



**Bird Rock Bio Receives Approval to Start First in Human Clinical Trial for Namacizumab, Enters Into Agreement with GE Healthcare for Process Development and Scale-up to Provide Clinical Phase 2 cGMP Material, and Enters into a Collaboration and Option Agreement with Janssen Pharmaceuticals, Inc.**

- *Namacizumab is a first-in-class and only-in-class negative allosteric modulating antibody (NAMA) that stabilizes the cannabinoid 1 receptor (CB1) in an inactive conformation.*
- *Namacizumab is being developed to treat large unmet medical needs in fibrotic and metabolic disease, including non-alcoholic steatohepatitis (NASH) and diabetic nephropathy.*
- *The double blind, placebo controlled, dose ranging Phase 1 clinical trial will include a Single Ascending Dose Study in healthy volunteers and a Multiple Ascending Dose Study in non-alcoholic fatty liver disease (NAFLD) patients, assessing outcomes of key biomarkers.*
- *Bird Rock Bio will be working with GE Healthcare on scale-up and down stream process optimization, subcutaneous formulation, and 1000 liter cGMP manufacture of namacizumab in preparation for Phase 2 clinical trials.*
- *Bird Rock Bio has entered into a collaboration and option agreement, pursuant to which Janssen Pharmaceuticals, Inc. has the exclusive right to acquire the company following the Phase 1 data readout.*

La Jolla, CA, January 11, 2017 -- [Bird Rock Bio, Inc.](#), a clinical stage biopharmaceutical company, announced today that it has received approval for the initiation of a two-part Phase 1 clinical trial for namacizumab, a novel therapeutic antibody to the cannabinoid 1 receptor (CB1). In addition, Bird Rock Bio has entered into an agreement with GE Healthcare for process development, formulation, and manufacture of namacizumab in preparation for Phase 2 studies. Furthermore, the Phase 1 trial, process development, and Phase 2 preparation will be funded under a collaboration and option agreement with Janssen Pharmaceuticals, Inc.

The trial is anticipated to provide important safety, tolerability and biomarker efficacy data for namacizumab to support differentiated clinical potential in fibrotic and metabolic disease. As a first-in-class and only-in-class negative allosteric modulating antibody (NAMA) that stabilizes



the inactive conformation of CB1, nacamizumab has the potential to build on the significant historic mechanistic and clinical data on the modulation of CB1 in disease.

“As we prepare for future phases of development, we will be working with GE Healthcare on downstream process development, subcutaneous formulation, and clinical scale manufacturing,” said **Paul Grayson, Bird Rock Bio’s CEO**. “While we are conducting the SAD and MAD clinical trial, we will also be completing supportive chronic toxicology and bioequivalence studies to be fully prepared for the next phases of clinical development.”

Bird Rock Bio has entered into a collaboration and option agreement with Janssen Pharmaceuticals, Inc. pursuant to which Janssen has an exclusive option to acquire the company following the Phase 1 data readout. “We believe that Janssen’s expertise in the development, manufacture, and commercialization of biologic therapeutics will allow Bird Rock to accelerate the development of nacamizumab,” added Grayson. “We look forward to working with Janssen on this important Phase 1 program. If the Phase 1 data are positive, it will signify a meaningful advancement for this novel potential therapeutic for NASH, and an important event for Bird Rock Bio’s shareholders.”

### **About Nacamizumab**

Discovered internally through Bird Rock Bio’s proprietary iCAPS platform, nacamizumab is scheduled to be the first and only known NAMA to the CB1 receptor to be entering clinical trials. Nacamizumab is a multi-modal therapeutic candidate with fibrotic, inflammatory and metabolic mechanisms of action. This provides for the opportunity for nacamizumab to have significant potential across a broad range of fibrotic and metabolic diseases including large unmet medical conditions such as NASH and diabetic nephropathy.

### **About iCAPS**

Bird Rock Bio’s iCAPS platform, the leading GPCR allosteric antibody drug discovery platform, can isolate and present functional GPCRs in the correct conformation to identify selective monoclonal antibody allosteric modulators. GPCRs are a valuable class of drug targets but have been largely unexplored in antibody discovery because of the difficulty in isolating GPCRs in the correct conformation and functional form.

### **About Bird Rock Bio, Inc.**



Backed by leading biotechnology venture investors, Bird Rock Bio's strategy leverages biologic targets with substantial human proof of mechanism for the development of first in class or best in class molecules with strong clinical and commercial differentiation. The Company is focused on developing proprietary antibodies for fibrotic, metabolic and inflammatory diseases, including RA, SA, NASH and diabetic nephropathy. Bird Rock Bio's science team is experienced with translating pioneering research into promising therapeutics with potential deep pharmacoeconomic benefits. For more, visit [www.birdrockbio.com](http://www.birdrockbio.com).

**Media Contact:** Jessica Yingling, Ph.D., Little Dog Communications Inc., [jessica@litldog.com](mailto:jessica@litldog.com), +1.858.344.8091