Synthetic Biologics Announces Planned Transformative Acquisition of VCN Biosciences; Developer of a Novel Oncolytic Virus Platform Targeting Pancreatic and other Solid Tumors

Lead drug candidate VCN-01 demonstrated clinical activity in multiple Phase 1 clinical trials

Designed for systemic delivery, high selectivity, and enhanced tumor access

VCN-01 granted Orphan Drug Designation in Pancreatic Cancer by the EMA

Synthetic Biologics and VCN Biosciences to host a conference call today, December 14th, at 10:00 a.m. Eastern Time

For Immediate Release

Rockville, MD, December 14, 2021 – 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 it has signed a definitive agreement to acquire VCN Biosciences, S.L. (VCN), which is developing a new oncolytic adenovirus (OV) platform designed for intravenous (IV) delivery to trigger tumor cell death and promote immune cell infiltration into tumors. Total upfront consideration for the acquisition is $4.7 million in cash plus the assumption of $2.4 million of VCN liabilities. Additionally, VCN will receive shares of Synthetic Biologics' common stock representing 19.99% of the total shares outstanding of the Company's common stock. The Company has also agreed to an additional $70.3 million of payments contingent upon the achievement of future milestones, a majority of which are tied to late-stage clinical development and regulatory achievements. The transaction is expected to close during the first quarter of 2022, and is subject to, among other things, the approval by the Spanish government of the Company's acquisition of VCN under Spain's Foreign Investment Act and other customary closing conditions. Additional details regarding the transaction are available in the Company's Current Report on Form 8-K, which has been filed with the Securities and Exchange Commission and is available on the Company's website.

VCN's technology platform is designed to overcome critical challenges that restrict the development of the majority of OV therapies today. Unlike many OVs that can only be administered by direct intratumoral injection, VCN's OVs are designed for systemic intravenous administration to target primary as well as metastatic tumors. Once inside the tumor, VCN's OVs are designed to replicate selectively and aggressively, and to produce hyaluronidase (PH20), an enzyme that digests hyaluronan, a key component of the dense tumor stroma that often plays a crucial role in tumor progression. Degradation of tumor stroma has been shown to diminish a significant physical and immunosuppressive barrier to cancer treatment and thereby improve access to the tumor by additional therapies such as chemo and immuno-therapies. Results from previously completed clinical trials demonstrate that this process can occur for weeks or months following a single intravenous injection with a VCN OV. VCN is seeking to leverage these unique capabilities to address cancers with a high unmet need.

VCN OVs are also designed to be administered intratumorally or intravitreally (in the eye), either as a monotherapy or in combination with standard of care, to treat a wide variety of cancer indications. Combination treatment of VCN OVs with a variety of chemotherapies and immunotherapies such as checkpoint inhibitors and CAR-T cells are in early clinical testing or planned. VCN has the rights to four exclusive patents for proprietary technologies, as well as technologies developed in collaboration with the Virotherapy Group of the Catalan Institute of Oncology (ICO-IDIBELL), with a number of additional patents pending.

VCN's lead drug candidate, VCN-01, has been evaluated in four Phase 1 clinical trials to date, including in patients with pancreatic cancer, head and neck squamous cell carcinoma, and retinoblastoma (Rb). In a Phase 1 clinical trial, patients with metastatic pancreatic ductal adenocarcinoma (PDAC) received the combination therapy of intravenous VCN-01 with the standard of care chemotherapy Gemcitabine plus Abraxane® (G/A). Best results were observed when VCN-01 was administered one week before the first G/A dose. VCN-01 was well tolerated and when combined with G/A demonstrated an improved median overall and progression free survival, as well as a high response rate compared to G/A alone. These data compare favorably with current standard of care and are the basis of a planned Phase 2 clinical trial of the higher dosing level.

VCN-01 is also being studied as a monotherapy in patients with retinoblastoma (RB) who previously failed chemotherapy. Intravitreal administration of VCN-01 produced a complete remission and a reduction of tumors in several patients. These promising outcomes form the basis for an Orphan Drug application with the FDA and are planned to be explored in a larger future clinical trial.

VCN is also developing a next generation Albumin Shield™ technology platform, VCN-11, which builds upon the pre-clinical and clinical results of VCN-01. VCN-11 incorporates an albumin binding domain in the virus outer shell designed to enable the virus to coat itself with host serum albumin, potentially preventing its inactivation by neutralizing antibodies in the bloodstream en route to the tumor. The addition of the Albumin Shield technology is not expected to interfere with VCN-11's ability to target tumor cells and may allow for repeated administration to optimize tumor exposure.

Steven A. Shallcross, Chief Executive Officer of Synthetic Biologics, commented, "We are excited to announce this transformative acquisition, as VCN's platform represents a potentially breakthrough approach to cancer treatment with oncolytic viruses by allowing for systemic delivery, high selectivity and enhanced tumor access. In addition to triggering tumor cell death, these therapies have been shown to elicit a strong anti-tumor immune response. The results of the Phase 1 clinical trial in PDAC, a highly aggressive and lethal malignancy, are very encouraging with respect to tumor response and survival. Significantly, biopsies in these patients confirmed up regulation of tumor immune markers and induction of a robust antitumor immune response, including increased tumor infiltration by cytotoxic T-cells. These results suggest VCN-01 holds significant potential to increase the addressable market for checkpoint inhibitors and CAR-T therapies, as these therapies have historically been less effective immunologically against "cold" tumors like PDAC."

"Based on encouraging results of prior preclinical and clinical trials of VCN-01, we plan to initiate a controlled Phase 2 clinical trial of VCN-01 at multiple centers across the US and EU. There is a significant unmet need for a safe and effective therapy for patients with pancreatic cancer, a condition in which most people diagnosed do not survive more than a year following their initial diagnosis. Based on highly encouraging early clinical results, we also plan to conduct a registrational trial in pediatric patients with advanced Rb. Importantly, this is an underserved patient population and we believe VCN-01 holds tremendous promise to preserve the eyes of these patients, who are typically less than two years old at diagnosis. We believe these trials can be conducted relatively quickly and efficiently. At the same time, we are also evaluating investigator-sponsored studies combining VCN-01 with CAR-T therapies, as well as VCN-01 in other orphan indications such as glioblastoma. We look forward to providing additional details on the timing and design of these trials in the near future."

"VCN was founded by internationally recognized experts in oncolytic adenoviruses for cancer treatment and I will be delighted to welcome them to our team. VCN's novel therapies allow for a robust and efficient manufacturing process, with an attractive cost structure. The platform is supported by a growing intellectual property (IP) portfolio that provides it patent protection through at least 2030 with additional patents underway that we believe would further strengthen our IP portfolio. Importantly, VCN-01 has been granted Orphan Drug Designation by the European Medicines Agency (EMA), which may provide a number of benefits including up to ten years of market exclusivity. Importantly, we have a strong balance sheet with over $72.1 million of cash as of September 30, 2021, which we believe will provide us significant runway to both support our existing programs, as well as to able to advance VCN-01 and VCN-011 through important milestones that we believe will drive significant shareholder value."

Manel Cascalló, PhD, Chief Executive Officer of VCN, noted, "Joining together with Synthetic Biologics is a significant opportunity as it allows us to partner with an experienced team, well-versed in drug development, manufacturing, and commercialization. We anticipate the combined company will have the financial resources to fund our clinical programs to key value inflection points and we look forward to a successful future together."

Conference Call

Synthetic Biologics will hold a conference call today, December 14, 2021, at 10:00 a.m. Eastern Time. The dial-in information for the call is as follows, U.S. toll free: 1-888-347-5280 or International: +1 412-902-4280. Participants are asked to dial in 15 minutes before the start of the call to register. The call will also be webcast over the Internet at https://www.webcaster4.com/Webcast/Page/1096/43946. An archive of the call will be available for replay at the same URL, https://www.webcaster4.com/Webcast/Page/1096/43946, for 90 days after the call.

About Synthetic Biologics, Inc.

Synthetic Biologics, Inc. (NYSE American: SYN) is a diversified clinical-stage company developing therapeutics designed to treat diseases in areas of high unmet need. The Company's lead candidates are: (1) SYN-004 (ribaxamase) which is designed to degrade certain commonly used intravenous (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.

About A.G.P./Alliance Global Partners

A.G.P./Alliance Global Partners served as excusive financial advisor to Synthetic Biologics in connection with the transaction.

A.G.P./Alliance Global Partners is a regional investment banking and advisory firm that has been a member of FINRA and registered with the SEC since 1980. A.G.P. specializes in wealth management and the middle-market institutional arena. With full-service capabilities, we possess a global ability to handle domestic as well as international customers. In addition, A.G.P. provides capital markets and corporate services. We offer advanced market expertise and deep industry knowledge to institutional clients and issuers alike. The core members of our team have been extremely active in the small and mid-cap investment banking space, including, but not limited to, Follow-On Offerings, PIPEs and Registered Directs.

About Tungsten Advisors

Tungsten Advisors served as the exclusive financial advisor to VCN Biosciences SL. Tungsten Advisors (www.tungstenadv.com) is an investment banking firm focused on strategic advisory and corporate finance for healthcare and technology companies. Tungsten provides transactional services including financings (private placements/PIPEs), corporate partnering and mergers and acquisitions (M&A). Tungsten also focuses on company incubation and makes direct investments alongside the creation of new companies in healthcare and technology.

Tungsten Partners, LLC and Ashland Securities, LLC are separate and unaffiliated entities. Securities and Investment Banking Services are offered through Ashland Securities, LLC.

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 the proposed acquisition of VCN by Synthetic Biologics, closing the transaction during the first quarter of 2022, VCN's platform representing a potentially breakthrough approach to cancer treatment with oncolytic viruses by allowing for systemic delivery, high selectivity and enhanced tumor access, VCN-01 holding significant potential to increase the addressable market for checkpoint inhibitors and CAR-T therapies, plans to initiate a controlled Phase 2 clinical trial of VCN-01 at multiple centers across the US and EU, plans to conduct a registrational trial in pediatric patients with advanced Rb given, providing additional details on the timing and design of the trials in the near future and Synthetic Biologics' balance sheet providing significant runway to both support Synthetic Biologics' existing programs, as well as to able to advance VCN-01 and VCN-011 through important milestones that will drive significant shareholder value. s. 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, the risk associated with Synthetic Biologics and VCN's ability to satisfy the conditions to consummate the proposed acquisition, including obtaining necessary governmental approvals, the timing of the closing of the proposed acquisition, the occurrence of any event, change or other circumstance or condition that could give rise to the termination of the Stock Purchase Agreement between the shareholders of VCN and Synthetic Biologics, unanticipated difficulties or expenditures relating to the proposed acquisition or development of VCN's drug candidates, the response of business partners and competitors to the announcement of the proposed acquisition, and/or potential difficulties in employee retention as a result of the announcement and pendency of the proposed acquisition, 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 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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