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Synthetic Biologics Completes Acquisition of VCN Biosciences

- Expands pipeline into oncology with unique, clinical-stage oncolytic viruses optimized for intravenous administration -

- Strong cash position to support multiple inflection points for VCN-01 with the start of a Phase 2 trial in combination with standard-of-care chemotherapy in patients with pancreatic ductal adenocarcinoma and a Phase 2/3 pivotal trial either as an adjunct to chemotherapy or a potential rescue therapy in advanced retinoblastoma pediatric patients -

ROCKVILLE, Md., March 11, 2022 (GLOBE NEWSWIRE) -- Synthetic Biologics, Inc. (NYSE American: SYN), a diversified clinical-stage company developing therapeutics designed to treat diseases in areas of high unmet need, today announced that it has completed the acquisition of VCN Biosciences, S.L. (VCN) following the satisfaction of all closing conditions.

VCN is a privately held clinical-stage biotech company focused on developing a new oncolytic adenovirus (OV) platform designed for intravenous (IV) and intravitreal (IVit) delivery to trigger tumor cell death, improve access of co-administered cancer therapies to the tumor, and promote a robust and sustained anti-tumor response by the patient's immune-system. The acquisition transforms Synthetic Biologics' pipeline with the addition of VCN's lead clinical-stage drug candidate, VCN-01, as well as preclinical stage VCN-11, both of which are next-generation OVs in development for the treatment of cancers with high unmet need. VCN-01 was granted Orphan Drug Designation in 2011 by the European Medicines Agency (EMA) for the treatment of pancreatic ductal adenocarcinoma (PDAC), and in February this year was granted Orphan Drug Designation by the U.S. FDA for the treatment of retinoblastoma (RB). VCN-11 is a modified version of VCN-01 that incorporates a proprietary albumin binding domain in the virus outer shell and was designed to improve systemic delivery by enabling the virus to coat itself with host serum albumin and prevent inactivation by neutralizing antibodies.

"The acquisition of VCN positions us at the forefront of oncolytic virus development and propels the Synthetic Biologics pipeline forward," said Steven A. Shallcross, Chief Executive Officer of Synthetic Biologics. "The therapeutic application of OVs has been limited, in part, by a need for local administration. Our OVs are designed for systemic administration to target primary as well as metastatic tumors. Once inside the tumor, our OVs are uniquely engineered to replicate selectively and aggressively within the tumor cells and to break down the tumor stroma through the expression of PH20, a differentiating benefit of VCN-01."

Mr. Shallcross continued, "We are highly encouraged by the promising clinical safety and efficacy data generated to date, and we plan to start a Phase 2 trial of VCN-01 in combination with gemcitabine/Abraxane® standard of care chemotherapy in PDAC patients.

The trial will be led by Dr. Manuel Hidalgo Medina, an internationally renowned physician, scientist and academic, with deep expertise in oncology, and a Member of the Board of Directors at Bristol Myers Squibb. Additionally, we plan to initiate a Phase 2/3 pivotal trial of VCN-01 as either an adjunct to chemotherapy or a potential rescue therapy in advanced RB pediatric patients. With a strong cash position and established collaborations with leaders in the field, we are poised to advance a robust multi-regional clinical program and maximize the clinical potential of our innovative product pipeline. We remain committed to driving shareholder value and look forward to providing updates on our progress as we work towards improving the lives of patients."

Transaction Details

As consideration for the purchase of VCN, at the closing of the transaction Synthetic Biologics paid US$4,700,000 to Grifols Innovation and New Technologies Limited, the owner of approximately 86% of the equity of VCN, and issued to the remaining shareholders and certain key employees and consultants of VCN 26,395,303 shares of common stock of Synthetic Biologics, representing 19.99% of the outstanding shares of Synthetic's Biologics common stock on December 14, 2021, the date of the Share Purchase Agreement with VCN and its shareholders. In addition to the consideration described above, under the terms of the Share Purchase Agreement, Synthetic Biologics has also agreed to make the following milestone payments to Grifols Innovation and New Technologies Limited:

Milestone Payments
US$3MM upon VCN-01 US IND Safe to Proceed – PDAC (or other *first* indication)
US$2.75MM upon VCN-01 US IND Safe to Proceed – RB (or other *second* indication)
US$3.25MM upon VCN-01 US first patient dosed– PDAC (or other *first* indication) after receipt of VCN-01 US IND Safe to Proceed for PDAC being informed
US$3.25MM upon VCN-01 US first patient dosed – RB (or other *second* indication) after receipt of VCN-01 US IND Safe to Proceed for RB being informed
US$6MM upon VCN-01 US Phase 2 trial meets the primary endpoint or if a Phase 2 trial is not conducted and only a Phase 3 trial is conducted then upon a Phase 3 being initiated – PDAC (or other *first* indication)
US$8MM upon VCN-01 Pivotal Trial meeting the primary endpoint or upon BLA Submission – RB (or other *second* indication)
US$12MM upon VCN-01 US Phase 3 trial meeting the primary endpoint or upon BLA Submission – PDAC (or other *first* indication)
US$16MM upon VCN-01 BLA Approval – PDAC (or other *first* indication)
US$16MM upon VCN-01 BLA Approval – RB (or other *second* indication)

In addition, Synthetic Biologics agreed as a post-Closing covenant to commit to fund VCN's research and development programs, including but not limited to VCN-01 PDAC Phase 2 trial, VCN-01 RB pivotal trial and necessary G&A within a budgetary plan of approximately US$27.8 million.

A.G.P./Alliance Global Partners served as exclusive financial advisor to Synthetic Biologics in connection with the transaction. Tungsten Advisors served as the exclusive financial advisor to VCN Biosciences SL.

About Synthetic Biologics, Inc.

Synthetic Biologics, Inc. (NYSE American: SYN) is diversified clinical-stage company developing therapeutics designed to treat diseases in areas of high unmet need. The Company recently consummated the acquisition of VCN Biosciences, S.L. (VCN), which is developing a new oncolytic adenovirus (OV) platform designed for intravenous (IV) and intravitreal delivery to trigger tumor cell death, improve access of co-administered cancer therapies to the tumor, and promote a robust and sustained anti-tumor response by the patient's immune-system. In addition, the Company's lead candidates are: (1) SYN-004 (ribaxamase) which is designed to degrade certain commonly used IV beta-lactam antibiotics within the gastrointestinal (GI) tract to prevent (a) microbiome damage, (b) Clostridioides difficile infection (CDI), (c) overgrowth of pathogenic organisms, (d) the emergence of antimicrobial resistance (AMR), and (e) acute graft-versus-host-disease (aGVHD) in allogeneic hematopoietic cell transplant (HCT) recipients, and (2) SYN-020, a recombinant oral formulation of the enzyme intestinal alkaline phosphatase (IAP) produced under cGMP conditions and intended to treat both local GI and systemic diseases. For more information, please visit Synthetic Biologics' website at www.syntheticbiologics.com.

Forward-Looking Statements

This release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. In some cases forward-*looking statements can be identified by terminology such as "may," "should," "potential," "continue," "expects," "anticipates," "intends," "plans," "believes," "estimates," and similar expressions, and include statements regarding strong cash position supporting multiple inflection points for VCN-01 with the start of a Phase 2 trial in combination with standard-of-care chemotherapy in patients with pancreatic ductal adenocarcinoma and a Phase 2/3 pivotal trial either as an adjunct to chemotherapy or a potential rescue therapy in advanced retinoblastoma pediatric patients, being poised to advance a robust multi-regional clinical program and maximize the clinical potential of Synthetic Biologics' product pipeline, VCN's new oncolytic adenovirus platform triggering tumor cell death, improving access of co-administered cancer therapies to the tumor, and promoting a robust and sustained anti-tumor response by the patient's immune-system, starting a Phase 2 trial of VCN-01 in combination with gemcitabine/Abraxane® standard of care chemotherapy in patients with pancreatic ductal adenocarcinoma and initiating a Phase 2/3 pivotal trial of VCN-01 as either an adjunct to chemotherapy or a potential rescue therapy in advanced RB pediatric patients. These forward-looking statements are based on management's expectations and assumptions as of the date of this press release and are subject to a number of risks and uncertainties, many of which are difficult to predict that could cause actual results to differ materially from current expectations and assumptions from those set forth or implied by any forward-looking statements. Important factors that could cause actual results to differ materially from current expectations include, among others, whether the combined business of Synthetic Biologics and VCN will be successful, Synthetic Biologics' and VCN's product candidates demonstrating safety and effectiveness, as well as results that are consistent with prior results, the ability to initiate clinical trials (including the planned Phase 2 trial of VCN-01 in combination with standard-of-care chemotherapy in patients with pancreatic ductal adenocarcinoma and a Phase 2/3 pivotal trial as either an adjunct to chemotherapy or a potential rescue therapy in in pediatric patients with advanced retinoblastoma, and if initiated, the ability to complete them on time and achieve the desired results and benefits continuing enrollment as expected, the ability to obtain regulatory approval for commercialization of product candidates or to comply with ongoing regulatory requirements,*

regulatory limitations relating to Synthetic Biologics' and VCN's ability to promote or commercialize their product candidates for the specific indications, acceptance of product candidates in the marketplace and the successful development, marketing or sale of Synthetic Biologics' and VCN's products, developments by competitors that render such products obsolete or non-competitive, Synthetic Biologics' and VCN's ability to maintain license agreements, the continued maintenance and growth of Synthetic Biologics' and VCN's patent estate and other factors described in Synthetic Biologics' Annual Report on Form 10-K for the year ended December 31, 2020 and its other filings with the SEC, including subsequent periodic reports on Forms 10-Q and 8-K. The information in this release is provided only as of the date of this release, and Synthetic Biologics undertakes no obligation to update any forward-looking statements contained in this release on account of new information, future events, or otherwise, except as required by law.

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