's 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's continuing compliance with applicable legal and regulatory requirements; Exelixis', Iconic's and Zymeworks' 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 November 5, 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.

Zymeworks Forward-Looking Statement

This press release includes "forward-looking statements" within the meaning of the U.S. Private Securities Litigation Reform Act of 1995 and "forward-looking information" within the meaning of Canadian securities laws, or collectively, forward-looking statements. Forward-looking statements in this press release include, but are not limited to, statements that relate to the payment to Zymeworks of a share of the \$20 million option fee received by Iconic, Zymeworks' eligibility to receive a share of future revenue received by Iconic as well as tiered royalties on worldwide sales, Zymeworks' clinical and preclinical development of its product candidates, and other information that is not historical information. When used herein, words such as "will", "plan", "intend", and similar expressions are intended to identify forward-looking statements. In addition, any statements or information that refer to expectations, beliefs, plans, projections, objectives, performance or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking. All forward-looking statements are based upon Zymeworks' current expectations and various assumptions. Zymeworks believes there is a reasonable basis for its expectations and beliefs, but they are inherently uncertain. Zymeworks may not realize its expectations, and its beliefs may not prove correct. Actual results could differ materially from those described or implied by such forward-looking statements as a result of various factors, including, without limitation, market conditions and the factors described under "Risk Factors" in Zymeworks' Quarterly Report on Form 10-Q for its quarter ended September 30, 2020 (a copy of which may be obtained at www.sec.gov and www.sedar.com). Consequently, forward-looking statements should be regarded solely as Zymeworks' current plans, estimates and beliefs. Investors should not place undue reliance on forward-looking statements. Zymeworks cannot guarantee future results, events, levels of activity, performance, or achievements. Zymeworks does not undertake and specifically declines any obligation to update, republish, or revise any forward-looking statements to reflect new information, future events or circumstances or to reflect the occurrences of unanticipated events, except as may be required by law.

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