



**Indapta Therapeutics and Lonza Announce Strategic Partnership  
to Advance a Next-generation, Off-the-shelf, Allogeneic Immuno-oncology Therapy**

*Indapta Developing First-in-class, Proprietary Cancer Therapy Based on a Specific, Potent  
Variety of Natural Killer Immune Cells  
for Use in Combination with Multiple Monoclonal Antibodies*

*Lonza to Provide Process Development, Clinical Manufacturing  
and Regulatory Support for IND Submission*

*Indapta Emerges from Stealth Mode,  
Unveils Founding Management Team and Scientific Advisors*

SAN FRANCISCO & BASEL, Switzerland, January 10, 2020 – Indapta Therapeutics, Inc., a biotechnology company focused on developing and commercializing a proprietary, first-in-class, off-the-shelf, non-engineered, allogeneic G-NK (FcRγ-deficient Natural Killer) cell therapy to treat multiple cancers, and Lonza today announced a strategic partnership. Indapta also announced its founding leadership team and scientific advisors.

Under the terms of the agreement, Lonza will manufacture Indapta's off-the-shelf, allogeneic G-NK cell therapy under current good manufacturing practices (cGMP) for use in clinical studies. Indapta will leverage Lonza's process development capabilities and expertise to ensure a robust, reproducible and scalable cGMP process. Process development and manufacturing will take place in Lonza's state-of-the-art cell and gene therapy manufacturing facility in Houston.

"We believe our first-in-class, off-the-shelf, allogeneic G-NK cell therapy will drive the next critical phase in the evolution of cancer therapies following CAR T-cell therapies," said Guy DiPierro, founder and chief executive officer of Indapta Therapeutics. "Current autologous CAR T-cell therapies have proven efficacy in various hematologic cancers but have been beset with serious clinical and manufacturing challenges. By providing an off-the-shelf solution with our G-NK cell therapy, we can eliminate the need for a patient-specific therapy. Additionally, because our investigational cell therapies are not engineered, they are likely to be more effective, less costly and have a simpler regulatory pathway."

"Lonza, with its demonstrated expertise in cell therapy manufacturing, is the ideal strategic partner to help us advance our clinical program and scale the production of our G-NK cell therapy," said Ronald Martell, co-founder and executive chairman of Indapta Therapeutics. "We are currently completing Investigational New Drug-enabling studies and plan to submit an IND application in late 2020 and initiate a first-in-human Phase 1/2 study in early 2021."

"Indapta's world-class team of NK cell scientists and clinicians and cell therapy experts has created an innovative off-the-shelf immuno-oncology therapy based on a subset of cancer-killing NK cells that could make a truly meaningful impact in the treatment of hematologic malignancies and solid tumors," said Scott Waldman, chief strategy officer at Lonza.

Alberto Santagostino, senior vice president, head of Cell & Gene Technologies at Lonza, added, "with our long-standing experience in cell therapy manufacturing, we are committed to providing Indapta with the expertise, resources and services it needs for cGMP manufacturing to advance its promising program into the clinic and beyond."

## **About Indapta's G-NK Cell Therapy**

Indapta Therapeutics is developing off-the-shelf, allogeneic FcεR1γ-deficient NK cells, known as G-NK cells.<sup>i,ii,iii</sup> These proprietary cells are a specific and potent subset of NK cells with specialized anti-tumor activity when used in combination with a monoclonal antibody. G-NK cells are NK cells that have undergone an epigenetic change after coming into contact with cytomegalovirus (CMV)-infected cells. As a result, they lack the FcεR1γ signaling adapter and, instead, use a different adapter protein, which predisposes them to a far more activated state of antibody-dependent cell-mediated cytotoxicity (ADCC) in the presence of a monoclonal antibody. When the monoclonal antibody binds to the tumor target and to the Fc receptor on G-NK cells, it initiates the release of dramatically more immune-stimulating cytokines and cell-killing enzymes than conventional NK cells, causing the direct killing of tumor cells and driving tumor cell death. G-NK cells have been demonstrated to be safe; in vivo studies demonstrate they do not cause graft-vs-host disease or cytokine release syndrome, which can occur with CAR-T cell therapies.

Preclinical research, conducted under NIH grants by scientists at the University of California, San Francisco (UCSF), demonstrated the safety and efficacy of G-NK cells administered in combination with a therapeutic monoclonal antibody. Clinical models of multiple myeloma and lymphoma demonstrated improved survival, a statistically significant decrease in tumor growth, and a statistically significant increase in the activity of the monoclonal antibody without causing graft-vs-host disease. When administered in combination with a monoclonal antibody, G-NK cells have been shown to be highly persistent (lasting four to nine months), to have the ability to preferentially bind to a therapeutic monoclonal antibody in the presence of a tumor cell, and to demonstrate superior ADCC function compared with conventional NK cells. Under a second Indapta NIH grant, researchers at Stanford University will be conducting in vivo studies in additional tumor models.

Indapta's off-the-shelf G-NK cell therapy is differentiated from an autologous therapy in that it is not necessary to collect cells from each individual patient and produce a unique therapy for every patient. Rather, it is derived from cells from healthy volunteers, which are highly functional and persistent. Indapta's process for producing G-NK cell therapy for use as an immunotherapy involves taking blood from CMV-seropositive donors, identifying and sorting G-NK cells from these samples, and expanding G-NKs cells using the company's proprietary, patented expansion method, which preferentially expands and activates GNK cells. Indapta has also developed a proprietary method for freezing and storing the G-NK cells in a GMP master cell bank for use as off-the-shelf allogeneic outpatient immunotherapy in cancer patients.

Developing off-the-shelf G-NK cells may sidestep some of the clinical and financial challenges presented by other, more customized and engineered immuno-oncology approaches, which involve time-consuming and costly manufacturing processes and often can only be delivered in specialized centers. The manufacturing COGS for Indapta's program will be relatively inexpensive compared to CAR-T or engineered NK cell therapies. Additionally, the regulatory approval process for Indapta's program may be more straightforward than that for autologous CAR-T cell therapy or engineered NK cells because it does not involve complicated cell engineering.

Not only are G-NK cells widely available from multiple sources, they have the potential to be used in combination with multiple monoclonal antibodies to treat numerous types of cancer (e.g., multiple myeloma, lymphoma, leukemia, melanoma, ovarian, colorectal, renal, liver, breast and lung).

## **Indapta's Founding Management Team**

- **Guy DiPierro, Founder and Chief Executive Officer**, has over 15 years of experience founding, building, funding and attracting world-leading talent to specialty pharma companies. Prior to Indapta, he was the founder, CEO, chairman and inventor at Chrono Therapeutics. Earlier in his career, he served as Executive Vice President and General Counsel of AMGI Capital. Before that, he was a corporate M&A and technology licensing attorney at Brown and Wood (now Sidley Austin) and Squadron Ellenoff (now Hogen Lovells). He is the inventor on 11 granted U.S. patents and over 36 global and pending patents.
- **Ronald Martell, Co-Founder and Executive Chairman**, has founded, led, built and/or managed a number of unique businesses in the biotech industry during the last 30 years. They include Encellin, ORCA BioSystems, Cetya Therapeutics, HAVAH Therapeutics, Achieve Life Sciences, Sevion Therapeutics, KaloBios, NeurogesX, Poniard Pharmaceuticals, and ImClone Systems. He is currently the president and CEO of Nuvelution Pharma.
- **Catherine Polizzi, Chief Intellectual Property (IP) Counsel**, is a partner at Morrison Foerster, where she assists emerging and established companies in obtaining patents, provides strategic portfolio counseling and management around breakthrough therapies in a variety of areas, including cancer immunotherapy, and offers strategic advice regarding freedom of operation and other forms of IP assessment. She was head IP attorney for Juno Therapeutics, which was acquired by Celgene for \$9 billion in part on the strength of the patent portfolio that she crafted.
- **Austin Bigley, Ph.D., Acting Director of Research and Development**, is a member of the Department of Health and Human Performance at the University of Houston. He is an NK cell expert, particularly in how CMV infection modulates NK cell activity against hematologic malignancies; NK cell expansion; ADCC; and the monoclonal antibody-NK cell cytotoxicity domain.
- **Kathy Leach, Ph.D., Chemistry, Manufacturing & Controls (CMC) and Quality Advisor**, was formerly a director of CMC Quality & Analytics at Juno Therapeutics, where she was responsible for the quality strategy and management of key CMC programs for the company's cell therapy products. Earlier in her career, she was a product quality director at Amgen and a formulation/analytical research scientist at Immunex.

#### **Indapta's Scientific Advisors**

- **Nina Shah, M.D.**, Associate Professor, Department of Medicine, UCSF. A hematologist specializing in the treatment of multiple myeloma, Dr. Shah treats patients at the Hematology and Blood Marrow and Transplant Clinic at UCSF. She has expertise in the intersection of immunology and oncology and helping patients fight multiple myeloma by boosting their immune system.
- **Sungjin Kim, Ph.D.**, Scientific Founder of Indapta; Inventor and Associate Professor, Department of Medical Microbiology and Immunology, University of California, Davis
- **John Sunwoo, M.D.**, Scientific Founder of Indapta; Professor, Stanford University School of Medicine
- **Todd A. Fehniger, M.D., Ph.D.**, Associate Professor of Medicine, Washington University School of Medicine
- **Vaughn Smider, M.D., Ph.D.**, Associate Professor, Molecular Medicine, The Scripps Research Institute
- **Arun Witt, M.D., Ph.D.**, Associate Professor, Department of Laboratory Medicine, UCSF

#### **About Indapta Therapeutics**

Indapta Therapeutics, Inc. is a biotechnology company focused on developing and commercializing a proprietary, first-in-class, off-the-shelf allogeneic cell therapy to treat multiple types of difficult-to-treat hematologic cancers and solid tumors. Headquartered in San Francisco, Indapta was founded in 2017 by Guy DiPierro along with Ronald Martell and scientists at the University of California, Davis, and Stanford University. The company has developed allogeneic FcεRIγ-deficient natural killer (NK) cells, known as G-NK cells, and is working to bring this off-the-shelf cell therapy to patients to address the limitations of currently available autologous T-cell therapies.

### **About Lonza**

Lonza is an integrated solutions provider that creates value along the Healthcare Continuum®. Through our Pharma Biotech & Nutrition segment and our Specialty Ingredients segment businesses, we harness science and technology to serve markets along this continuum. We focus on creating a healthy environment, promoting a healthier lifestyle and preventing illness through consumers' preventive healthcare, as well as improving patient healthcare by supporting our customers to deliver innovative medicines that help treat or even cure severe diseases. Patients and consumers benefit from our ability to transfer our pharma know-how to the healthcare, hygiene and fast-moving consumer goods environment and to the preservation and protection of the world where we live.

Founded in 1897 in the Swiss Alps, Lonza today is a well-respected global company with more than 100 sites and offices and approximately 15,500 full-time employees worldwide at the end of 2018. The company generated sales of CHF 5.5 billion in 2018 with a CORE EBITDA of CHF 1.5 billion. Further information can be found at [www.lonza.com](http://www.lonza.com).

### **Additional Information and Disclaimer**

Lonza Group Ltd has its headquarters in Basel, Switzerland, and is listed on the SIX Swiss Exchange. It has a secondary listing on the Singapore Exchange Securities Trading Limited ("SGX-ST"). Lonza Group Ltd is not subject to the SGX-ST's continuing listing requirements but remains subject to Rules 217 and 751 of the SGX-ST Listing Manual.

Certain matters discussed in this news release may constitute forward-looking statements. These statements are based on current expectations and estimates of Lonza Group Ltd, although Lonza Group Ltd can give no assurance that these expectations and estimates will be achieved. Investors are cautioned that all forward-looking statements involve risks and uncertainty and are qualified in their entirety. The actual results may differ materially in the future from the forward-looking statements included in this news release due to various factors. Furthermore, except as otherwise required by law, Lonza Group Ltd disclaims any intention or obligation to update the statements contained in this news release.

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<sup>i</sup> Hwang I, Zhang T, Scott JM, et al. Identification of human NK cells that are deficient for signaling adaptor FcRγ and specialized for antibody-dependent immune functions. *Int Immunol*. 2012;24(12):793-802.

<sup>ii</sup> Lee J, Zhang T, Lanier LL, Kim S. Epigenetic modification and antibody-dependent expansion of memory-like NK cells in human cytomegalovirus-infected individuals. *Immunity*. 2015;42:431-442.

<sup>iii</sup> Zhang T, Scott JM, Hwang I, Kim S. Antibody-dependent memory-like NK cells distinguished by FcRγ deficiency, *Immunol*. 2013;190(4):1402-1406.