



Phio Pharmaceuticals and AgonOx, Inc. Announce Collaboration on Clinical Development of Novel T Cell-based Cancer Immunotherapies

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MARLBOROUGH, Mass., March 1, 2021 /PRNewswire/ -- Phio Pharmaceuticals Corp. (Nasdaq: PHIO), a biotechnology company developing the next generation of immuno-oncology therapeutics based on its proprietary self-delivering RNAi (INTASYL™) therapeutic platform, today announced it has entered into a clinical development collaboration with AgonOx, Inc. to develop novel T cell-based cancer immunotherapies using Phio's lead INTASYL based product candidate PH-762 and AgonOx's "double positive" (DP) tumor-infiltrating lymphocyte (TIL) technology. The companies have shown that the combination of their respective technologies can result in enhanced TIL therapeutics, and based on these data, the collaboration will focus on conducting a clinical study for PH-762 treated DP TILs. The study is expected to start enrolling patients later this year.

Logo - https://mma.prnewswire.com/media/786567/Phio_Pharmaceuticals_Logo.jpg

AgonOx in collaboration with the Earle A. Chiles Research Institute, a division of the Providence Cancer Institute, developed a method for the identification, isolation and expansion of tumor-specific CD8 T cells from cancer patients. AgonOx has also shown that "double positive" (DP) CD8 T cells isolated from human solid tumors have increased tumor killing activity when compared to CD8 TIL that were not enriched prior to expansion. Preclinical data presented at SITC 2020 by AgonOx in collaboration with Phio show that treating the DP CD8 TIL with Phio's PH-762, increases the tumor killing activity of the CD8 DP TIL even further (two-fold increase). As a result, the use of PH-762 treated DP CD8 TIL is expected to enhance therapeutic responses in cancer patients.

Under the terms of the collaboration agreement, AgonOx will receive financial support for the clinical trial from Phio and Phio is entitled to certain future development milestones and sales related royalty payments from AgonOx's DP TIL technology.

"Autologous T cell therapies hold a lot of promise, however, there is still a lot of research needed to be done to unlock its full therapeutic potential, including ways to improve upon the first generation of TIL products, and ways to use TIL therapy in more types of cancer," said Dr. Gerrit Dispersyn, President and CEO of Phio Pharmaceuticals. "By joining forces with AgonOx, we believe our collaboration can fulfil these unmet needs, without the need for complex and costly technologies, such as genetic engineering."

"Our collaboration with Phio is based on data showing that PH-762 increases the activity of our CD8 DP TIL technology, therefore we believe this combination should increase the therapeutic efficacy of this first-in-man study," stated by Dr. Andrew Weinberg, President/CSO of AgonOx, Inc. and Full Member at the Earle A. Chiles Research Institute.

Dr. James Cardia, VP of Business Operations of Phio Pharmaceuticals, commented: "Both the clinical community and the investment community are embracing the broad potential of cell-based immunotherapy, and TIL therapy in specific, based on recent clinical and corporate development activities in this field. Our data show the important role that INTASYL based products can play in improving adoptive cell therapy, and we look forward to working with AgonOx to bring better cell therapies to patients."

About TIL Therapy and "DP" TILs

In TIL therapy, T cells are extracted from a patient's own tumor. These cells are then expanded *ex-vivo*, and infused back into the patient. The infused TIL naturally recognize the tumor and then attack the cancer cells. Currently, clinical applications focus on indications such as metastatic melanoma and cervical cancer. Increasing the frequency of tumor-reactive cells within TIL products should allow for improved response rates in these indications and expand the use of this form of treatment to patients with locally advanced, recurrent or metastatic cancers including head and neck, non-small cell lung cancer and other solid tumor types. AgonOx developed methods to enrich for tumor-killing T cells, which could greatly improve the immune response in cancer patients – potentially leading to successful treatment of tumors. Their research in collaboration with the Earle A. Chiles Research Institute, entitled "Co-expression of CD39 and CD103 identifies tumor-reactive CD8 positive T cells in human solid tumors" was published in Nature Communications and forms the basis of this clinical study (Duhon, T., Duhon, R., Montler, R. et al, 2018: Co-expression of CD39 and CD103 identifies tumor-reactive CD8 T cells in human solid tumors. Nat Commun 9, 2724).

About PH-762

PH-762 is a self-delivering RNAi compound that targets the checkpoint protein PD-1. Checkpoint proteins, such as PD-1, normally act as a type of "off switch" that prevents T cells from attacking certain cells, such as cancer cells, in the body. PH-762 silences PD-1 checkpoint expression, thereby removing the "off switch" and resulting in enhanced T cell activation and tumor cytotoxicity. Experimental data shows that PH-762 can silence the expression of PD-1 in target human T cells in a potent and durable manner, and can increase function of patient derived TILs or engineered cells, such as CAR T-cells for use in adoptive cell therapy. PH-762 use does not involve genetic engineering, and its cell delivery does not require special formulations or other complex delivery tools.

About AgonOx, Inc.

Agonox, Inc. is a privately held, Portland, OR-based biotechnology company that grew out of the Earle A. Chiles Research Institute at the Providence Cancer Institute, Portland, OR. The company is developing a pipeline of novel immunotherapy drugs targeting key regulators of the immune response to cancer. For additional information, visit the company's website, www.agonox.com.

About Phio Pharmaceuticals Corp.

Phio Pharmaceuticals Corp. (Nasdaq: PHIO) is a biotechnology company developing the next generation of immuno-oncology therapeutics based on its self-delivering RNAi (INTASYL™) therapeutic platform. The Company's efforts are focused on silencing tumor-induced suppression of the immune

system through its proprietary INTASYL platform with utility in immune cells and the tumor micro-environment. Our goal is to develop powerful INTASYL therapeutic compounds that can weaponize immune effector cells to overcome tumor immune escape, thereby providing patients a powerful new treatment option that goes beyond current treatment modalities. For additional information, visit the Company's website, www.phioharma.com.

Forward Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are neither historical facts nor assurances of future performance. These statements are based only on our current beliefs, expectations and assumptions regarding the impact to our business and operations by the recent coronavirus outbreak, results from our preclinical and clinical activities, the development of our product candidates, the ability to obtain future financing, the future of our business, future plans and strategies, projections, anticipated events and trends, the economy and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of our control. Our actual results may differ materially from those indicated in the forward-looking statements as a result of a number of important factors, including, but not limited to, market and other conditions and those identified in our Annual Report on Form 10-K and subsequent Quarterly Reports on Form 10-Q under the caption "Risk Factors" and in other filings the Company periodically makes with the SEC. Readers are urged to review these risk factors and to not act in reliance on any forward-looking statements, as actual results may differ from those contemplated by our forward-looking statements. Phio does not undertake to update forward-looking statements to reflect a change in its views, events or circumstances that occur after the date of this release, except as required by law.

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