



Bird Rock Bio Receives Approval from ANVISA and CONEP to Initiate the First Phase 2 Study in Brazil of Gerilimzumab for Rheumatoid Arthritis

- *Working with Techtrials International, Bird Rock Bio obtained unprecedented approval for a first in patient trial in Brazil with a novel therapeutic antibody.*
- *Gerilimzumab potency, half-life, cost of goods, and related price flexibility and affordable access are ideal for this rapidly emerging economy.*
- *Over 1.2 million rheumatoid arthritis (RA) patients in Brazil could benefit from access to a best in class anti-IL-6 antibody (more than 2.7 million throughout LATAM).*

La Jolla, Calif., January 3, 2017 – Bird Rock Bio, Inc., a clinical stage biopharmaceutical company, announced today that it had received approval for the initiation of a 200 patient, Phase 2 rheumatoid arthritis (RA) clinical trial for gerilimzumab, a novel therapeutic antibody to the IL-6 cytokine, to be conducted solely in Brazil. Working closely with leading rheumatologists, Techtrials International, CONEP, and ANVISA, Bird Rock Bio designed a clinical protocol specifically to address the patient population in Brazil. The trial is designed to evaluate three dose regimens; 1) a 20 mg subcutaneous (SC) loading dose followed by a 10 mg maintenance dose after 8 weeks, or 2) a 10 mg SC loading dose followed by a 5 mg maintenance dose after 8 weeks, or 3) a low 5 mg SC loading dose followed by a 2 mg maintenance dose after 8 weeks, all in combination with methotrexate, compared to methotrexate control.

“A challenge of developing novel therapeutics in markets such as the U.S., where the therapeutic landscape is more mature and most patients are already being treated with the first, second or even third biologic, is that the standard of care is not as relevant and the patient population of interest is not as available,” said Paul Grayson, CEO of Bird Rock Bio. “The largest medical need in RA outside the U.S. is still affordable access; however, a therapeutic with low, infrequent dosing and low cost of goods such as gerilimzumab, also requires a creative clinical development strategy. Working with global leaders in RA, along with the top rheumatologist in Brazil, and Techtrials International, the leading Brazilian CRO, we were able to design a thoughtful clinical protocol to address the needs of the patient, ethics committees, and regulatory agencies of Brazil.”

“This is a very exciting time to be conducting clinical trials in Brazil,” said Douglas Valverde, CEO of Techtrials. “This is one of the fastest approvals for a trial with a novel biologic by CONEP and ANVISA and shows a new degree of responsiveness to well thought out clinical



trial designs. We are very excited to work with the 25 sites identified in Brazil to conduct this ‘first of a kind’ clinical program.”

About Gerilimumab

Gerilimumab is the result of a unique collaborative model, involving Bird Rock Bio, argenx (Euronext Brussels: ARGX), and Genor Biopharma. In late 2012, Bird Rock Bio entered into a collaboration for the worldwide rights to gerilimumab from argenx, a biopharmaceutical company focused on creating and developing differentiated antibodies for the treatment of cancer and severe autoimmune diseases. Early in 2013, Bird Rock Bio partnered gerilimumab with Genor Biopharma for IND enablement, manufacturing process development and commercialization for China. Bird Rock Bio has retained all other commercial rights of gerilimumab for the rest of the world.

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 NASH and RA. 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.

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