Hemispherx Biopharma Announces Significant Progress in its Ampligen Pancreatic Cancer Program and Multiple Ampligen+Checkpoint Blockade Immuno-Oncology Programs

Hemispherx Provides Quarterly Summary of Rapidly Advancing Oncology Clinical Programs

OCALA, Fla., March 13, 2019 (GLOBE NEWSWIRE) -- **Hemispherx Biopharma Inc.** (NYSE American: HEB) ("Hemispherx" or the "Company"), an immuno-pharma R&D company focused on unmet medical needs in immunology, announced today the first of a series of planned quarterly press release updates highlighting the progress and achievement of milestones in the Company's ongoing clinical trials evaluating Ampligen's ability to reprogram tumor microenvironments and increase the effectiveness of existing cancer immunotherapy, such as checkpoint blockade therapies. The Company has recently refocused its efforts to concentrate on the use of Ampligen as an immuno-therapy based on preclinical and early clinical evidence supporting the drug candidate's potential in the fight against cancer.

"We believe steady progress in these combination therapy clinical trials will be an important driver for Hemispherx's long-term success. It is our intention to update our progress in immuno-oncology on a quarterly basis mid-month every three months so the market, potential co-development candidates in big pharma, research analysts and the media have easy access to updated information, which will be a precursor to and mirror to the greatest extent possible our subsequent quarterly filings," states Thomas K. Equels, Hemispherx's CEO. "To date, multiple clinical programs have been initiated, with patients being screened and enrolled at both Roswell Park Comprehensive Cancer Center and the University of Pittsburgh Medical Center, testing both safety and proof of concept in humans. Two additional combination therapy clinical trials with pembrolizumab have been approved and patient enrollment screening has been initiated at both centers. These studies will test Ampligen in conjunction with pembrolizumab. Finally, five additional studies that will evaluate Ampligen in combination with various checkpoint blockade therapies are in various stages of pre-enrollment at the above medical centers as well as the Buffet Cancer Center, for a total of nine U.S.-based trials in various stages of advancement. In Europe, we are in the clinic in a recently extended Early Access Program and making meaningful progress in advanced pancreatic cancer at Erasmus MC in Rotterdam, the Netherlands."

In June 2018, the Company announced new data showing Ampligen's positive role in reprograming the tumor microenvironment. In a head-to-head study in a human ovarian cancer explant culture model, Ampligen activated the TLR3 pathway and promoted an accumulation of killer T cells but, unlike the other two TLR3 agonists, it did so without causing suppressor T cell (Treg) attraction. These findings are considered important because they show that Ampligen selectively reprograms the tumor microenvironment by inducing the beneficial aspects of tumor inflammation (attracting killer T cells), without amplifying immune-suppressive elements such as regulator T cells. The study, conducted at the University of Pittsburgh and Roswell Park Comprehensive Cancer Center, as a part of the NIH-funded P01 CA132714 and Ovarian Cancer Specialized Program of Research Excellence (SPORE), was published online in the journal *Cancer Research*. See: http://cancerres.aacrjournals.org/content/early/2018/05/31/0008-5472.CAN-17-3985.

Roswell Park scientific lead Pawel Kalinski, MD, PhD, Vice Chair for Translational Research and Professor of Oncology, Department of Medicine at the Buffalo, NY, cancer center, commented, "Previous work provides a strong foundation for moving forward with solid tumor studies to clinically demonstrate the extent to which Ampligen reprograms the tumor microenvironment in various clinical settings, with the goal of developing more effective immune therapies with checkpoint blockers."

"Preclinical studies in mice combining Ampligen with checkpoint inhibitors in various mouse models have yielded very promising results. Transitioning to human tumor explant work has established that Ampligen modifies the human tumor microenvironment by increasing T effector cells without raising T suppressor cell levels, thus creating a better environment for checkpoint therapy," said David Strayer, MD, Chief Scientific Officer of Hemispherx. "The objective of our currently ongoing clinical trials is to determine the optimal integration of Ampligen with standard checkpoint inhibitor therapy in the clinic in a variety of solid tumors with the goal of improving survival."

Clinical Development Overview

PANCREATIC CANCER - An Early Access Program (EAP) approved by the Inspectorate of Healthcare in the Netherlands for pancreatic cancer at Erasmus Medical Center has been ongoing for two years. Supervised by Prof. Casper van Eijck, MD, a world-renowned specialist in this dread malignancy, and Diba Latifi, MD, the team at Erasmus is making progress. As disclosed recently, the Dutch government has approved and extended the therapeutic program for an additional year. Early progress was reported in a published abstract from Erasmus, and a copy of the abstract can be found

at http://ir.hemispherx.net/Events_Presentations. The abstract was part of a larger original report covering a variety of medical topics, which can be found at https://www.pancreasclub.com/wp-content/uploads/2018/06/Poster-Abstracts.pdf.

As of today, we are pleased to report that 4 out of 24 patients with either locally advanced or metastatic disease have survived for more than one year on the Ampligen protocol without additional therapy. Another 4 patients have survived for more than one year since the start of the Ampligen protocol with palliative chemotherapy. However, in this group of patients 15 died within 7 months since start of Ampligen. Of the 5 resected patients 2 died on Ampligen, 24 and 27 months after resection. The other 3 patients are still alive with a mean survival of 26 months after resection and adjuvant Ampligen treatment.

All patients reported improvement in quality of life during treatment. We expect within 60 days a more comprehensive update from the Erasmus team on the immunological response in relation to survival. Hemispherx hopes to work with Dr. Van Eijck, Dr. Latifi, and Erasmus M.C. to initiate a combination therapy program to extend the results seen thus far in the Netherlands by combining Ampligen with checkpoint blockade therapy.

The four Ampligen immuno-oncology clinical trials initiated/ongoing in the U.S. are summarized as follows:

RECURRENT OVARIAN CANCER - Phase 1 / 2 study of intraperitoneal chemo-immunotherapy in recurrent ovarian cancer at University of Pittsburgh Medical Center. Dr. R. Edwards, PI. Study underway. An interim report from Dr. Edwards' team is expected within thirty days and a summary of same will be disclosed upon receipt. See: https://clinicaltrials.gov/ct2/show/NCT02432378

COLORECTAL CANCER - Phase 2a study of Ampligen as component of chemokine modulatory regimen on colorectal cancer metastatic to liver at Roswell Park Comprehensive Cancer Center. Dr. P. Boland, PI. Study underway. See: https://clinicaltrials.gov/ct2/show/NCT03403634

METASTATIC TRIPLE NEGATIVE BREAST CANCER - Open label study of metastatic triple-negative breast cancer using chemokine modulation therapy, including Ampligen and pembrolizumab, at Roswell Park Comprehensive Cancer Center. Dr. M. Opyrchal, PI. Initiation of study is expected in the near future and will be announced forthwith. See: https://www.clinicaltrials.gov/ct2/show/NCT03599453

RECURRENT OVARIAN CANCER - This is a Phase 2 investigator-sponsored trial being conducted in advanced recurrent ovarian cancer at the University of Pittsburgh Medical Center that will evaluate Ampligen in combination with pembrolizumab. Patient enrollment has been initiated in this study designed for 45 subjects. Dr. Robert Edwards, world renowned expert in ovarian cancer is the lead investigator. For more important details see: https://clinicaltrials.gov/ct2/show/NCT03734692

In addition, five Ampligen clinical trials are planned for initiation in 2019, subject to funding:

1. Phase 2 study that will evaluate Ampligen in combination with pembrolizumab in refractory metastatic colorectal carcinoma at Roswell Park Comprehensive Cancer Center. Dr. P. Boland, PI. Study design and budget being developed.
2. Phase 2 study of advanced urothelial (bladder), melanoma and renal cell carcinoma, resistant to checkpoint blockade, that will evaluate Ampligen in combination with a checkpoint blockade therapy at Roswell Park Comprehensive Cancer Center. Dr. M. Opyrchal, PI. Protocol design currently being finalized. Hemispherx Biopharma signed a clinical trial agreement with Roswell Park Comprehensive Cancer Center to study Ampligen in combination with checkpoint inhibitors in a phase 2a study in urothelial carcinoma, renal cell carcinoma and melanoma. This Phase 2a study will be led by Mateusz Opyrchal, MD, PhD, Assistant Professor of Medicine and Associate Director of the Early Phase Clinical Trial Program at Roswell Park, in collaboration with Dr. Kalinski.
3. First-line therapy for non-small cell lung cancer with SOC chemotherapy that will evaluate Ampligen in combination with pembrolizumab at University of Nebraska Medical Center. Dr. V. Ernani, PI. Study design and budget being developed.
4. Phase 2 study in advanced pancreatic cancer using checkpoint blockade plus Ampligen at University of Nebraska Medical Center. Dr. K. Klute, PI. Protocol and budget being developed. Based upon success in the initial animal studies, an additional round of more extensive and comprehensive pre-clinical animal pancreatic cancer studies are being conducted at University of Nebraska to reconfirm results, test additional PC tumor types, examine anti-PD-1 in addition to the prior anti-PD-L1 analysis, then fine tune the focus of the proposed future pancreatic cancer clinical trial and reduce the chances of error in clinical trial design. This information will also be used to formulate proposed future combination therapy clinical activity in the Kingdom of the Netherlands.
5. Phase 2 study of neoadjuvant conditioning of prostate cancer using Ampligen as a component of chemokine

modulation at Roswell Park Comprehensive Cancer Center. Dr. G. Chatta, PI. An Independent New Drug application has been filed and is under review by the FDA.

About Hemispherx Biopharma

Hemispherx Biopharma, Inc. is an immuno-pharma R&D and emerging commercial growth company focused on unmet medical needs in immunology. Hemispherx's flagship products include the Argentina-approved drug rintatolimod (trade names Ampligen® or Rintamod®) and the FDA-approved drug Alferon N Injection®. Based on results of published, peer-reviewed pre-clinical studies and clinical trials, Hemispherx believes that Ampligen® may have broad-spectrum anti-viral and anti-cancer properties. Clinical trials of Ampligen® already conducted include studies of the potential treatment of cancer patients with renal cell carcinoma and malignant melanoma. These and other potential uses will require additional clinical trials to generate the safety and effectiveness data necessary to support regulatory approval. Rintatolimod is a double-stranded RNA being developed for globally important debilitating diseases and disorders of the immune system.

Cautionary Statement

Some of the statements included in this press release may be forward-looking statements that involve a number of risks and uncertainties. Among other things, for those statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995. Any forward-looking statements set forth in this press release speak only as of the date of this press release. Among other things, no assurance can be given as to whether the ongoing or planned trials will be successful or yield favorable data and the trials are subject to many factors including lack of regulatory approval(s), lack of study drug, or a change in priorities of the Cancer Centers sponsoring these trials. We do not undertake to update any of these forward-looking statements to reflect events or circumstances that occur after the date hereof. This press release and prior releases are available at www.hemispherx.net. The information found on our website is not incorporated by reference into this press release and is included for reference purposes only.

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