

iTolerance, Inc. and Northway Biotech Announce Partnership Agreement for the Manufacturing of Streptavidin-FasL Fusion Protein for Innovative iTOL-100 Immunomodulatory Technology

iTOL-100 technology has broad applicability and can be applied to both allogenic and stem cell-derived organoids across a number of diseases

Manufacturing agreement supports advancement of iTolerance's development of iTOL-100 towards first in human clinical study for lead program, iTOL-102

MIAMI, FL and VILNIUS, Lithuania – August 1, 2023 – iTolerance, Inc. (“iTolerance” or the “Company”), an early-stage regenerative medicine company developing technologies to enable tissue, organoid or cell therapy without the need for life-long immunosuppression, and Northway Biotech, an end-to-end biologics Contract Development and Manufacturing Organization (CDMO), today announced they have entered into a partnership agreement for the manufacturing of iTolerance's Streptavidin-FasL (SA-FasL) fusion protein, a crucial component of the proprietary iTOL-100 platform technology. The SA-FasL fusion protein has shown great potential in pre-clinical studies, establishing durable, localized immune tolerance and enabling implanted tissue, organoid, or cell therapy to function as a viable replacement for damaged native cells.

Under the terms of the agreement, Northway Biotech will leverage its expertise to develop a robust manufacturing process for the SA-FasL fusion protein. This involves producing a Master Cell Bank (MCB), developing and qualifying analytical methods, optimizing the formulation, development and scaling up of the production process, and manufacturing a cGMP drug substance batch for clinical studies.

“We believe this strategic partnership is not only a significant step for iTolerance, but also in developing advanced regenerative medicine technologies. We are incredibly delighted to establish this important partnership with Northway Biotech, a pre-eminent CDMO, to manufacture the clinical supplies necessary for our first in human clinical study for our lead program, iTOL-102,” commented Dr. Anthony Japour, Chief Executive Officer of iTolerance. “We look forward to working closely with the Northway Biotech team to advance our iTOL-100 technology and progress towards providing treatment options that have the potential to cure diseases without the need for chronic immunosuppression.”

“We are excited to be working with Northway Biotech on this critical component of our iTOL-100 technology. Northway has unique experience working with our cell line which we believe will accelerate our ability to prepare cGMP protein to support our planned first in human clinical study,” added Dennis M. Hester, PhD, SVP of Chemistry, Manufacturing and Controls at iTolerance, Inc.

Prof. Vladas Algirdas Bumelis, Chief Executive Officer and Chairman of the Board at Northway Biotech expressed his enthusiasm, stating, “We are delighted to embark on this dynamic project focused on producing the SA-FasL fusion protein for iTolerance. We believe this partnership is an exciting development in the regenerative medicine field, and we are honored to play a role in

advancing this important work. With a commitment to meeting contractual timelines, our primary objective is to ensure the punctual delivery of these crucial materials to our esteemed partners at iTolerance."

André Markmann, PhD, VP of Business Development at Northway Biotech, added, "The partnership with iTolerance has been smooth sailing from the start. We are pleased to commence this project built on mutual trust and a collaborative spirit that drives both companies to perform at the highest level and deliver exceptional results."

About iTOL-100

iTolerance's iTOL-100 immunomodulatory technology is a biotechnology-derived Streptavidin-FasL fusion protein, a synthetic form of the naturally occurring protein FasL, mixed with a biotin-PEG microgel (SA-FasL microgel) that potentially allows convenient and effective co-administration with implanted cells or organoids to induce local immune tolerance without the need for life-long immunosuppression. This proprietary technology has broad applicability and can be applied to allogenic and stem cell-derived organoids across several diseases.

About iTolerance, Inc

iTolerance is an early-stage privately-held regenerative medicine company developing technologies to enable tissue, organoid or cell therapy without requiring life-long immunosuppression. Leveraging its proprietary biotechnology-derived Streptavidin-FasL fusion protein/biotin-PEG microgel (SA-FasL microgel) platform technology, iTOL-100, iTolerance is advancing a pipeline of programs using both allogenic pancreatic islets and stem cells that have the potential to cure diseases. The Company's lead program, iTOL-102, leverages significant advancements in stem cells to derive pancreatic islets, which allows an inexhaustible supply of insulin-producing cells. Utilizing iTOL-100 to induce local immune tolerance, iTOL-102 has the potential to be a cure for Type 1 Diabetes without the need for life-long immunosuppression. Additionally, the Company is developing iTOL-201 for treating liver failure by utilizing hepatocytes and iTOL-401 as a nanoparticle formulation for large organ transplants without the need for life-long immunosuppression. For more information, please visit www.itolerance.com.

About Northway Biotech

Northway Biotech is a leading contract development and manufacturing organization (CDMO) supporting customers worldwide. Its highly experienced, professional team executes projects at any stage, from cell line construction and process development to cGMP manufacturing of biopharmaceutical products. The company's wide-ranging expertise and vertically integrated service offering translate to the ability to rapidly execute multiple projects from its state-of-the-art GMP facilities while ensuring complete process and product compliance at all stages of research, development and commercial manufacturing. Northway Biotech is a privately owned company founded in 2004 and located in Vilnius, Lithuania, London, United Kingdom, and Waltham, MA, US. Further information can be found on Northway's website at www.northwaybiotech.com.

Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of the "safe-harbor" provisions of the Private Securities Litigation Reform Act of 1995. When used herein, words such as

“anticipate”, “being”, “will”, “plan”, “may”, “continue”, 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 iTolerance’s current expectations and various assumptions. The Company believes there is a reasonable basis for its expectations and beliefs, but they are inherently uncertain. The Company 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 important factors, including, without limitation, anticipated levels of revenues, future national or regional economic and competitive conditions, and difficulties in developing the Company’s platform technology. Consequently, forward-looking statements should be regarded solely as the Company’s current plans, estimates and beliefs. Investors should not place undue reliance on forward-looking statements. The Company cannot guarantee future results, events, levels of activity, performance or achievements. The Company 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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