Pfizer Logo

Pioneers in Oncolytic Virus and Gene Therapy Fields Announce Formation of IGNITE Immunotherapy Inc., a Company Focused on Oncolytic Cancer Vaccine Discovery and Development

Monday, December 12, 2016 - 08:00am

Lead investor Pfizer Inc. will collaborate on IGNITE's new research program to help discover potential novel vaccinia viruses

Alameda, CA, December 12, 2016 — IGNITE Immunotherapy Inc. (IGNITE), a new company focused on oncolytic virus vaccine design, discovery and development today announced its formation. Along with strategic collaborative partner and lead investor Pfizer Inc. (NYSE: PFE), IGNITE will focus on the discovery and development of targeted and proprietary next-generation intravenous oncolytic (cancer cell lysing) virus vaccines for the immunotherapy of cancer. These biotherapeutics may be optimized for use in combination with immune checkpoint inhibitors. IGNITE is developing a robust and proprietary vector discovery platform, Oncolytic Vaccine Evolution, to potentially discover novel vectors for use in its lytic cancer vaccine products.

Key terms of the agreement with Pfizer include Pfizer holding a 50 percent equity investment in IGNITE, Pfizer providing full research and development funding for three years, and Pfizer having an exclusive option to acquire IGNITE after the initial research program is completed. Pfizer also has two seats on IGNITE's board of directors. Financial terms were not disclosed.

"We are excited to announce the formation of IGNITE Immunotherapy, which we hope will emerge as a leader in the oncolytic virus cancer vaccine and immunotherapy fields. Our founding scientific team has deep expertise in the fields of oncolytic virus design and development, cancer immunotherapy, gene therapy and biotech entrepreneurship", said Dr. David Kirn, co-founder and Executive Chairman of IGNITE. "I'm thrilled and honored to be working with my co-Founders and internationally-recognized scientific leaders Dr. David Schaffer and Dr. Douglas Hanahan. Together with our collaborators at Pfizer, we have highly complimentary skill sets that will help enable our success in this complex and promising field. Our mission is to create intravenous oncolytic cancer vaccines that will be safe and highly effective in combination with immune checkpoint inhibitors, which we hope will ultimately cure patients with metastatic cancers."

"This partnership with IGNITE represents a significant advancement in Pfizer's investment in oncolytic viruses, which we believe strengthens our position as a leader in next-generation immuno-oncology," said James Merson, Ph.D., Chief Scientific Officer, Vaccine Immunotherapeutics at Pfizer and a member of IGNITE's scientific advisory board and board of directors. "Pfizer has a strong and growing portfolio of immuno-oncology assets, and we remain committed to developing unique cancer therapies and novel combination therapies that may

benefit patients around the world.

About the Senior Scientific co-Founders and Board of IGNITE Immunotherapy Inc.

David Kirn, MD: co-Founder & Executive Chairman
Dr. Kirn is a physician-scientist, biotech entrepreneur and pioneer in oncolytic virus design, research and development with over 20 years in the field. IGNITE is his 4th start-up company in the field. He is also currently co-founder, Chairman and CEO of 4D Molecular Therapeutics, an AAV gene therapy company, and adjunct Professor of Bioengineering at UC Berkeley. Dr. Kirn has led the preclinical or clinical development of over 10 oncolytic virus therapeutics, including clinical trials involving over 800 patients in first-in-man through Phase 3 trials (including products from Onyx, Jennerex & Novartis/Cell Genesys). He has co-authored over 100 publications in the field. He has degrees from UC Berkeley (BA), UCSF (MD; Clinical Research & Biostatistics), and Haas Business School at UC Berkeley, and trained in internal medicine at Harvard (Brigham & Women's Hospital) and in oncology at UCSF.

Dave Schaffer, PhD: co-Founder & SAB co-Chair
Dr. Schaffer is a leader in viral vector gene therapy and stem cell discovery, research and development. IGNITE is his 2nd start-up company in the field. At UC Berkeley, he is Professor of Chemical and Bioengineering, and Director of the Stem Cell Center. He is also currently co-founder & acting CSO of 4D Molecular Therapeutics, an AAV gene therapy company developing his directed vector evolution discovery platform. He has co-authored over 100 publications. He has degrees from Stanford (BS) and MIT (PhD), and his post-doctoral training was at The Salk Institute with Rusty Gage.

Doug Hanahan: co-Founder & SAB co-Chair
Dr. Hanahan is a leader in cancer research with over 25 years of experience in the fields of cancer biology, mouse tumor models, tumor resistance mechanisms and experimental therapeutics (including oncolytic viruses). IGNITE is his 3rd start-up company in the field (previous SAB member at Jennerex and Onyx). He is Director of the Swiss Institute for Cancer Research (ISREC), and Professor at EPFL (Lausanne, Switzerland); he previously was on the faculty at UCSF Medical School. He has co-authored over 100 publications, including the seminal Cell paper "The Hallmarks of Cancer" with Robert Weinberg (2000 and 2011). He serves on the cancer advisory board for Pfizer. He has degrees from MIT (BS) and Harvard (PhD), and post-doctoral training at Cold Spring Harbor.

Theresa Janke: co-Founder & Board member
Ms. Janke has over 15 years of clinical research and operations, alliance and program management, and business operations start-up experience in the biopharmaceutical industry, including work in immunotherapy, gene therapy and oncolytic virus therapy. She is currently SVP of Operations and Alliance/ Program Management at 4D Molecular Therapeutics.

James Merson: Board member
James Merson, Ph.D. is Senior Vice President and Chief Scientific Officer of the Vaccine Immunotherapeutics Research Unit at Pfizer. Prior to his current role, Dr. Merson was Chief Scientific Officer of Pfizer's Vaccine Research Unit, Head of the Antivirals Therapeutic Area, and leader of Pfizer's first efforts into immuno-gene therapy. Dr. Merson received his B.A. in Biology from Bellarmine College in Louisville, Kentucky, and his Ph.D. in Microbiology and Immunology from Baylor College of Medicine in Houston, Texas. He is a member of the British Society for Immunology, International Society of Vaccines, and is an adjunct professor at the Scripps Research Institute.

Bob Smith: Board member
Bob Smith is Pfizer's Senior Vice President, Gene Therapy Business and Early Commercial Development, Rare

Disease, for Pfizer's Innovative Health Business. Prior to his current role, Bob was SVP of Business Development for Pfizer's Worldwide Research and Development organization, and SVP of Global Business Development and Mergers & Acquisitions at Wyeth. Bob received his B.S. in Neuroscience from the University of Rochester, NY, and his M.B.A. in Finance and Corporate Accounting from the William E. Simon Graduate School of Business Administration at the University of Rochester, NY.
For more information on IGNITE and its product design and discovery efforts, please visit www.igniteimmunotherapy.com.

About IGNITE Immunotherapy Inc.
IGNITE is focused on the discovery and development of targeted oncolytic virus vaccines for the intravenous immunotherapy of cancer. IGNITE's founding team, led by Drs. David Kirn (Executive Chairman), David Schaffer (SAB co-Chair) and Douglas Hanahan (SAB co-Chair), has deep expertise in oncolytic virus design and development, cancer immunotherapy, gene therapy vector discovery, experimental cancer therapeutics and biotech entrepreneurship. Our discovery platform, termed Oncolytic Vaccine Evolution, is designed to discover optimized gene and immunotherapy delivery vehicles to target cancer cells in diverse patient populations with common metastatic tumor types. These products may be designed for intravenous administration, antibody resistance, tumor-specificity and combination efficacy with immune checkpoint inhibitors.

About IGNITE's Oncolytic Vaccine Evolution
Oncolytic virus cancer vaccines have demonstrated promising antitumoral activity and tolerability, and the oncolytic virus IMLYGIC (Amgen; talimogene laherperepvec) was approved by the US FDA in 2015 for the local treatment of unresectable cutaneous, subcutaneous and nodal lesions in patients with melanoma recurrent after initial surgery. While oncolytic viruses represent a promising new approach to cancer immunotherapy, hurdles to this approach still exist. First, IMLYGIC and many other clinical-stage agents require direct intratumoral injection, a method with significant disadvantages versus standard intravenous (IV) infusions that are used for blockbuster cancer biotherapeutics such as monoclonal antibodies (e.g. most patients with metastatic cancer have tumor metastases that are not directly injectable in the clinic). Second, if administered IV, many of these immunotherapeutic viruses are rapidly cleared by the immune system (e.g. by antibodies and/or complement). Finally, the number of immune-activating transgenes that can be expressed from the vector is limited by these viruses' transgene-encoding capacities. Novel oncolytic vaccine vectors are needed for the IV delivery of diverse immunostimulatory transgenes to metastatic cancers.

IGNITE Immunotherapy is advancing the field of oncolytic cancer vaccines by taking advantage of evolution to help discover vectors that are designed to efficiently and selectively target cancer cells after IV administration. Our Oncolytic Vaccine Evolution platform empowers us to potentially discover and engineer optimized and proprietary oncolytic vectors for use in cancer immunotherapy. The resulting products may be evolved and designed for intravenous infusion, resistance to immune-mediated clearance (e.g. by antibodies, complement), tumor-specific replication and cell lysis, and immune-activating transgene expression.