



## **Aerpio Announces Initiation of Patient Dosing in the TIME-2b Study, a Phase 2b Clinical Trial of Lead Candidate AKB-9778 in Patients with Diabetic Retinopathy**

June 29, 2017, CINCINNATI-- Aerpio Pharmaceuticals, Inc., a biopharmaceutical company focused on advancing first-in-class treatments for ocular diseases, today announced the initiation of patient dosing in the company's TIME-2b study, a Phase 2b clinical trial designed to assess the efficacy and safety of Aerpio's lead candidate AKB-9778 for patients with moderate to severe non-proliferative diabetic retinopathy.

The TIME-2b study is a double-masked, placebo-controlled, multi-center trial that will enroll 150 patients randomized 1:1:1 to receive either AKB-9778 15 mg subcutaneously once daily, AKB-9778 15 mg twice daily, or placebo for a 12-month period. The primary endpoint of the TIME-2b study is the percentage of patients who improve by at least 2 steps in diabetic retinopathy Severity Score (DRSS) in the study eye. Secondary objectives include assessment of safety and tolerability of both dosing regimens. Victor H. Gonzalez, MD of Valley Retina Institute (McAllen, TX), who enrolled the first patient in TIME-2b, stated "TIME-2b is an exciting study because it allows us to evaluate a patient self-administered investigational drug for the treatment of moderate to severe non-proliferative diabetic retinopathy. An early treatment option that potentially improves diabetic retinopathy in both eyes without the need for intraocular injections could completely change our approach to diabetic eye disease." More information about the clinical trial is available at: <https://clinicaltrials.gov/ct2/show/NCT03197870>.

"The start of our TIME-2b study builds upon our clinical proof of concept data, for which we reported that AKB-9778 monotherapy was able to improve underlying diabetic retinopathy by 2 or more steps in DRSS in both eyes" said Joseph Gardner, President & CEO of Aerpio. "Diabetic retinopathy remains an area of significant unmet medical need. An estimated one out of three individuals with diabetes has retinopathy, which generally progresses over time and can lead to loss of vision due to proliferative diabetic retinopathy or diabetic macular edema. Our goal with AKB-9778 is to treat early diabetic eye disease before the onset of these vision threatening conditions."

### **About Aerpio Pharmaceuticals**

Aerpio Pharmaceuticals, Inc. is a biopharmaceutical company focused on advancing first-in-class treatments for ocular diseases. The Company's lead compound, AKB-9778, is a small molecule activator of the Tie2 pathway and is in clinical development for the treatment of non-proliferative diabetic retinopathy. For more information please visit [www.aerpio.com](http://www.aerpio.com).

## About AKB-9778

AKB-9778 is being developed as a subcutaneous injection for the treatment of non-proliferative diabetic retinopathy. AKB-9778 binds to and inhibits the intracellular domain of VE-PTP, the most critical negative regulator of Tie2. AKB-9778 has demonstrated the ability to activate the Tie2 receptor irrespective of extracellular levels of its binding ligands, angiopoietin-1 (agonist) or angiopoietin-2 (antagonist), and may be the most efficient pharmacologic approach to activating Tie2.

## About Diabetic Retinopathy

Diabetic retinopathy (DR) is a complication of diabetes caused by damage to blood vessels in the retina. Severity of DR ranges from mild non-proliferative diabetic retinopathy to more advanced proliferative diabetic retinopathy, the hallmark of which is the development of new abnormal blood vessels. DR is the leading cause of blindness among working aged adults around the world.

## Forward Looking Statements

This press release contains forward-looking statements. Statements in this press release that are not purely historical are forward-looking statements. Such forward-looking statements include, among other things, the timeline of, and other developmental plans for, AKB-9778 for non-proliferative diabetic retinopathy or otherwise, the therapeutic potential of the Company's product candidates, including AKB-9778. Actual results could differ from those projected in any forward-looking statements due to several risk factors. Such factors include, among others, the ability to raise the additional funding needed to continue to develop AKB-9778 or other product development plans, the inherent uncertainties associated with the FDA and drug development process, including the timing of patient enrollment and progress in our study, competition in the industry in which the Company operates and overall market conditions. These forward-looking statements are made as of the date of this press release, and the Company assumes no obligation to update the forward-looking statements, or to update the reasons why actual results could differ from those projected in the forward-looking statements, except as required by law. Investors should consult all the information set forth herein and should also refer to the risk factor disclosures set forth in the reports and other documents the Company files with the SEC available at [www.sec.gov](http://www.sec.gov).

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