

# Immunophotonics, CIRSE, and Next Research Announce Innovative Phase 2/3 Clinical Trial: INJECTABL-3

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Immunophotonics, Inc., a clinical-stage biopharma company developing novel immune-stimulating drugs to augment routine tumor destruction techniques – such as tumor ablation or radiation – is pleased to announce a collaboration with The Cardiovascular and Interventional Radiological Society of Europe (CIRSE) around a groundbreaking Phase 2/3 clinical trial.

The trial is designed in collaboration with a Steering Committee nominated by CIRSE and managed by CIRSE's contract research organization, Next Research. This trial, entitled INJECTABL-3, will be a phase 2/3 clinical trial conducted in two phases and is expected to enroll an estimated 300–500 patients in a randomized, controlled study in the United States and Europe.

This pivotal trial will evaluate the safety and efficacy of Immunophotonics's lead clinical asset, IP-001, in combination with ablation treatments in key indications where tumor ablation is the current standard of care.

Prof. Dr. Philippe L. Pereira, MD, an interventional radiologist and the incoming president of CIRSE, commented, "The collaboration between Immunophotonics, CIRSE, and Next Research highlights the importance of multidisciplinary partnerships in advancing major medical breakthroughs for patients in need. Tumor recurrence following radical tumor ablation is a major



unmet medical need, and Immunophotonics's novel approach is not only practical for clinicians and patients, but early data indicates it has tremendous promise."

Immunophotonics is the global pioneer of a concept called Interventional Immuno-Oncology™. This concept has been carefully developed for over a decade and is the combination of tumor destruction techniques with IP-001. This combination has been shown to induce a cancer-specific immune response in multiple solid tumor indications and is intended to eliminate circulating tumor cells and reduce or eliminate cancer recurrence.

CIRSE is the largest non-profit organization in the world supporting teaching, research, and clinical practice in cardiovascular and interventional radiology. With almost 10,000 members in 96 countries, CIRSE is a leading global community for healthcare professionals in minimally invasive procedures, including tumor ablation. For over 10 years, Next Research, an affiliate of CIRSE, has focused on providing high-quality clinical research support for the development of interventional radiology technologies and image-guided therapies.

The collaboration between Immunophotonics, CIRSE, Next Research started with a proposal from leading interventional radiologists and medical oncologists on the ideal study designs to advance the promising Interventional Immuno-Oncology™ approach through clinical development and provides a well-rounded team to execute on the proposed clinical trial. "This partnership signifies an important step in advancing the emerging field of Interventional Immuno-Oncology™," remarked Nathalie Kaufmann, COO at Next Research. "It's just the start, and we look forward to combining the expertise of our organizations to advancing the potential of IP-001."

Prof. Dr. Uwe Martens, MD, Medical Oncologist at SLK-Clinics Heilbronn GmbH and future PI of the INJECTABL-3 study, stated, "We are looking forward to playing a part in the INJECTABL-3 trial and seeing the potential for IP-001 to become a game-changing treatment option for patients that receive tumor ablation. Early data demonstrates tolerability of the investigational product along with promise in terms of IP-001's ability to drive abscopal effects. This type of immune-mediated response could be quite beneficial for patients, and therefore it will be important to conduct this clinical trial."

Tumor ablation is a routine treatment happening in most hospitals around the world. Presently, the approach is successful in eliminating the targeted tumors, just like surgery; however, it has the potential to be much more. "Immunophotonics is dedicated to transforming routine tumor destruction techniques, such as ablation, into something much more powerful for patients," said Lu Alleruzzo, CEO and co-founder of Immunophotonics. "The tumor ablation will liberate tumor information that IP-001 will use to drive a systemic tumor specific immune response. Our clinical data thus far demonstrates the potential of our technology, and we are thrilled to be collaborating with the global clinical experts at CIRSE and Next Research on INJECTABL-3. I believe that together we will forever change the way cancer is treated."

### About IP-001

IP-001 is a proprietary glycan polymer that acts both as an antigen depot and a potent, multimodal immune stimulant capable of inducing immunological responses against cancer. It is designed to (1) prolong the availability of the target antigens, whether sourced through formulation or tumoricidal therapies, (2) facilitate the recruitment and activation of innate immune cells such as antigen-presenting cells (APCs), (3) increase the uptake of the tumor antigens into the APCs, and (4) lead to a downstream adaptive immune response against the antigenic targets. This systemic, adaptive immune response then seeks out and eliminates its target throughout the body.

### About Immunophotonics

Immunophotonics, Inc. is a privately owned clinical-stage biotech company pioneering the field of Interventional Immuno-Oncology™. IP-001, which is the first asset from the company's intellectual property platform and is currently administered in multiple clinical trials, has the potential to overcome the local defenses of the tumor microenvironment to enable a tumor-specific anticancer immune response in solid tumor indications. By combining routine interventions that use energy to destroy tumors, such as ablation or radiation, with intratumoral injection of its proprietary immunoadjuvant, IP-001, Immunophotonics aims to trigger a systemically active cancer immunotherapy, also known as an abscopal effect. The company's world headquarters is in St. Louis, Missouri, USA, and its European headquarters is in Bern, Switzerland.

### About CIRSE

CIRSE is a non-profit making, educational and scientific association aiming to improve patient care through the support of teaching, science, research and clinical practice in the field of interventional radiology.

### About Next Research

Next Research is a Contract Research Organization (CRO) specializing in comprehensive clinical trial management services, supporting high-quality research and development.

### Cautionary Note Regarding Forward-Looking Statements

This press release may contain forward-looking statements. Such statements involve inherent risks and uncertainties, and numerous factors could cause actual results to differ materially from those made or implied herein. All information provided in this press release is as of the date of this press release, and Immunophotonics, Inc. undertakes no duty to update such information, except as required under applicable law.

For more information about the INJECTABL-3 trial:

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