



FOR IMMEDIATE RELEASE

Pique Therapeutics Announces Positive Results in Phase 2 Clinical Trial of Lead Immunotherapy for Non-Small Cell Lung Cancer

- ***PT 107 showed improvement in overall survival and significant improvement in time to progression, as compared to control***
- ***In non-squamous patients, the benefit of PT 107 in overall survival was striking and highly significant***
- ***PT 107 was well tolerated, with no drug-related serious adverse events reported***

Durham, North Carolina – November 7, 2017 -- Pique Therapeutics, Inc. today announced positive results for PT 107 from its Phase 2 clinical trial in patients with late-stage, second-line non-small cell lung cancer (NSCLC). These results will be presented at the Society for the Immunotherapy of Cancer's (SITC) 32nd Annual Meeting, being held November 8-12 at the Gaylord National Hotel & Convention Center in National Harbor, Maryland.

Primary Endpoint

Median overall survival for patients receiving treatment with PT 107 (PT 107 arm) was 12.5 months versus 8.4 months for patients who received placebo (control arm), with a hazard ratio of 0.65 ($p=0.06$, all p -values two-sided). In the subset of 71 non-squamous patients, median overall survival was 15.5 months (PT 107 arm) vs. 5.8 months (control arm), with a hazard ratio of 0.46 ($p<0.01$).

"We are very encouraged to see such positive results with a single agent in late stage non-small cell lung cancer," said Christopher S. Meldrum, President of Pique Therapeutics. "The improvement in overall survival, particularly the significant 10-month benefit seen in non-squamous patients, highlight the promise of PT 107."

Secondary Endpoints

Median time to progression for the PT 107 arm was 4.0 months versus 2.5 months for the control arm, with a statistically significant hazard ratio of 0.45 ($p=0.01$). Median progression-free survival for the PT 107 arm was 3.9 months versus 2.9 months for the control arm, with a hazard ratio of 0.67 ($p=0.08$).

Safety

There were no drug-related serious adverse events reported for patients on PT 107, consistent with previous clinical experience, and minimal causal grade 3+ toxicity (5%).

“We will now seek to move PT 107 forward in collaboration with a partner,” said Meldrum. “The results of this trial indicate that this first-in-class therapeutic vaccine has tremendous potential as a therapy for non-small cell lung cancer, both as a stand-alone treatment, as well as in conjunction with other treatments, such as standard of care checkpoint inhibitors.”

The Phase 2 trial was a multi-center, randomized (2:1) double-blind clinical trial, and enrolled 94 patients with Stage IIIB/IV non-small cell lung cancer whose disease had progressed following previous therapy. The Phase 2 trial was seeking to confirm the safety of PT 107, and further evaluate the efficacy of the drug. PT 107 had similar survival benefits across a variety of subgroup analyses, including by age, smoking status, and stage of cancer, but was distinct by type of NSCLC, with non-squamous patients faring much better than squamous patients, as compared to placebo.

About Pique Therapeutics

Pique Therapeutics is a biopharmaceutical company seeking to become the leader in the development and commercialization of new therapeutic vaccines, focused initially on the treatment of cancer. The Company was founded on research licensed from the University of Miami and discovered by the late Eckhard R. Podack, M.D., Ph.D., one of the pioneering researchers in the field of immunotherapy. Dr. Podack was the discoverer of perforin-1 and perforin-2, and also created the technology underlying brentuximab (Adcetris®), used in the treatment of Hodgkin lymphoma.

About PT 107

Pique’s lead product, PT 107, is a first-in-class allogeneic whole cell vaccine for the treatment of non-small cell lung cancer. In a previous Phase 1 trial, PT 107 was shown to induce robust cytolytic T cells that persisted for more than two years, was well tolerated, and exhibited a very good safety profile in cancer patients. In this trial, PT 107 showed a dramatic improvement in median overall survival for patients with second-line, late-stage non-small cell lung cancer, more than doubling the expected survival in these patients. Remarkably, over 30% of PT 107-treated patients survived 4 years or longer.

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