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Synthetic Biologics Announces VCN Biosciences' VCN-01 Receives Orphan Drug Designation for Retinoblastoma from the U.S. FDA

Follows recent announcement of planned acquisition of VCN Biosciences by Synthetic Biologics

ROCKVILLE, Md., Feb. 8, 2022 /PRNewswire/ --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 VCN Biosciences, S.L.'s (VCN) VCN-01 received Orphan Drug Designation for retinoblastoma from the U.S. Food & Drug Administration (FDA). This announcement follows Synthetic Biologics' recent announcement that it had entered a definitive agreement to acquire VCN, which is subject to conditions that must be met prior to closing. VCN is developing a new oncolytic adenovirus (OV) platform designed to trigger tumor cell death and promote immune cell infiltration into tumors.

The FDA's Office of Orphan Products Development grants orphan status to drugs being developed to treat, diagnose or prevent a rare disease or condition affecting fewer than 200,000 people in the United States. Orphan Drug Designation is designed to provide drug developers with various benefits to support the development of novel drugs, including the potential for market exclusivity for seven years upon FDA approval, eligibility for tax credits for qualified clinical trials, waiver of application fees, reduced annual product fees, clinical protocol assistance and potential qualification for expedited development programs.

Steven Shallcross, Chief Executive Officer and Chief Financial Officer of Synthetic Biologics, commented, "We are pleased to report that VCN's VCN-01 was granted Orphan Drug Designation for retinoblastoma by the FDA. We believe VCN-01 may represent a novel rescue therapy for patients who fail standard therapy, or may be used as an adjunct to chemotherapy, to provide improved outcomes for these patients. We are highly encouraged by the preliminary clinical data thus far and look forward to conducting a pivotal Phase 2/3 trial in these patients following our expected completion of the acquisition."

About VCN Biosciences

VCN Biosciences is a clinical-stage immuno-oncology company focused on the development of the next generation of oncolytic adenoviruses. VCN candidates are designed to obtain clinical activity after systemic administration and are able to remodel the complex matrix in the tumor to allow enhanced spreading of therapeutic molecules and the immune system. VCN Biosciences lead product, VCN-01, is a oncolytic adenovirus with unique characteristics being studied in clinical trials for cancers for which there is no cure, including pancreatic carcinoma and retinoblastoma. For more information, please visit www.vcnbiosciences.com.

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 announced it has entered into 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. 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. In addition, 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.

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, the planned acquisition of VCN, VCN-01 representing a novel rescue therapy for patients who fail standard therapy, or being used as an adjunct to chemotherapy, to provide improved outcomes for these patients, and conducting a pivotal Phase 2/3 trial in these patients following the expected completion of the acquisition . 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 VCN, 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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